AGGREGATE PRODUCTION QUOTA HISTORY FOR SELECTED SUBSTANCES*

(In kilograms of anhydrous acid or base)

Controlled Substance	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
4-Anilino-N-phenethyl-4-piperidine (1)	N/A	N/A	N/A	N/A	N/A	1,100.000	1,600.000	1,600.000	2,250.000	2,687.500	2,687.500
Alfentanil	2.800	7.200	5.200	8.000	8.000	8.000	12.800	29.002	36.250	17.625	17.750
Amobarbital	0.002	101.000	0.003	0.003	0.003	0.003	40.007	40.007	0.009	0.009	25.125
Amphetamine (conversion)	-	-	5,000.000	5,000.000	7,500.000	7,500.000	8,500.000	13,300.000	22,875.000	18,375.000	21,875.000
Amphetamine (sale)	14,500.000	17,000.000	17,000.000	17,000.000	17,000.000	18,600.000	25,300.000	33,400.000	47,186.000	49,000.000	37,500.000
Cocaine	228.000	286.000	286.000	247.000	247.000	247.000	216.000	216.000	240.000	240.000	275.000
Codeine (conversion)	55,000.000	59,000.000	59,000.000	71,000.000	65,000.000	65,000.000	65,000.000	65,000.000	81,250.000	68,750.000	50,000.000
Codeine (sale)	39,605.000	39,605.000	39,605.000	39,605.000	39,605.000	39,605.000	39,605.000	39,605.000	49,506.250	46,125.000	49,500.000
Dextropropoxyphene	167,365.000	120,000.000	120,000.000	106,000.000	106,000.000	92,000.000	0.007	0.007	0.019	0.019	0.019
Dihydrocodeine	750.000	1,261.000	2,435.000	1,200.000	1,200.000	600.000	255.000	400.000	250.000	100.750	226.375
Diphenoxylate	833.000	828.000	828.000	761.000	947.000	827.000	730.000	900.000	887.500	1,288.750	1,337.500
Ecgonine	73.000	83.000	83.000	83.000	83.000	83.000	83.000	83.000	144.000	174.375	174.375
Fentanyl	1,428.000	1,428.000	1,428.000	1,428.000	1,428.000	1,428.000	1,428.000	1,428.000	2,108.750	2,108.750	2,150.000
Gamma-hydroxybutyric acid	8,000.000	8,000.000	23,600.000	21,940.000	24,200.000	52,156.000	5,772.000	37,000.000	67,500.000	70,250.000	70,250.000
Hydrocodone	37,604.000	42,000.000	46,000.000	55,000.000	55,500.000	55,000.000	59,000.000	79,700.000	99,625.000	99,625.000	99,625.000
Hydromorphone	3,300.000	2,500.000	3,300.000	3,300.000	3,340.000	3,455.000	3,455.000	4,207.000	6,750.000	6,750.000	7,000.000
Levorphanol	5.000	5.000	6.000	10.000	10.000	10.000	3.600	3.600	4.500	4.625	7.125
Lisdexamfetamine (2)	N/A	N/A	6,200.000	6,200.000	8,200.000	9,000.000	10,400.000	12,000.000	21,000.000	23,750.000	29,750.000
Marihuana	4,500.000	4,500.000	4,500.000	4,500.000	4,500.000	21.000	21.000	21.000	21.000	650.000	125.000
Meperidine	9,753.000	9,753.000	9,753.000	8,600.000	8,600.000	5,600.000	5,500.000	5,500.000	6,875.000	6,250.000	6,250.000
Methadone	17,940.000	25,000.000	25,000.000	25,000.000	25,000.000	20,000.000	20,000.000	23,100.000	33,125.000	31,875.000	31,875.000
Methadone Intermediate	20,334.000	26,000.000	26,000.000	26,000.000	26,000.000	26,000.000	26,000.000	29,970.000	40,500.000	38,875.000	34,375.000
Methamphetamine	2,360.000	3,130.000	3,130.000	3,130.000	3,130.000	3,130.000	3,130.000	3,130.000	3,912.500	2,611.375	2,061.375
l-Desoxyephedrine	700.000	680.000	680.000	680.000	680.000	750.000	750.000	750.000	987.500	1,250.000	1,250.000
Methamphetamine (conversion)	1,615.000	2,405.000	2,405.000	2,405.000	2,405.000	2,331.000	2,331.000	2,331.000	2,863.750	1,500.000	750.000
Methamphetamine (sale)	45.000	45.000	45.000	45.000	45.000	49.000	49.000	49.000	61.250	61.375	61.375
Methylphenidate	35,000.000	35,000.000	50,000.000	50,000.000	50,000.000	50,000.000	56,000.000	64,600.000	96,750.000	98,750.000	83,750.000
Morphine (conversion)	110,774.000	100,000.000	110,774.000	110,000.000	100,000.000	83,000.000	70,000.000	83,000.000	91,250.000	91,250.000	91,250.000
Morphine (sale)	35,000.000	35,000.000	35,000.000	35,000.000	36,300.000	39,000.000	39,000.000	48,200.000	61,125.000	62,500.000	62,500.000
Noroxymorphone (conversion)	4,000.000	5,600.000	11,000.000	9,000.000	9,000.000	9,000.000	7,200.000	7,200.000	9,000.000	17,500.000	17,500.000
Noroxymorphone (sale)	1.002	1,002.000	1.002	10.000	10.000	41.000	401.000	1,981.000	1,262.500	1,262.500	1,475.000
Opium (3)	1,280.000	1,360.000	1,400.000	1,400.000	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Opium (powdered)	N/A	N/A	N/A	N/A	230.000	230.000	63.000	73.000	91.250	112.500	112.500
Opium (tincture)	N/A	N/A	N/A	N/A	1,250.000	1,500.000	1,000.000	1,000.000	1,287.500	780.000	687.500
Oripavine (4)	N/A	N/A	N/A	15,000.000	15,000.000	15,000.000	8,000.000	15,300.000	22,750.000	30,625.000	35,000.000
Oxycodone (conversion)	920.000	4,610.000	3,100.000	4,820.000	4,500.000	5,600.000	5,600.000	7,600.000	10,250.000	9,250.000	8,350.000
Oxycodone (sale)	50,490.000	58,000.000	70,000.000	70,000.000	94,000.000	105,500.000	98,000.000	105,200.000	153,750.000	149,375.000	137,500.000
Oxymorphone (conversion)	-	2,400.000	15,300.000	12,000.000	12,000.000	12,800.000	12,800.000	12,800.000	18,375.000	25,000.000	29,000.000
Oxymorphone (sale)	534.000	806.000	1,800.000	2,000.000	2,570.000	3,070.000	3,070.000	5,500.000	7,000.000	7,750.000	7,750.000
Pentobarbital	20,335.000	28,000.000	35,200.000	28,000.000	28,000.000	28,000.000	34,000.000	34,000.000	42,500.000	35,000.000	35,000.000
Phenylacetone	-	-	-	0.001	250.001	12,500.001	8,000.000	16,000.000	42,393.750	45,750.000	9,375.000
Secobarbital	0.002	0.002	0.002	0.002	67.000	67.000	336.002	336.002	215.003	215.003	215.003
Sufentanil	4.500	6.500	10.300	10.300	10.300	7.000	5.000	6.732	6.880	6.255	6.255
Tapentadol (5)	N/A	N/A	N/A	N/A	1,000.000	403.000	5,400.000	5,400.000	13,750.000	17,500.000	12,500.000
Tetrahydrocannabinols	312.500	336.000	312.500	312.500	312.500	264.000	393.000	393.000	491.000	491.000	497.500
Thebaine	72,453.000	78,000.000	126,000.000	126,000.000	126,000.000	126,000.000	116,000.000	116,000.000	145,000.000	145,000.000	125,000.000

* DEA publishes a complete list of Schedule I and II controlled Substance Aggregate Production Quotas in the Federal Register

(1) 4-Anilino-N-phenethyl-4-piperidine became a schedule II controlled substance August 30, 2010 (75 FR 37296)

(2) Lisdexamfetamine became a schedule II controlled substance June 4, 2007 (85 FR 24532)

(3) Opium was split into separate categories beginning in 2009

(4) Oripavine became a separate basic drug class code September 24, 2007 (184 FR 54208)

(5) Tapentadol became a schedule II controlled substance June 22, 2009 (74 FR 23760)

Updated October 8, 2014

Substance	2012 KG	2013 KG	% Change	2014 KG	% Change	EST 2015 KG	% Change
AMPHETAMINE *	**22,664.555**	**22,574.791**	**-0.40%**	**24,622.361**	**9.07%**	**26,533.368**	**7.76%**
COCAINE	**43.833**	**38.680**	**-11.30%**	**35.481**	**-8.74%**	**35.828**	**0.98%**
CODEINE	22,756.728	21,747.588	-4.43%	21,716.915	-0.14%	27,997.461	28.92%
DIHYDROCODEINE	**75.021**	**35.987**	**-52.03%**	**3.314**	**-90.79%**	**18.836**	**468.38%**
DIPHENOXYLATE	413.016	411.425	-0.39%	385.932	-6.20%	389.646	0.96%
DRONABINOL	**106.128**	**111.177**	**4.76%**	**117.394**	**5.59%**	**116.165**	**-1.05%**
EPHEDRINE	1,972.090	2,079.301	5.44%	2,234.629	7.47%	2,133.284	-4.54%
FENTANYL	**515.025**	**471.712**	**-8.41%**	**472.441**	**0.15%**	**467.650**	**-1.01%**
HYDROCODONE	**63,179.515**	**61,710.790**	**-2.32%**	**56,372.635**	**-8.65%**	**50,046.773**	**-11.22%**
HYDROMORPHONE	**1,913.040**	**1,927.636**	**0.76%**	**1,834.406**	**-4.84%**	**1,752.294**	**-4.48%**
LEVORPHANOL	1.544	2.314	49.87%	2.691	16.29%	2.882	7.11%
LISDEXAMFETAMINE	**14,001.470**	**13,652.692**	**-2.49%**	**14,245.693**	**4.34%**	**15,111.185**	**6.08%**
MEPERIDINE	1,880.965	1,522.736	-19.04%	1,243.493	-18.34%	1,147.088	-7.75%
METHADONE	**6,777.086**	**5,805.070**	**-14.34%**	**5,251.161**	**-9.54%**	**4,957.310**	**-5.60%**
METHAMPHETAMINE	14.399	13.192	-8.38%	11.910	-9.72%	11.278	-5.30%
METHYLPHENIDATE **	**21,759.744**	**20,137.904**	**-7.45%**	**20,175.671**	**0.19%**	**18,893.332**	**-6.36%**
MORPHINE	28,706.443	26,272.879	-8.48%	24,603.452	-6.35%	24,084.883	-2.11%
NALBUPHINE	**63.599**	**41.766**	**-34.33%**	**40.868**	**-2.15%**	**36.675**	**-10.26%**
NALOXONE	433.684	481.367	10.99%	522.199	8.48%	550.850	5.49%
NALTREXONE	**646.518**	**743.593**	**15.02%**	**927.244**	**24.70%**	**1,388.838**	**49.78%**
Noroxymorphone products (sum)	1,143.801	1,266.726	10.75%	1,490.310	17.65%	1,976.362	32.61%
OPIUM	**80.986**	**77.417**	**-4.41%**	**76.702**	**-0.92%**	**74.977**	**-2.25%**
OXYCODONE	**66,704.849**	**60,357.506**	**-9.52%**	**58,911.473**	**-2.40%**	**59,620.924**	**1.20%**
OXYMORPHONE	**1,958.281**	**1,863.432**	**-4.84%**	**1,930.455**	**3.60%**	**1,946.653**	**0.84%**
PENTAZOCINE	698.430	565.292	-19.06%	422.871	-25.19%	428.603	1.36%
PENTOBARBITAL	**46.612**	**24.226**	**-48.03%**	**16.541**	**-31.72%**	**15.872**	**-4.04%**
PHENYLPROPANOLAMINE		2.966	#DIV/0!	1.058	-64.34%	0.792	-25.11%
PSEUDOEPHEDRINE***	**187,867.353**	**186,436.285**	**-0.76%**	**181,452.065**	**-2.67%**	**103,271.206**	**-43.09%**
REMIFENTANIL	1.105	1.158	4.75%	1.225	5.83%	1.270	3.71%
SECOBARBITAL	**15.670**	**12.040**	**-23.17%**	**11.470**	**-4.73%**	**12.480**	**8.81%**
SUFENTANIL	0.051	0.047	-8.82%	0.041	-11.40%	0.042	1.94%
TAPENTADOL	**6,388.449**	**5,989.766**	**-6.24%**	**5,645.768**	**-5.74%**	**5,642.812**	**-0.05%**

2015 Data based on Jan - Mar 2015 data

* corrected based on historical IMS data for d,l and d

** added dexmethylphenidate to methylphenidate

*** corrected based on IMS capture of OTC market

IMS DATA 2012 - 2015 (est)

Basic Class: 8787-6
Total PQ Requested: 704 256

2016 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Num	2016 Requested MQ	2016 Revised MQ	2014 Sales	2016 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2016 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		2 000	7 000	0 000	8 670 000	0.000	0.000	0.000	0 000	0 500	0 000	1.500	1.500	1 500	1.500	1.500	-1.000	1.500
		8,500 000	14 100 000	9 670 000	9,670 000	1.000	704 256	7,902 000	10,444 000	11,164 000	0 000	4,208 000	44.000	18,278 500	5,070 256	826 256	4,418 320	4,418 320
MQ Totals:		9,502 000	14,103,000															4,417 820

2016 Final Initial APQ:	14,200,000
2016 Final Revised APQ:	0 000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	14,200,000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	14,200 000

ALFENTANIL

Basic Class: M19-0

Total PQ Requested 1.000

2018 Initial APQ Worksheet

FDA Est:

IMS Est:

Company	DEA Num	2018 Requested MQ	2015 Revised MQ	2016 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2018 Total PQ	2014 Inventory	2018 Projected Exports	2018 Projected Sales	2018 Projected Exports	2018 Projected Inventory	2018 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CPR 80% Invent
(b)(4);(b)(7)(E)		2.000	2.000	0.000	0.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500	1.500	1.500	1.500	-1.000
MQ Totals:		2.000	2.000														

2018 Final Initial APQ:	2.000
2018 Final Revised APQ:	0.000
FDA Est: (2018 Initial APQ * 1 + FDA Est):	3.000
IMS Est: (2018 Initial APQ * 1 + IMS Est):	3.000

ALPHAPRODINE

Basic Class: 9143-0

Total PQ Requested: 5.000

2016 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ/Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Asset Calc	Calc Using Company Inward	Calc Using Dea Inward	Calc Using CFR 90% Inward	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	0.000	0.000	0.000	0.000	0.000	5.000	0.000	0.000	0.000	3.750	0.000	0.000	1.250	1.250
		5.000	5.000	0.000	0.000	0.000	0.000	0.000	0.000	5.000	0.000	4.000	4.000	3.750	4.000	4.000	-2.750	4.000
MQ Totals:		10.000	10.000															5.250

2016 Final Initial APQ:	15.000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	15.000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	15.000

Basic Class: 9050-A
Total PQ Requested: 10,300,400,000

2016 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Num	2016 Requested MQ	2016 Revised MQ	2016 Sales	2016 DEA MQ Sales	% of 2016 Sales	Share of 2016 Total PQ	2016 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		15,200,000,000	10,661,224,000	38,845,000	20,375,505,000	0.000	19,087,244	4,509,745,000	0.000	0.000	0.000	0.000	15,190,987,000	11,303,240,250	19,087,244	15,210,054,244	-12,498,846,944	15,210,054,244
		17,900,000,000	24,031,070,000	18,468,189,000	20,375,505,000	0.000	9,800,963,887	2,749,346,000	0.000	17,914,940,000	0.000	4,965,000,000	8,896,478,000	20,050,893,500	14,505,143,887	18,459,561,887	8,148,384,454	8,148,384,454
MQ Totals:		33,100,000,000	34,713,294,000															24,308,448,729

2016 Final Initial APQ:	40,000,000,000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	40,000,000,000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	40,000,000,000

CODEINE (FOR CONVERSION)

BASIC CLASS: Codeine (conversion) 9050-A

Company:	(b)(4)					
Request:	17900.0			15200.0		
Current Year MQ:	24031.1			10681.2		
Year end inventory	2743.3			4509.8		
Calculations (quota requested)	amt needed	substance MQ	yield	amt needed	substance MQ	yield
dihydrocodeine	226.667	170.000	0.750			
hydrocodone (for sale)	23908.046	20800.000	0.870	5302.391	3770.000	0.711
oxycodone (for sale)				9687.500	4650.000	0.480
					(use yield from other location)	
total needed	24134.713			14989.891		
INITIAL MQs						
est need	33432.810			16897.907		
MQ:						
Total Initial MQs:	17900.000			15200.000		

Total MQs:	33100.000	+ others	0.005	=	33100.005

FURTHER CALCULATIONS

Proposed Initial APQ 40000

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 122835 | Date Submitted: 21-APR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
CODEINE (FOR CONVERSION)

Schedule/List Number: 2
Drug Code: 9050-A
Quota Year: 2016
DEA Registration Number: (b)(4);(b)(7)(E)

Name and Address of Registrant
(b)(4)

Contact Person: (b)(6)
Email Address: (b)(4);(b)(6)
Fax No: (b)(6)
Phone No.

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	9,603,000.0	10,681,224.0	0.0	15,200,000.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	2,897,068.0	0.0	0.0	0.0
b.In-Process Material...	1,612,695.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms...	0.0	0.0	0.0	0.0
	4,509,763.0	0.0	0.0	0.0
Disposition(Sale)/Utilization				
a.Domestic...	38,643.0	0.0	0.0	0.0
b Exports...	0.0	0.0	0.0	0.0
	38,643.0	0.0	0.0	0.0
Acquisition/Production				
a.Domestic Sources...	5,015.0	0.0	15,200,000.0	15,200,000.0
	5,015.0	0.0	15,200,000.0	15,200,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield
OXYCODONE (FOR SALE)	9143-B	0	0	6,209,911	61.10

(4650)

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant | Explanation of Transfer

Date of Destruction | Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

(b)(4);(b)(7)(E)

Remarks

We will sell a portion of the material to [redacted] to produce Oxycodone HCl and Hydrocodone Bitartrate, and we will use some of the material internally to produce Oxycodone Base.

APPLICATION FOR PROCUREMENT QUOTA

Request ID 122831		Date Submitted	21-APR-15
Name of Basic Class or List 1 Chemical (only 1 per DEA-250)			
CODEINE (FOR CONVERSION)		Drug Schedule/List	2
Name and Address of Registrant		Drug Code	9050-A
(b)(4)		Quota Year	2016
		DEA Registration	(b)(4),(b)(7)(E)
Contact Person (b)(6)		Fax. No	(b)(6)
Email Address (b)(4),(b)(6)		Phone No.	

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	9,603,000.0	7,913,400.0	0.0	10,300,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Current Year Estimates	Quota Year Estimates
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	0.0	0.0	1,238,706.0	3,238,706.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	0.0	0.0	3,238,706.0	3,238,706.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	10,260,000.0	10,260,000.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	10,260,000.0	10,260,000.0
Acquisition/Production				
a.Domestic Sources.....	1,299,528.0	0.0	10,260,000.0	10,260,000.0
b.Importation.....	0.0	0.0	0.0	0.0
	1,299,528.0	0.0	10,260,000.0	10,260,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug Code	Amount Used for this Purpose 2013	2014	2015	% Yield
HYDROCODONE (FOR SALE)	9193-B			6,293,104	71.10
OXYCODONE (FOR SALE)	9143-B			5,098,347	48.00

If the Purpose is to Manufacture the Basic Class or List 1 Chemical into Dosage Forms, Furnish the Following Information:

Name of Dosage Form (include product form, i.e., tablets, patches, etc. and strengths)	Authority to Market	Drug Sched	Amount Used for this Purpose 2013	2014	Estimate for 2016	Estimate for Year Quota is Requested

Transfer Registrant | Explanation of Transfer

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Estimated Quantity	Estimated Completion

Date of Destruction | Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

(b)(4),(b)(7)(E)

Remarks

We will purchase the material from [redacted] and convert it to both Hydrocodone and Oxycodone.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 123362 | Date Submitted: 30-APR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
CODEINE (FOR CONVERSION)

Schedule/List Number: 2
Drug Code: 9050-A
Quota Year: 2016
DEA Registration Number: (b)(4);(b)(7)(E)

Name and Address of Registrant
(b)(4)

Contact Person: (b)(6)
Email Address: (b)(4);(b)(6)
Fax. No.
Phone No.: (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	24,506,599.0	24,031,070.0	0.0	17,900,000.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	1,696,445.0	0.0	1,985,060.0	1,985,060.0
b.In-Process Material.....	1,046,903.0	0.0	3,000,000.0	3,000,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	2,743,348.0	0.0	4,985,060.0	4,985,060.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	17,914,940.0	17,914,940.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	17,914,940.0	17,914,940.0
Acquisition/Production				
a.Domestic Sources.....	4.0	0.0	17,900,000.0	17,900,000.0
	4.0	0.0	17,900,000.0	17,900,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield
DIHYDROCODEINE	9120-0	0	0	226,667	75.00
HYDROCODONE (FOR SALE)	9193-B	24,053,232	15,168,586	17,588,273	87.00

20,850

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

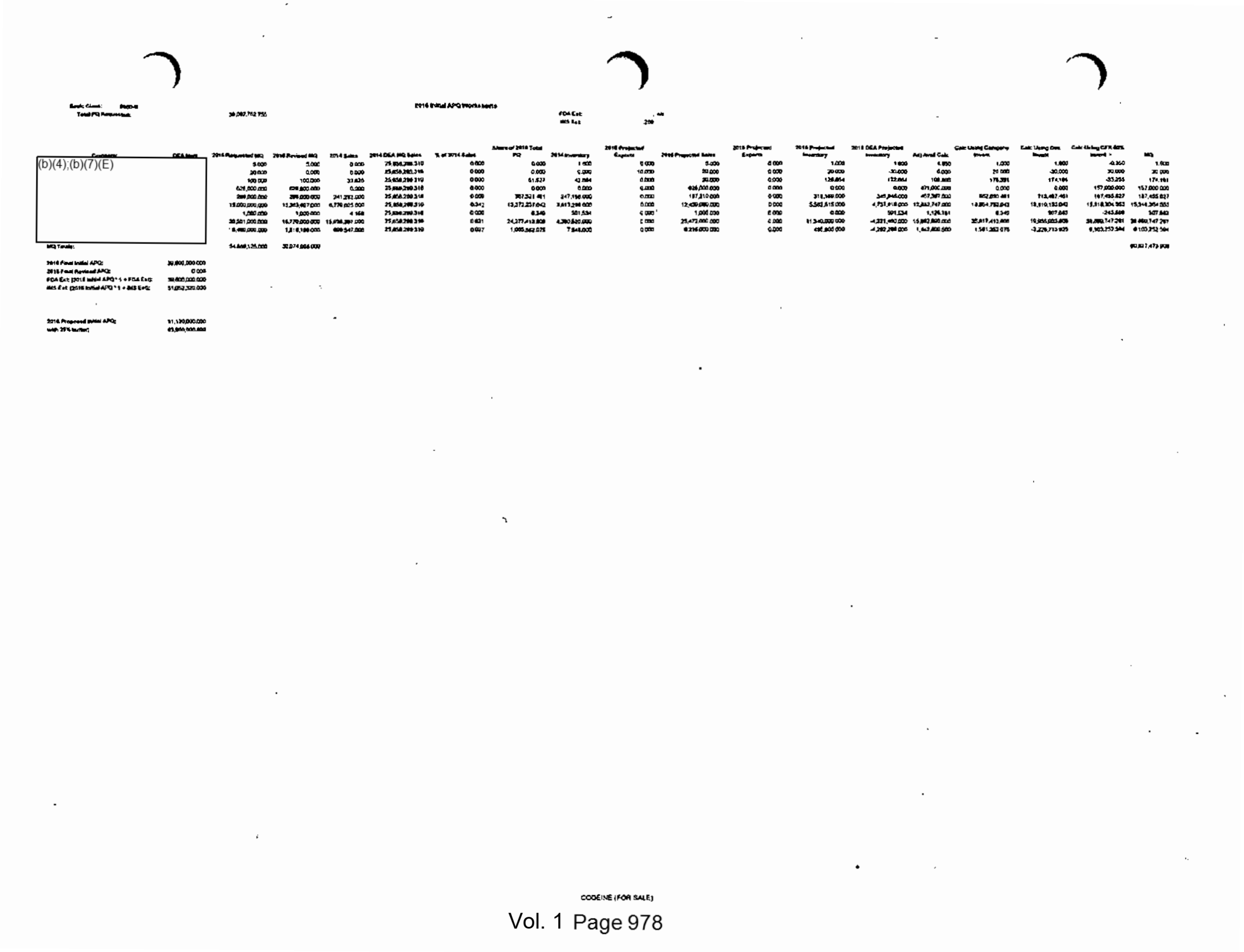
Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks

(b)(4);(b)(7)(E)



Manufacturer	2012 KG	2013 KG	2014 KG	2015 (4 mo) KG	Est 2015 KG
(b)(4)					
CODEINE	1,126.1979	898.9867	706.0595	218.197	654.591
HYDROCODONE	28,394.0724	23,340.5311	16,389.2893	5,154.1804	15,462.5412
(b)(4)					
CODEINE	0.12	183.945	359.94	381.519	1144.557
HYDROCODONE	2,488.2869	3,575.701	3,670.15	1,268.0513	3,804.1539
(b)(4)					
CODEINE	201.9216	187.7034	208.9938	91.2671	273.801
HYDROCODONE	116.1139	586.0412	488.6063	183.1848	549.5544
(b)(4)					
CODEINE	2,650.5719	720.8188	1,136.1235	302.7691	908.307
HYDROCODONE	14,828.2431	18,125.9265	12,832.8585	4,199.7663	12,599.2989
(b)(4)					
CODEINE	213.1261	137.8527	90.8124	51.0658	153.197
HYDROCODONE	144.9083	180.3861	102.8207	40.5091	121.5273
(b)(4)					
CODEINE	9,458.2497	9,627.1545	8,896.6084	3,568.0183	10704.055
HYDROCODONE	15,228.8441	13,752.8883	20,627.9477	4,403.7651	13,211.2953
(b)(4)					
CODEINE	6,189.2934	6,990.8199	6,846.4338	3,258.7383	9776.215
HYDROCODONE	284.5845	226.044	98.4863	0.0008	.0024
Grand Total - Codeine	**19,839.4806**	**18,747.281**	**18,244.9714**	**7,871.5746**	**23,614.7238**
Grand Total - Hydrocodone	**61,485.0532**	**59,787.5182**	**54,210.1588**	**15,249.4578**	**45,748.3734**

KG Audit from May 2009 to April 2015.
A. Includes all available columns.
Title NSP KG
Sub Title
Audit NSPKG
--- Report Filters ---
Manufacturer (b)(4)
(b)(4)
Molecule CODEINE, HYDROCODONE, restricted to: 4-HYDROXYBUTYRIC ACID, ALFENTANIL, ALPRAZOLAM, AMOBARBITAL, ATOMOXETINE, BELLADONA, BENZPHETAMINE, BUPRENORPHINE, BUPROPION, BUTABARBITAL, BUTALBITAL, BUTORPHANOL, CARBINOXAMINE, CARISOPRODOL, CHLORAL HYDRATE, CHLORDIAZEPOXIDE, CLONAZEPAM, CLORAZEPATE, COCAINE, CODEINE, CYCLOBENZAPRINE, DEXMETHYLPHENIDATE, DEXTROAMPHETAMINE, DEXTROMETHORPHAN, DIAZEPAM, DICHLORALPHENAZONE, DIETHYLPROPION, DIFENOXIN, DIHYDROCODEINE, DIPHENHYDRAMINE, DIPHENOXYLATE, DRONABINOL, EPHEDRINE, ESTAZOLAM, ESZOPICLONE, FENTANYL, FLUOXETINE, FLUOXYMESTERONE, FLURAZEPAM, FOSPROPOFOL, GABAPENTIN, HYDROCODONE, HYDROMORPHONE, KETAMINE, LACOSAMIDE, LEVORPHANOL, LISDEXAMFETAMINE, LORAZEPAM, LORCASERIN, MEPERIDINE, MEPROBAMATE, METHADONE, METHAMPHETAMINE, METHOHEXITAL, METHYLPHENIDATE, METHYLPHENOBARBITAL, METHYLTESTOSTERONE, MIDAZOLAM, MODAFINIL, MORPHINE, NABILONE, NALBUPHINE, NALOXONE, NALTREXONE, NANDROLONE, OPIUM, OXANDROLONE, OXAZEPAM, OXYCODONE, OXYMETHOLONE, OXYMORPHONE, PEMOLINE, PENTAZOCINE, PENTOBARBITAL, PERAMPANEL, PHENDIMETRAZINE, PHENOBARBITAL, PHENTERMINE, PHENYLEPHRINE, PHENYLPROPANOLAMINE, PREGABALIN, PROPOFOL, PROPOXYPHENE, PSEUDOEPHEDRINE, QUAZEPAM, REMIFENTANIL, RETIGABINE, SECOBARBITAL, SIBUTRAMINE, STANOZOLOL, SUFENTANIL, SUVOREXANT, TAPENTADOL, TEMAZEPAM, TESTOSTERONE, THIOPENTAL, TRAMADOL, TRIAZOLAM, ZALEPLON, ZOLPIDEM
Month 2015, 2014, 2013, 2012

Manufacturer	Q1 2014 KG	Q2 2014 KG	Q3 2014 KG	Q4 2014 KG	Q1 2015 KG
(b)(4)					
CODEINE	199.196	171.9742	167.7635	167.1198	166.864
HYDROCODONE	4,402.9031	4,189.8282	4,217.5459	3,579.0086	3,960.3623
(b)(4)					
CODEINE	61.824	63.321	80.019	154.752	285.339
HYDROCODONE	829.2086	902.4588	960.3325	978.0847	971.6628
(b)(4)					
CODEINE	71.9536	41.5798	30.4825	64.9778	77.7549
HYDROCODONE	131.85	130.411	128.539	97.7638	141.272
(b)(4)					
CODEINE	174.7263	165.6367	320.4232	475.3253	267.9936
HYDROCODONE	2,829.3403	2,864.0804	3,810.4553	3,328.9653	3,170.0892
(b)(4)					
CODEINE	22.7157	18.166	21.6082	28.3214	37.2305
HYDROCODONE	51.0996	14.2548	16.1151	21.3512	33.4326
(b)(4)					
CODEINE	2,394.4384	2,063.125	1,940.0434	2,498.9755	2,369.1516
HYDROCODONE	6,060.3932	6,019.3266	5,178.0557	3,369.9379	3,405.4567
(b)(4)					
CODEINE	1,594.2957	1,530.9222	1,552.5138	2,168.6856	2,547.2826
HYDROCODONE	50.2253	39.423	8.7825	0.0555	0.0008
Grand Total - Codeine	**4,519.1497**	**4,054.7249**	**4,112.8536**	**5,558.1574**	**5,751.6162**
Grand Total - Hydrocodone	**14,355.0201**	**14,159.7828**	**14,319.826**	**11,375.167**	**11,682.2764**

IMS Health Data for Manufacturers of both codeine and hydrocodone products for 2014-2015 (1st qtr.)

KG Audit from April 2009 to March 2015.
A. Includes all available columns.
Title NSP KG
Sub Title
Audit NSPKG
--- Report Filters ---
Manufacturer (b)(4)
(b)(4)
Molecule CODEINE, HYDROCODONE, restricted to: 4-HYDROXYBUTYRIC ACID, ALFENTANIL, ALPRAZOLAM, AMOBARBITAL, ATOMOXETINE, BELLADONA, BENZPHETAMINE, BUPRENORPHINE, BUPROPION, BUTABARBITAL, BUTALBITAL, BUTORPHANOL, CARBINOXAMINE, CARISOPRODOL, CHLORAL HYDRATE, CHLORDIAZEPOXIDE, CLONAZEPAM, CLORAZEPATE, COCAINE, CODEINE, CYCLOBENZAPRINE, DEXMETHYLPHENIDATE, DEXTROAMPHETAMINE, DEXTROMETHORPHAN, DIAZEPAM, DICHLORALPHENAZONE, DIETHYLPROPION, DIFENOXIN, DIHYDROCODEINE, DIPHENHYDRAMINE, DIPHENOXYLATE, DRONABINOL, EPHEDRINE, ESTAZOLAM, ESZOPICLONE, FENTANYL, FLUOXETINE, FLUOXYMESTERONE, FLURAZEPAM, FOSPROPOFOL, GABAPENTIN, HYDROCODONE, HYDROMORPHONE, KETAMINE, LACOSAMIDE, LEVORPHANOL, LISDEXAMFETAMINE, LORAZEPAM, LORCASERIN, MEPERIDINE, MEPROBAMATE, METHADONE, METHAMPHETAMINE, METHOHEXITAL, METHYLPHENIDATE, METHYLPHENOBARBITAL, METHYLTESTOSTERONE, MIDAZOLAM, MODAFINIL, MORPHINE, NABILONE, NALBUPHINE, NALOXONE, NALTREXONE, NANDROLONE, OPIUM, OXANDROLONE, OXAZEPAM, OXYCODONE, OXYMETHOLONE, OXYMORPHONE, PEMOLINE, PENTAZOCINE, PENTOBARBITAL, PERAMPANEL, PHENDIMETRAZINE, PHENOBARBITAL, PHENTERMINE, PHENYLEPHRINE, PHENYLPROPANOLAMINE, PREGABALIN, PROPOFOL, PROPOXYPHENE, PSEUDOEPHEDRINE, QUAZEPAM, REMIFENTANIL, RETIGABINE, SECOBARBITAL, SIBUTRAMINE, STANOZOLOL, SUFENTANIL, SUVOREXANT, TAPENTADOL, TEMAZEPAM, TESTOSTERONE, THIOPENTAL, TRAMADOL, TRIAZOLAM, ZALEPLON, ZOLPIDEM

Basic Class: 9273-0

Total PQ Requested: 61.000

2016 Initial APQ Worksheets

FDA Est
IMS Est

Company	DEA Num	2016 Requested PQ	2016 Revised PQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2015 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Acct Calc	Calc Using Company Inven	Calc Using Dea Inven	Calc Using CFR 80% Inven
(b)(4);(b)(7)(E)		5.000	5.000	0.000	39,252.000	0.000	0.000	0.000	0.000	4.000	0.000	0.000	1.000	3.750	0.000	1.000	0.250
		20.000	0.000	0.000	39,252.000	0.000	0.000	0.000	10.000	20.000	0.000	20.000	-30.000	0.000	20.000	-30.000	30.000
		10.000	10.000	0.000	39,252.000	0.000	0.000	6.087	0.000	1.000	0.000	15.087	15.087	12.065	15.087	15.087	-12.587
MQ Totals:		35.000	15.000														

2015 Final Initial APQ:	15.000
2015 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	15.000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	15.000
2016 Proposed Initial APQ:	35.000

Basic Class: 9120-0

Total PQ Requested: 9,112,000

2016 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2016 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent
(b)(4);(b)(7)(E)		5,000	5,000	0.000	59,754,017	0.000	0.000	0.000	0.000	5,000	0.000	1.000	0.000	3,750	1.000	0.000	1,250
		20,000	0.000	0.000	59,754,017	0.000	0.000	0.000	10,000	20,000	0.000	20,000	-30,000	0.000	20,000	-30,000	30,000
		5,000	5,000	0.417	59,754,017	0.000	0.084	14,243	0.000	1,000	0.000	16,343	16,243	14,452	16,407	16,307	-16,814
		170,000,000	160,000,000	59,753,000	59,754,017	1.000	9,118,645	143,086,000	0.000	134,000,000	0.000	199,000,000	189,068,000	242,316,000	206,111,845	195,199,845	-132,696,184
		1,000,000	300,000	0.000	59,754,017	0.000	0.091	0.050	0.000	1,000,000	0.000	0.000	-699,950	225,038	0.091	-699,859	275,064
MQ Totals:		171,030,000	160,310,000														

2015 Final Initial APQ:	181,100,000
2015 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	181,100,000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	181,100,000

DIHYDROCODEINE

Basic Class: 9170-A

Total PQ Requested: 0.000

2016 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Reg	2015 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2014 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Asset Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent
(b)(4);(b)(7)(E)		10,000.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	12,675.000	0.000	5,169.000	-12,675.000	0.000	5,169.000	-12,675.000	12,675.000
MQ Totals:		10,000.000	0.000														

2015 Final Initial APQ:	0.000
2015 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	0.000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	0.000
2016 Proposed Initial APQ:	25,000.000
with 25% buffer	31,250.000

Basic Class: 8170-B

Total PQ Requested: 0.000

2016 Initial APQ Worksheets

FDA Est.

BIS Est:

Company	DEA Num	2016 Requested MQ	2016 Revised MQ	2016 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 40% Invent
(b)(4);(b)(7)(E)		2.000	2.000	0.000	712,472.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500	1.500	1.500	1.500	-1.000
		10,000.000	15,610.000	0.000	712,472.000	0.000	0.000	32,448.000	4,830.000	4,400.000	0.000	25,048.000	36,999.000	38,324.250	25,048.000	36,999.000	-35,048.500
		800,000.000	740,000.000	712,472.000	712,472.000	1.000	0.000	192,711.000	16,400.000	653,200.000	0.000	250,707.000	261,111.000	699,533.250	250,707.000	261,111.000	-78,411.000
MQ Totals:		810,002.000	755,612.000														

2016 Final Initial APQ:	1,070,000.000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	1,070,000.000
BIS Est: (2016 Initial APQ * 1 + BIS Est):	1,070,000.000

DIPHENOXYLATE (FOR SALE)

Basic Class: 9190-8

Total PQ Requested: 0.000

2018 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2018 Requested MQ	2018 Revised MQ	2016 Sales	2016 DEA MQ Sales	% of 2016 Sales	Share of 2018 Total PQ	2016 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 80% Invent	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	0.000	0.000	0.000	0.744	0.000	0.500	0.000	1.744	2.244	2.088	1.744	2.244	-1.744	2.244
MQ Totals:		2.000	2.000															2.244

2018 Final Initial APQ:	2.000
2018 Final Revised APQ:	0.000
FDA Est: (2018 Initial APQ * 1 + FDA Est):	2.000
IMS Est: (2018 Initial APQ * 1 + IMS Est):	2.000

ETHYLMORPHINE

Basic Data: 9914

Total PQ Requested: 663,429,462

2016 Initial APQ Worksheet

FDA Est: -.038

IMS Est: -.01

Company	DEA Share	2016 Requested PQ	2016 Revised PQ	2016 Sales	2014 DEA PQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	4Q Annl Calc	Calc Using Company Trend	Calc Using Dist Trend	Calc Using EFR 50% Trend	IMS
(b)(4);(b)(7)(E)		5,000	5,000	0.000	1,160,160,467	0.000	0.000	0.125	0.000	4.000	0.000	1.000	4.100	3.675	1.000	1.100	0.150	0.150
		200,000,000	153,469,000	39,845,000	1,160,160,467	0.035	25,863,015	55,806,000	0.000	200,000,000	0.000	45,000,000	6,474,000	157,905,350	73,863,011	56,352,011	65,647,013	89,647,013
		20,000	0.000	0.000	1,160,160,467	0.000	0.000	0.000	15,000	35,000	0.000	20,000	-30,000	0.000	20,000	-30,000	50,000	50,000
		3,000	2,000	0.463	1,160,160,467	0.000	0.538	2,322	0.000	-0.500	0.000	2,363	3,788	3,212	3,722	4,121	-2,858	4,121
		39,960,000	10,940,000	10,174,805	1,160,160,467	0.009	7,360,898	9,503,000	0.000	39,960,000	0.000	1,000,000	-25,787,000	9,864,756	8,360,889	-19,386,101	37,985,824	37,985,824
		200,000,000	345,665,000	273,135,000	1,160,160,467	0.235	165,128,917	387,124,000	0.000	364,119,000	0.000	532,878,000	541,873,000	979,481,750	531,002,617	740,001,617	-164,465,879	740,001,617
		600,000,000	671,515,000	738,839,000	1,160,160,467	0.621	536,858,000	232,756,000	279,562,000	660,179,000	0.000	415,579,000	-114,260,000	625,200,250	651,434,000	421,565,000	1,001,961,361	1,001,961,361
		87,500,000	29,000,000	16,396,000	1,160,160,467	0.014	11,467,188	14,160,000	0.000	74,000,000	0.000	29,000,000	-34,640,000	29,376,000	36,847,184	-22,673,614	55,823,963	85,823,963
6AQ Totals:		1,816,487,000	1,979,745,000															1,800,963,000

2016 Final Initial APQ:	1,725,000,000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	1,710,340,000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	1,703,028,000
2016 Proposed Initial APQ:	1,840,000,000
with 25% buffer:	2,300,000,000

FENTANYL

Basic Class: 9193-A

Total PQ Requested: 0.000

2016 Initial APQ Worksheet

FDA Est:
IMS Est:

Company	DEA Mark	2016 Requested PQ	2015 Revised PQ	2014 Sales	2014 DEA PQ Sales	% of 2014 Sales	Source of 2014 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Annual Calc	Calc Using Company Issued	Calc Using Our Issued	Calc Using CFR 80% Limit
(b)(4);(b)(7)(E)		187,515.000	101,000.000	0.000	0.000	0.000	0.000	0.000	0.000	187,515.000	0.000	0.000	-85,515.000	35,750.000	0.000	85,515.000	111,765.000
		20.000	0.000	0.000	0.000	0.000	0.000	0.000	10.000	20.000	0.000	0.000	-30.000	0.000	0.000	-35.000	30.000
PQ Totals:		187,535.000	101,000.000														

2015 Final Initial APQ:	110,000.000
2015 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	110,000.000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	110,000.000
2016 Proposed Initial APQ:	188,000.000
with 25% buffer:	235,000.000

Basic Class: 9193-B

Total PQ Requested: 34,008,467,172

2016 Initial APQ Worksheet

FDA Est: -.077

IMS Est. -.112

Company	DEA REG#	2016 Requested PQ	2016 Revised PQ	2014 Sales	2016 DEA PQ Basis	% of 2014 Sales	Shorts of 2016 Total PQ	2016 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Imports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Commerce Index	Calc Using Dos Inputs	Calc Using CSR 20% Buffer
(b)(4);(b)(7)(E)		5,000	5,000	0.000	48,387,859,915	0.000	0.000	0.051	0.000	4,000	0.000	1.000	1.051	3,786	1.000	1.051	0.786
		164,700,000	74,500,000	10.000	48,387,859,915	0.000	13.387	0.000	0.000	164,700,000	0.000	7,000,000	-93,150,000	56,813,300	7,017,387	-93,132,613	106,808,234
		20,000	20,000	8,735	48,387,859,915	0.000	11,710	86,422	0.000	8,000	0.000	86,733	78,433	84,617	78,433	80,132	-68,754
		499,000,000	140,500,000	16,105,000	48,387,859,915	0.000	33,313,717	23,205,000	0.000	499,000,000	0.000	5,000,000	-355,444,000	122,649,000	38,317,717	-289,350,283	369,115,649
		5,900,000	5,900,000	5,305,180	48,387,859,915	0.000	0.015,382	1,673,047	0.000	5,900,000	0.000	0.000	1,673,047	5,679,785	8,215,385	10,888,429	11,201,141
		3,770,000,000	810,000,000	1,901,901,000	48,387,859,915	0.039	3,809,629,700	3,139,901,000	0.000	3,853,000,000	0.000	1,775,853,000	99,881,000	2,612,200,150	5,063,572,700	3,403,431,700	-4,188,424,875
		20,800,000,000	20,544,800,000	17,263,125,000	48,387,859,915	0.357	10,015,290,584	9,699,469,000	12,200,000	48,650,810,000	0.000	7,716,149,000	9,087,181,000	30,947,478,350	37,731,429,584	39,082,446,584	23,517,318,480
		9,000,000,000	3,830,000,000	1,898,838,000	48,387,859,915	0.034	3,805,847,818	543,309,000	0.000	9,149,000,000	0.000	0.000	-3,586,691,000	2,886,791,750	5,645,647,818	480,963,364	7,908,795,920
		83,852,000,000	26,132,000,000	29,886,112,000	48,387,859,915	0.556	46,762,325,311	2,771,888,000	0.000	20,500,000,000	0.000	11,674,000,000	6,401,886,000	29,877,888,500	56,636,325,311	55,184,191,311	56,564,846,243
		9,832,800,000	1,438,550,000	575,109,000	48,387,859,915	0.012	668,935,874	3,703,045,000	0.000	6,830,000,000	0.000	1,998,000,000	-400,518,000	4,008,863,000	3,665,935,874	830,419,874	2,490,278,063
		6,000,000,000	6,120,270,000	48,154,000	48,387,859,915	0.001	63,924,881	5,788,292,000	0.000	8,100,000,000	0.000	1,700,000,000	5,940,558,000	8,837,418,000	1,292,324,881	5,800,292,881	-3,661,832,781

IRQ Totals: 74,912,825,000 59,922,295,000

2016 Final Initial APQ:	78,700,000,000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	71,563,100,000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	70,737,600,000
2016 Proposed Initial APQ:	70,600,000,000
with 20% buffer:	88,600,000,000

Basic Class: 9150-0

Total PQ Requested: 2,403,890,106

2018 Initial APQ Worksheets

FDA Est: -037

IMS Est: -045

(b)(4);(b)(7)(E)

Company	DEA Num	2018 Requested MQ	2018 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 60% Invent
		5,000	5,000	0.000	4,046,947,268	0.000	0.000	0.000	0.000	1.000	0.000	1.000	1.000	5.750	1.000	1.000	0.250
		108,800,000	87,925,000	0.000	4,046,947,268	0.000	0.000	0.000	0.000	108,800,000	0.000	6,000,000	-49,275,000	43,145,750	6,000,000	-49,275,000	63,856,250
		20,000	0.000	0.000	4,046,947,268	0.000	0.000	0.000	10.000	20.000	0.000	20.000	-30.000	0.000	20.000	-30.000	30.000
		30,000	30,000	0.000	4,046,947,268	0.000	0.041	40.527	0.000	3.000	0.000	56.216	73.527	56.695	56.269	73.568	-65.878
		57,850,000	74,173,000	23,891,000	4,046,947,268	0.006	14,784,455	12,368,000	0.000	87,850,000	0.000	0.000	28,581,000	94,800,750	14,784,455	43,273,495	6,432,665
		691,400,000	374,157,000	405,470,322	4,046,947,268	0.120	249,171,915	318,677,853	5,800,000	576,223,000	0.000	123,000,000	209,691,853	383,111,140	424,171,915	507,863,768	308,907,291
		443,000,000	522,452,000	393,569,000	4,046,947,268	0.097	242,536,952	78,933,000	0.000	573,400,000	0.000	148,915,000	222,584,000	446,538,000	380,551,952	466,120,952	206,200,190
		670,000,000	1,160,000,000	756,765,000	4,046,947,268	0.187	467,802,552	663,888,000	0.000	809,215,000	0.000	432,585,000	1,036,780,000	1,304,408,250	600,187,552	1,504,342,552	-157,279,610
		1,000,000	0.000	0.000	4,046,947,268	0.000	0.000	0.000	0.000	1,000,000	0.000	0.000	-1,000,000	0.000	0.000	-1,000,000	1,000,000
		3,250,000,000	2,225,000,000	2,173,738,000	4,046,947,268	0.537	1,339,261,828	517,097,000	0.000	2,252,000,000	0.000	1,027,000,000	510,087,000	2,056,372,750	2,368,261,828	1,949,358,928	1,720,230,037
		1,062,000,000	0.000	0.000	4,046,947,268	0.000	0.000	0.000	0.000	0.000	0.000	1,062,000,000	0.000	0.000	1,062,000,000	0.000	0.000
		1,900,000,000	600,000,000	186,048,000	4,046,947,268	0.026	64,738,008	2,716,000	667,500,000	698,800,000	0.000	189,100,000	-1,061,682,000	377,038,500	233,826,008	496,945,001	1,269,803,012
MQ Totals:		7,343,263,000	5,133,722,000														

2016 Final Initial APQ:	5,800,000,000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	5,383,380,000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	5,348,120,000

HYDROMORPHONE

Basic Class: 8226-8
Total PQ Requested: 0.000

2016 Initial APQ Worksheets

FDA Est: .
BES Est: .

Company	DEA Num	2014 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2016 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Due Invent	Calc Using CFR 80% Invent	MQ
(b)(4);(b)(7)(E)		3.000	2.000	0.000	0.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500	1.500	1.500	1.500	-1.000	1.500
MQ Totals:		2.000	2.000															1.500

2016 Final Initial APQ:	4.000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	4.000
BES Est: (2016 Initial APQ * 1 + BES Est):	4.000

ISOMETHADONE

Basic Class: 9650.0

Total PQ Requested: 0.000

2016 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2016 Requested MQ	2016 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invest	Calc Using Dea Invest	Calc Using DFR 80% Invest
(b)(4);(b)(7)(E)		2.000	2.000	0.000	0.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500	1.500	1.500	1.500	-1.000
MQ Totals:		2.000	2.000														

2016 Final Initial APQ:	3.000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	3.000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	3.000

Basic Class: 8210-0

Total PQ Requested: 0.000

2015 Initial APQ Worksheets

FDA Est.

IMS Est.

Company	DEA Num	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dev Invent	Calc Using CFR 50% Invent
(b)(4);(b)(7)(E)		20.000	0.000	0.000	0.160	0.000	0.000	0.000	10.000	20.000	0.000	20.000	-30.000	0.000	20.000	-30.000	20.000
		5.000	2.000	0.160	0.160	1.000	0.000	0.988	0.000	2.000	0.000	4.488	0.988	2.241	4.488	0.988	-0.488
MQ Totals:		25.000	2.000														

2015 Final Initial APQ:	5.000
2015 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	5.000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	5.000
2016 Proposed Initial APQ:	30.000

LEVOMETHORPHAN

Basic Class: 9120-6

2016 Initial APQ Worksheets

Total PQ Requested: 4,197,000

FDA Est:
IMS Est:

Company	DEA Num	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Basis of 2016 Total PQ	2044 Inventory	2015 Projected Exports	2015 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Report	Calc Using Dist Report	Calc Using CFR 80% Report
(b)(4);(b)(7)(E)		2,000	2,000	0,000	3,084,000	0.000	0.000	0.000	0.000	0.000	0.000	1,500	1,500	1,500	1,500	1,500	-1,000
		4,500,000	3,732,000	3,084,000	3,084,000	1.000	4,197,000	117,000	0.000	3,532,000	0.000	1,534,000	999,000	2,158,750	5,591,000	3,508,000	6,816,250
MQ Totals:		4,502,000	3,734,000														

2016 Final Initial APQ: 5,700,000
2015 Final Revised APQ: 0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est): 5,700,000
IMS Est: (2016 Initial APQ * 1 + IMS Est): 6,700,000

Basic Class: 9230-2

Total PQ Requested: 1,552,613,526

2016 Initial APQ Worksheets

FDA Est: -178

IMS Est: -078

Company	DEA Num	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR60% Invent
(b)(4);(b)(7)(E)		5,000	0.000	0.000	1,675,745.000	0.000	0.000	0.000	0.000	4.000	0.000	1.000	1.000	3.750	1.000	1.000	0.250
		20,000	0.000	0.000	1,675,745.000	0.000	0.000	0.000	10.000	20.000	0.000	20.000	-30.000	0.000	20.000	-30.000	30.000
		5,000	5.000	0.000	1,675,745.000	0.000	0.000	4.243	0.000	1.000	0.000	9.743	8.243	6.932	5.743	8.243	-6.993
		630,000.000	602,312.000	21,579.000	1,675,745.000	0.043	10,895.860	72,094.000	0.000	652,500.000	0.000	257,053.000	21,906.000	505,804.500	277,058.980	41,801.860	153,608.975
MQ Totals:		630,000.000	602,322.000														

2015 Final Initial APQ: 5,000,000.000

2016 Final Revised APQ: 0.000

FDA Est: (2016 Initial APQ * 1 + FDA Est): 4,108,500.000

IMS Est: (2015 Initial APQ * 1 + IMS Est): 4,612,500.000

Note:

(b)(4) has not submitted request applications as of 5-26-15

2014 Proposed Initial APQ: 4,360,000.000 used avg between FDA & IMS estimate

with 25% buffer: 6,450,000.000

(b)(4) Historical use

	Requested	Granted	Manufactured	% used
2008		3,908,000.00	3,550,807.00	90.9%
2009		3,908,000.00	3,668,279.00	93.9%
2010		2,917,000.00	2,783,964.00	95.4%
2011		3,800,000.00	2,133,800.00	56.2%
2012		3,131,000.00	2,130,331.00	68.0%
2013		3,105,000.00	1,490,280.00	48.1%
2014		3,339,895.00	3,139,475.00	94.0%

MEPERIDINE

Basic Class: 9333-0

Total PQ Requested: 0.000

2015 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Sum	2015 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2015 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2015 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 80% Invent
(b)(4);(b)(7)(E)		3.000	3.000	0.000	3.000	0.000	0.000	0.000	0.000	1.000	0.000	2.000	2.000	2.250	2.000	2.000	-1.250
MQ Totals:		3.000	3.000														

2015 Final Initial APQ:	5.000
2015 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	5.000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	5.000

MEPERIDINE-INTERMEDIATE-A

Basic Class: 9213-C

Total PQ Requested: 1,000

2016 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Mult	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2015 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Audit Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc using CFR Sch. Invent
(b)(4);(b)(7)(E)		5,000	5,000	2,710	2,710	1.000	1.000	3,514	0.000	2,500	0.000	5,514	6,514	6,386	6,514	7,014	-3,514
MQ Totals:		5,000	5,000														

2015 Final Initial APQ:	8,000
2015 Final Revised APQ:	0,000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	8,000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	8,000
2016 Proposed Initial APQ:	9,000

Basic Class: 9334.0

Total PQ Requested: 0.000

2016 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Mult	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2015 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using Effective Invent
(b)(4);(b)(7)(E)		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	0.000	2.000	2.000	2.250	2.000	3.000	-1.250
MQ Totals:		0.000	0.000														

2016 Final Initial APQ:	0.000
2016 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	0.000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	0.000

MEPERIDINE-INTERMEDIATE-C

Basic Class: 9260-0

Total PQ Requested: 18,298,318,512

2018 Initial APQ Worksheets

FDA Est:

MIS Est:

Company	DEA Num	2018 Requested MQ	2018 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2018 Total PQ	2014 Inventory	2018 Projected Exports	2018 Projected Sales	2018 Projected Exports	2018 Projected Inventory	2018 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 80% Invent
(b)(4);(b)(7)(E)		5,000	5,000	0.000	11,857,499,620	0.000	0.000	0.000	0.000	5,000	0.000	0.000	0.000	3,750	0.000	0.000	1,250
		20,000	0.000	0.000	11,857,499,620	0.000	0.000	0.000	10,000	20,000	0.000	20,000	-30,000	0.000	20,000	-30,000	30,000
		10,000	10,000	0.620	11,857,499,620	0.000	0.653	5,787	0.000	2,000	0.000	12,785	13,787	11,625	14,618	14,618	-10,200
		265,220,000	262,111,000	11,650,000	11,857,499,620	0.001	16,013,105	35,914,000	0.000	265,220,000	0.000	0.000	33,805,000	223,516,750	16,813,105	48,818,105	52,739,131
		14,600,000,000	11,301,841,000	8,500,573,000	11,857,499,620	0.717	11,564,168,964	7,680,300,000	0.000	13,652,600,000	0.000	4,916,366,000	418,647,000	10,554,110,250	16,802,566,964	12,103,715,864	17,031,124,480
		6,142,000,000	4,035,367,000	3,345,276,000	11,857,499,620	0.282	4,598,133,571	1,070,615,000	0.000	4,327,500,000	0.000	1,153,300,000	978,640,000	3,829,635,000	9,751,473,571	5,476,813,571	6,677,828,713
MQ Totals:		21,007,256,000	15,609,384,000														

2018 Final Initial APQ:	25,500,000,000
2018 Final Revised APQ:	0.000
FDA Est: (2018 Initial APQ * 1 + FDA Est):	25,500,000,000
MIS Est: (2018 Initial APQ * 1 + MIS Est):	25,500,000,000

METHADONE

Basic Class: 1154-4

Total PO Requested: 0.000

2016 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2016 Requested MQ	2016 Revised MQ	2016 Sales	2016 DEA MQ Sales	% of 2016 Sales	Share of 2016 Total PO	2016 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Old Invent	Calc Using CFR 50% Invent
(b)(4);(b)(7)(E)		- 10.000	10.000	0.000	13,584,544.000	0.000	0.000	0.000	0.000	5.000	0.000	3.000	5.000	7.500	6.000	5.000	-2.500
		578,450.000	524,222.000	58,508.000	13,584,544.000	0.004	0.000	12,187.000	0.000	578,450.000	0.000	0.000	-42,071.000	402,284.250	0.000	-42,071.000	173,178.500
		16,200,000.000	14,189,368.000	8,025,649.000	13,584,544.000	0.592	0.000	1,054,646.000	0.000	14,086,964.000	0.000	2,717,341.000	1,187,146.000	11,440,519.500	2,717,341.000	1,187,146.000	2,369,893.500
		8,860,000.000	4,960,000.000	4,871,307.000	13,584,544.000	0.359	0.000	516,525.000	0.000	6,680,000.000	0.000	620,000.000	-3,203,425.000	4,107,431.250	620,000.000	-3,203,425.000	4,440,425.000
MQ Totals:		25,458,450.000	19,683,598.000														

2016 Final Initial APQ:	27,500,000.000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	27,500,000.000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	27,500,000.000

METHADONE-INTERMEDIATE

Basis Class: 8000-A

Total PQ Requested: 1,162,510.000

2016 Initial APQ Worksheets

FDA Est: .

INS Est: .

Company	DEA Rank	2016 Requested MQ	2016 Revised MQ	2016 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2014 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Inven	Calc Using Dea Inven	Calc Using CFR 80% Inven
(b)(4);(b)(7)(E)		749,000.000	749,000.000	0.000	34,744,762.800	0.000	0.000	0.000	0.000	749,000.000	0.000	0.000	0.000	581,750.000	0.000	0.000	187,250.000
		4,320,000.000	4,000,777.000	22,680.000	34,744,762.800	0.001	772.201	1,632,369.000	3,840,000.000	3,840,000.000	0.000	480,000.000	-1,816,965.000	4,397,531.250	480,772.201	-1,816,132.790	2,629,952.002
		36,000,000.000	37,000,000.000	30,883,365.000	34,744,762.800	0.604	710,748.092	10,177,733.000	0.000	36,018,160.000	0.000	10,088,848.000	11,158,375.000	35,383,299.000	10,780,698.082	11,870,320.092	-1,021,138.883
		23,002,000.000	13,464,000.000	12,572,153.000	34,744,762.800	0.362	407,883.851	1,980,420.000	0.000	23,168,000.000	0.000	4,779,000.000	-7,701,560.000	11,563,065.000	5,209,882.851	-7,273,497.149	11,603,433.564
		2,000.000	2,000.000	479.050	34,744,762.800	0.000	16.304	0.000	0.000	2,000.000	0.000	0.000	0.000	1,500.000	16.304	16.304	520.380
		1,260,000.000	0.000	0.000	34,744,762.800	0.000	0.000	0.000	0.000	1,260,000.000	0.000	0.000	-1,260,000.000	0.000	0.000	-1,260,000.000	1,260,000.000
MQ Totals:		67,333,000.000	55,145,727.000														

2016 Final Initial APQ:	73,000,000.000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	73,000,000.000
INS Est: (2016 Initial APQ * 1 + INS Est):	73,000,000.000

MORPHINE (FOR CONVERSION)

Basic Class: 9300-B

Total PQ Requested: 42,389,755.916

2016 Initial APQ Worksheets

FDA Est:

IMS Est:

(b)(4);(b)(7)(E)

Company	DEA Num	2016 Requested PQ	2016 Revised PQ	2014 Sales	2014 DEA PQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Gas Invent	Calc Using CPR 50% Invent
		5.000	5.000	0.000	28,952,008.335	0.000	0.000	0.000	0.000	4.000	0.000	1.000	1.000	3.770	1.000	1.000	0.224
		20.000	0.000	0.000	28,952,008.335	0.000	0.000	0.000	10.000	20.000	0.000	20.000	-30.000	0.000	20.000	-30.000	30.000
		100.000	100.000	0.085	28,952,008.335	0.000	11.808	120.750	0.000	30.000	0.000	194.079	180.750	165.589	205.859	202.587	-150.000
		218,000.000	75,200.000	0.000	28,952,008.335	0.000	0.000	0.000	0.000	218,000.000	0.000	0.000	-140,800.000	54,400.000	0.000	-140,800.000	750,000.000
		2,140,000.000	4,700,000.000	71,327.000	28,952,008.335	0.002	104,433.821	1,983,870.000	0.000	3,127,658.000	0.000	0.000	4,508,211.000	5,012,802.500	104,433.821	4,660,643.621	-3,250,870.223
		11,700,000.000	13,800,000.000	9,844,843.000	28,952,008.335	0.343	14,560,828.634	4,159,713.000	638,250.000	11,444,750.000	0.000	5,188,525.000	5,671,713.000	13,488,764.750	18,747,154.624	20,252,343.324	18,079,273.000
		26,753,000.000	19,546,000.000	16,108,944.000	28,952,008.335	0.558	23,582,800.000	8,865,061.000	0.000	10,163,000.000	0.000	9,750,000.000	7,266,081.000	19,832,310.750	33,341,600.085	30,062,861.000	27,065,419.100
		1,000.000	1,000.000	0.000	28,952,008.335	0.000	0.000	0.000	0.000	1,000.000	0.000	0.000	0.000	750.000	0.000	0.000	250.000
		10.000	10.000	0.000	28,952,008.335	0.000	0.000	0.000	0.000	10.000	0.000	0.000	0.000	7.500	0.000	0.000	2.500
		7,100,000.000	22,500.000	0.000	28,952,008.335	0.000	0.000	2,777,000.000	0.000	3,770,000.000	0.000	5,020,000.000	-670,500.000	3,098,625.000	5,020,000.000	-670,500.000	675,125.000
		500,000.000	275,000.000	0.000	28,952,008.335	0.000	0.000	0.000	0.000	461,250.000	0.000	213,350.000	-186,250.000	206,250.000	213,350.000	-186,250.000	355,000.000
PQ Totals:		48,459,135.000	35,421,815.000														

2016 Final Initial APQ:	50,000,000.000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	50,000,000.000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	50,000,000.000

MORPHINE (FOR SALE)

Basic Class: 9630-0

Total PQ Requested: 1,115,000,000

2016 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent
(b)(4);(b)(7)(E)		44,000,000	37,014,000	39,494,000	202,165,000	0.195	217,821,138	9,816,000	0.000	44,000,000	0.000	3,933,000	1,830,000	34,372,500	221,755,138	219,851,138	279,899,920
		140,000,000	430,000,000	132,200,000	202,165,000	0.654	720,122,252	174,442,000	0.000	134,000,000	0.000	203,590,000	496,442,000	468,331,500	832,712,252	1,219,584,252	533,480,815
		60,000,000	20,000,000	0.000	202,165,000	0.000	0.000	0.000	0.000	40,000,000	0.000	20,000,000	-20,000,000	15,000,000	20,000,000	-20,000,000	25,000,000
MQ Totals:		244,000,000	507,014,000														

2016 Final Initial APQ:	550,000,000
2015 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	550,000,000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	550,000,000

OPIUM TINCTURE

Basic Class: 9639-0

Total PQ Requested: 41,972,000

2016 Initial APQ Worksheets

FDA Est:
845 Est:

Company	DEA Hub	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Annl Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using DFW 50% Invent
(b)(4);(b)(7)(E)		50,000,000	56,000,000	33,546,000	33,546,000	100	41,972,000	23,566,000	0.000	32,000,000	0.000	24,566,000	47,566,000	39,866,500	66,570,000	89,570,000	18,867,000
MQ Totals:		50,000,000	56,000,000														

2016 Final Initial APQ:	50,000,000
2016 Final Revised APQ:	0.000
FDA Est: [2015 Initial APQ * 1 + FDA Est]:	60,000,000
845 Est: [2015 Initial APQ * 1 + 845 Est]:	60,000,000

Basic Class: 5330 4

Total PQ Requested: 405,000,000

2018 Initial APQ Worksheets

FDA Est:

IHS Est:

Company	DEA Num	2015 Requested PQ	2016 Revised PQ	2014 Sales	2014 DEA PQ Sales	% of 2014 Sales	Share of 2015 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Inventory	Calc Using Dec Inventory	Calc Using CPR 40% Inventory
(b)(4);(b)(7)(E)		5,000	5,000	0 000	18,280,674 000	0.000	0.000	0 000	0.000	0 000	0.000	0 000	0.000	3.750	0 000	0 000	0.250
		627,375 000	627,375,000	623,553 000	18,280,674 000	0 034	13,718,012	377,361 000	0 000	877,375 000	0 000	0 000	377,361 000	902,953,000	13,716 012	361,177 812	-133,371,310
		725,000,000	1,075,000 000	1,070,808 000	18,280,674,000	0 059	23,280,701	685,084 000	0 000	730,000,000	0 000	0 000	1,049,294 000	1,325,875 300	23,580 701	1,072,706,701	-750,888 579
		12,300,000,000	10,476,062 000	13,475,297,000	18,280,674 000	0 737	288,908,088	0 000	0 000	12,370,333,000	0 000	39,846 000	-1,006,571 000	7,857,721 300	306,753 088	-1,358 484 Bbs	-4,845,744 280
		9,502,000,000	4,051,000,000	2,360,096 000	18,280,674 000	0 131	53,617,672	656,801,000	0 000	4,170,000,000	0 000	1,120,000 000	533,801 000	3,530,700 750	1,160,697 622	945,218 822	545,021 778
		1,000 000	0 000	0 000	18,280,674 000	0 000	0 000	0 000	0 000	1,000,000	0 000	0 000	+1,000 000	0 000	0 000	-1,000 000	1,000 000
		400,000 000	0 000	318,342 000	18,280,674 000	0 017	7,038,177	915 000	0 000	400,000 000	0 000	832,000,000	-399,085 000	484 250	639,036 177	-392,348 823	408,180 721
		2,450,000 000	1,000,000 000	200,000 000	18,280,674 000	0 011	4,408,873	21,400 000	0 000	2,450,000 000	0 000	160,450 000	-1,439,600 000	788,050 000	184,008,872	-1,424,193 516	1,634,406 346
MQ Totals:		29,200,380,000	17,430,842 000														

2018 Final Initial APQ:	29,000,000 000
2018 Final Revised APQ:	0 000
FDA Est: (2018 Initial APQ * 1 + FDA Est):	29,000,000 000
IHS Est: (2018 Initial APQ * 1 + IHS Est):	29,000,000 000
2018 Proposed Initial APQ:	29,000,000 000
with 20% buffer:	30,900,000 000

ORIPAVINE

2016 Proposed Initial Quota Worksheets

BASIC CLASS: Oripavine 9330

Company:	(b)(4)																	
Request:	827.4			720.0			12300.0			6502.0			400.0			2450.0		
Current Year MQ:	827.4			1075.6 (buprenorphine pd)			10477.0			4051.0			0.0			100.0		
Year end inventory	377.4			693.7			0.0			656.6			615.0 (PQ inventory)			21.4		
Calculations	amt needed	subtance MQ	yield	amt needed	subtance MQ	yield	amt needed	substance MQ	yield	amt needed	substance MQ	yield	amt needed	substance MQ	yield	amt needed	subtance MQ	yield
hydromorphone				128.778	57.950	0.45				2903.475	2256.000	0.78				2261.905	1900.000	0.84
oripavine				500.000 (for (b)(4)						2.000 (ref stds)								
oripavine/buprenorphine derivative	400.000 (for (b)(4)												800.000	400.000	0.50			
oxymorphone (sale)				77.089	34.690	0.45										214.286	90.000	0.42
oxymorphone (conv)							14415.584	11100.000	0.77								(full request = 525	
losses										1980.000							but part will be	
																	derived from thebaine)	
total needed	400.000			705.867			14415.584			4885.475			800.000			2476.190		
INITIAL MQs																		
est need	329.483			457.536			20638.731			6462.993			385.000			3098.838		
MQ:																		
Total Initial MQs:	827.375			720.000			12300.000			6500.000			400.000			2450.000		

Total MQs: 23197.375 + others 0.005 = 23197.380

FURTHER CALCULATIONS

Proposed Initial APQ 24000

oripavine

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 123476 | Date Submitted: 01-MAY-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
CRIPAVINE

Schedule/List Number: 2
Drug Code: 9330-0
Quota Year: 2016

Name and Address of Registrant
(b)(4)

DEA Registration Number: (b)(4),(b)(7)(E)

Contact Person: (b)(6)
Email Address: (b)(4),(b)(6)

Fax. No
Phone No.: (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	1,100,000.0	827,375.0	0.0	827,375.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	9,150.0	0.0	0.0	0.0
b.In-Process Material.....	368,211.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	377,361.0	0.0	0.0	0.0
Disposition(Sale)/Utilization				
a.Domestic.....	622,552.0	0.0	827,375.0	827,375.0
b Exports.....	0.0	0.0	0.0	0.0
	622,552.0	0.0	827,375.0	827,375.0
Acquisition/Production				
a.Domestic Sources.....	1,008,021.0	0.0	827,375.0	827,375.0
	1,008,021.0	0.0	827,375.0	827,375.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

(b)(4),(b)(7)(E)

Remarks

Our exclusive customer, (b)(4) DEA Reg# [redacted] has delayed their order for Buprenorphine Intermediate originally placed for 2015 until 2016. Therefore, we would like to have the same amount of quota for next year to perform the work not performed this year.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 122336 — Date Submitted: 31-MAR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
ORIPAVINE

Schedule/List Number: 2
Drug Code: 9330-0
Quota Year: 2016

Name and Address of Registrant
(b)(4)

DEA Registration Number: (b)(4);(b)(7)(E)

Contact Person: (b)(6)
Email Address: (b)(4);(b)(6)
Fax. No
Phone No.: (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	1,674,318.0	1,075,600.0	0.0	720,000.0

Production Data	2nd. Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	693,694.0	0.0	0.0	0.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	693,694.0	0.0	0.0	0.0
Disposition(Sale)/Utilization				
a.Domestic.....	1,000,361.0	0.0	720,000.0	720,000.0
b Exports.....	0.0	0.0	0.0	0.0
	1,000,361.0	0.0	720,000.0	720,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	720,000.0	720,000.0
	0.0	0.0	720,000.0	720,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield
OXYMORPHONE (FOR ~~CONVERSION~~) SALE	9652-A	0	0	34,690	45.00
Hydromorphone	9000-0	0	0	57,950	45.00

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant — Explanation of Transfer

Date of Destruction — Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

(b)(4)

Remarks
Quota is for supply of 500 Kg to (b)(4);(b)(7)(E) [redacted] will also use Oripavine for internal conversion to Oxymorphone and Hydromorphone. See supporting documentation submitted via email for sales breakdown.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 123314 | Date Submitted: 29-APR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
ORIPAVINE

Schedule/List Number: 2
Drug Code: 9330-0
Quota Year: 2016

Name and Address of Registrant
(b)(4)

DEA Registration Number: (b)(4);(b)(7)(E)

Contact Person: (b)(6)
Email Address: (b)(4);(b)(6)

Fax. No
Phone No.: (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	13,900,000.0	10,476,962.0	0.0	12,300,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	0.0	0.0	39,846.0	39,846.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	0.0	0.0	39,846.0	39,846.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	12,333,333.0	12,333,333.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	12,333,333.0	12,333,333.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	12,300,000.0	12,300,000.0
	0.0	0.0	12,300,000.0	12,300,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield
OXYMORPHONE (FOR CONVERSION)	9652-A	7,854,778	10,039,033	12,333,333	77.00

(11,100,000 requested)

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant | Explanation of Transfer

Date of Destruction | Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 123340 | Date Submitted: 30-APR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
ORIPAVINE

Schedule/List Number: 2
Drug Code: 9330-0
Quota Year: 2016

Name and Address of Registrant
(b)(4)

DEA Registration Number: (b)(4),(b)(7)(E)

Contact Person: (b)(6)
Email Address: (b)(4),(b)(6)
Fax. No
Phone No.: (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA			
	2014	2015	2016	Quota Requested
	5,250,000.0	4,765,455.0	0.0	6,502,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	1.0	0.0	1,128,000.0	1,128,000.0
b.In-Process Material.....	656,600.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	656,601.0	0.0	1,128,000.0	1,128,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	10,392.0	0.0	4,175,000.0	4,175,000.0
b Exports.....	0.0	0.0	0.0	0.0
	10,392.0	0.0	4,175,000.0	4,175,000.0
Acquisition/Production				
a.Domestic Sources.....	3.41	0.0	6,502,000.0	6,502,000.0
	3.41	0.0	6,502,000.0	6,502,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2013	2014	2016	
HYDROMORPHONE	9150-0	1,965,400.34	1,650,449	2,255,000	77.70

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant | Explanation of Transfer

Date of Destruction | Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks
2,000 grams to support reference standards business. 4,173,000 grams to be put into process for conversion. Process losses estimated at 1,980,000 grams.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID.123235 | Date Submitted | 28-APR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)

ORIPAVINE | Schedule/List Number | 2

Name and Address of Registrant | Drug Code | 9330-0

(b)(4) | Quota Year | 2016

DEA Registration Number | (b)(4),(b)(7)(E)

Contact Person (b)(6) | Fax. No | (b)(6)

Email Address (b)(4),(b)(6) | Phone No.

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	0.001	0.0	0.0	400,000.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	0.0	0.0	832,000.0	832,000.0
b.In-Process Material.....	615.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	615.0	0.0	832,000.0	832,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	3,183.0	0.0	400,000.0	400,000.0
b.Exports.....	0.0	0.0	0.0	0.0
	3,183.0	0.0	400,000.0	400,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	400,000.0	400,000.0
	0.0	0.0	400,000.0	400,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield
Buprenorphine base	0000-0	0	0	200,000	50.00
Buprenorphine HCl	0000-0	0	0	200,000	50.00

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant | Explanation of Transfer

Date of Destruction | Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks

It is a multistep conversion of intermediate purchased from a CMO against procurement quota, and using manufacturing quota to produce Buprenorphine base and Buprenorphine HCl.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 122880		Date Submitted	24-APR-15
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
ORIPAVINE		Schedule/List Number	2
Name and Address of Registrant		Drug Code	9330-0
(b)(4)		Quota Year	2016
		DEA Registration Number	(b)(4),(b)(7)(E)
Contact Person (b)(6)		Fax. No	(b)(6)
Email Address (b)(4),(b)(6)		Phone No.	

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA			
	2014	2015	2016	Quota Requested
	430,000.0	1,000,000.0	0.0	2,450,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	21,400.0	0.0	160,400.0	160,400.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	21,400.0	0.0	160,400.0	160,400.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	2,450,000.0	2,450,000.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	2,450,000.0	2,450,000.0
Acquisition/Production				
a.Domestic Sources.....	221,613.0	0.0	2,450,000.0	2,450,000.0
	221,613.0	0.0	2,450,000.0	2,450,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2013	2014	2016	

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant | Explanation of Transfer

Date of Destruction | Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks

(b)(4) has a new Hydromorphone HCl customer, (b)(4) Their demand in 2016 is 750 kg (667,500 grams as base). 2,250,000 grams of Oripavine will be used in Hydrmorphone and 200,000 in Oxymorphone.

516 ↑ 1,900 ↑ 525

Basic Class: 9143-A

Total PQ Requested: 114,100,000

2018 Initial APQ Worksheets

FDA Est:

MS Est:

Company	DEA Num	2018 Requested MQ	2018 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2018 Total PQ	2018 Inventory	2018 Projected Exports	2018 Projected Sales	2018 Projected Exports	2018 Projected Inventory	2018 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent
(b)(4);(b)(7)(E)		10,000	0.000	0.000	486,895.000	0.000	0.000	0.000	0.000	5.000	0.000	5.000	-5.000	0.000	5.000	-5.000	5.000
		600,000.000	0.000	0.000	486,895.000	0.000	0.000	0.000	0.000	600,000.000	0.000	120,000.000	-680,000.000	0.000	120,000.000	-680,000.000	680,000.000
		2,000,000.000	3,000,000.000	486,895.000	486,895.000	1.000	114,100.000	465,864.000	0.000	1,864,812.000	0.000	701,066.000	1,520,872.000	2,614,413.000	815,198.000	1,635,072.000	629,347.000
MQ Totals:		3,600,010.000	3,000,000.000														

2018 Final Initial APQ:	6,680,000.000
2018 Final Revised APQ:	0.000
FDA Est: (2018 Initial APQ * 1 = FDA Est):	6,680,000.000
MS Est: (2018 Initial APQ * 1 = MS Est):	6,680,000.000
2018 Proposed Initial APQ:	5,000,000.000
with 25% buffer:	6,250,000.000

OXYCODONE (FOR CONVERSION)

BASIC CLASS: Oxycodone (conversion) 9143-A

Company:	(b)(4)					
Request:	2000.0			800.0		
Current Year MQ:	3000.0			0.0		
Year end inventory	485.9			0.0		
Calculations	amt needed	substance MQ	yield	amt needed	substance MQ	yield
oxymorphone (sale)	1964.912	1120.000	0.570	666.667	100.000	0.150
total needed	1964.912			666.667		
INITIAL MQs						
est need	2720.256			833.333		
MQ:						
Total Initial MQs:	3000.000			800.000		

Total MQs:	3800.000	+ others	0.005	=	3800.005

FURTHER CALCULATIONS

Proposed Initial APQ 5000

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 123355 | Date Submitted: 30-APR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
OXYCODONE (FOR CONVERSION)

Schedule/List Number: 2
Drug Code: 9143-A
Quota Year: 2016

Name and Address of Registrant
(b)(4)

DEA Registration Number: (b)(4);(b)(7)(E)

Contact Person: (b)(6)
Email Address: (b)(4);(b)(6)
Fax. No
Phone No.: (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	4,157,639.0	3,000,000.0	0.0	2,000,000.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	369,371.0	0.0	701,088.0	701,088.0
b.In-Process Material.....	116,513.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	485,884.0	0.0	701,088.0	701,088.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	1,964,912.0	1,964,912.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	1,964,912.0	1,964,912.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	2,000,000.0	2,000,000.0
	0.0	0.0	2,000,000.0	2,000,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield
OXYMORPHONE (FOR SALE)	9652-B	5,937,600	474,776	1,964,912	57.00

(1,120 requested)

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 122687 | Date Submitted | 14-APR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
OXYCODONE (FOR CONVERSION)

Schedule/List Number: 2
Drug Code: 9143-A
Quota Year: 2016

Name and Address of Registrant
(b)(4)

DEA Registration Number: (b)(4),(b)(7)(E)

Contact Person: (b)(6)
Email Address: (b)(4),(b)(6)
Fax, No
Phone No. (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA: 2014	2015	2016	Quota Requested
	0.0	0.0	0.0	800,000.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	0.0	0.0	120,000.0	120,000.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	120,000.0	120,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	680,000.0	680,000.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	680,000.0	680,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	800,000.0	800,000.0
	0.0	0.0	800,000.0	800,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield
OXYMORPHONE (FOR SALE)	9652-B	0	0	100,000	15.00

(715 requested)

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks
We will be producing an Oxymorphone derivative for (b)(4). This same material was produced at a smaller scale by (b)(4) (b)(4) in late 2014, and it will move to (b)(4) next year. More information will be made available to the DEA as time progresses.

Basic Class: 9143-B

Total PQ Requested: 88,880,772,773

2014 Initial APQ Worksheets

FDA Est: -.014

IMS Est: .012

Company	DEA Item	2016 Requested MQ	2016 Revised MQ	2014 Sales	2016 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent
(b)(4);(b)(7)(E)		5,000	10,000	0.000	75,172,640,417	0.000	0.000	1,635	0.000	5,000	0.000	1,000	6,635	5,729	1,000	6,635	-4,135
		20,000	0.000	0.000	75,172,640,417	0.000	0.000	0.000	10,000	20,000	0.000	20,000	-30,000	0.000	20,000	-30,000	30,000
		80,000	80,000	8,417	75,172,640,417	0.000	11,046	800,029	0.000	20,000	0.000	848,030	840,029	845,022	858,076	851,075	-811,222
		5,277,980,000	4,842,016,000	263,725,000	75,172,640,417	0.004	346,081,420	118,500,000	0.000	5,277,980,000	0.000	0.000	-317,575,000	5,730,303,750	346,081,420	25,516,420	1,880,665,024
		180,800,000	100,000,000	0.000	75,172,640,417	0.000	0.000	0.000	0.000	190,800,000	0.000	0.000	-90,800,000	75,000,000	0.000	-90,800,000	115,000,000
		4,850,000,000	1,350,000,000	0.000	75,172,640,417	0.000	0.000	0.000	0.000	4,634,146,000	0.000	0.000	-3,284,146,000	1,012,500,000	0.000	-3,284,146,000	2,621,646,000
		2,430,000,000	3,400,632,000	1,322,385,000	75,172,640,417	0.018	1,726,385,172	364,673,000	0.000	4,975,200,000	0.000	3,000,212,000	-2,149,905,000	2,148,671,250	4,735,577,172	-414,808,828	4,834,266,985
		12,000,000,000	15,800,000,000	7,714,405,000	75,172,640,417	0.103	10,121,782,825	14,940,073,000	58,954,000	12,891,778,000	0.000	5,853,224,000	18,294,343,000	22,833,604,750	15,479,888,625	25,368,905,825	-1,834,808,344
		40,702,000,000	65,470,000,000	47,157,546,000	75,172,640,417	0.627	61,883,398,239	18,579,710,000	0.000	44,046,000,000	0.000	22,865,000,000	41,001,710,000	63,787,262,500	64,270,308,231	102,887,075,231	52,722,497,768
		1,000,000	2,000,000	0.000	75,172,640,417	0.000	0.000	0.000	0.000	1,000,000	0.000	0.000	1,000,000	1,500,000	0.000	1,000,000	-500,000
		35,000,000,000	14,303,000,000	16,995,301,000	75,172,640,417	0.241	23,746,951,663	6,337,932,000	0.000	30,343,000,000	0.000	8,156,000,000	-6,704,000,000	17,730,000,000	31,814,831,663	17,042,863,663	39,963,462,034
		9,800,000,000	2,510,000,000	619,700,000	75,172,640,417	0.000	613,244,299	622,934,000	0.000	4,194,000,000	0.000	1,706,200,000	-1,061,000,000	2,348,700,500	2,321,444,299	-247,621,701	2,705,121,373
MQ Totals:		130,051,865,000	108,837,707,000														

2016 Final Initial APQ:	113,000,000,000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	100,471,000,000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	114,320,000,000

OXYCODONE (FOR SALE)

Basic CMH: 9452-A

Total PQ Requested: 8,400,200.000

2018 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2018 Requested MQ	2018 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2018 Total PQ	2014 Inventory	2018 Projected Exports	2018 Projected Sales	2018 Projected Exports	2018 Projected Inventory	2018 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Disclosure	Calc Using CAR 90% Invent
(b)(4);(b)(7)(E)		11,160,000.000	9,656,822.000	8,852,344.000	12,265,897.000	0.539	6,363,462.361	3,013,092.000	0.000	11,100,256.000	0.000	1,169,745.000	1,571,959.000	9,593,696.300	8,983,707.361	8,915,421.361	7,546,240.451
		3,750,000.000	2,249,000.000	1,663,433.000	10,265,897.000	0.162	1,067,257.639	434,479.000	0.000	2,430,000.000	0.000	1,849,000.000	-719,521.000	2,025,358.250	2,877,237.639	517,715.639	3,582,566.049
		3,000.000	1,000.000	0.000	10,265,897.000	0.000	0.000	0.000	0.000	2,000.000	0.000	0.000	-1,000.000	750.000	0.000	-1,000.000	1,250.000
		2,760,000.000	0.000	0.000	10,265,897.000	0.000	0.000	0.000	0.000	2,760,000.000	0.000	0.000	-2,760,000.000	0.000	0.000	-2,760,000.000	2,760,000.000
MQ Totals:		17,913,000.000	11,906,822.000														

2018 Final Initial APQ:	23,200,000.000
2018 Final Revised APQ:	0.000
FDA Est: (2018 Initial APQ * 1.4 FDA Est):	23,200,000.000
IMS Est: (2018 Initial APQ * 1.4 IMS Est):	23,200,000.000

2016 Proposed Initial Quota Worksheets

BASIC CLASS: Oxymorphone (conversion) 9652-A

Company:	(b)(4)											
Request:	11100.0			3756.0			2.0			2760.0		
Current Year MQ:	9659.8			2266.0			1.0			0.0		
2013 Year end inventory	3012.1			434.5			0.0			0.0		
Calculations	amt needed	substance MQ	yield	amt needed	substance MQ	yield	amt needed	substance MQ	yield	amt neede	substance	yield
noroxymorphone (conv)	12238.806	8200.000	0.670	3500.000	(for (b)(4)	nal-drugs)	2.000	ref stds				
				1000.000	(for (b)(4)	nal-drugs)						
				400.000	(for (b)(4)	nal-drugs)						
naloxone										3000.000	1200.000	0.400
total needed	12238.806			4900.000			2.000			3000.000		
INITIAL MQs												
est need	14701.371			6257.021			2.750			3750.000		
MQ:												
Total Initial MQs:	11100.000			3756.000			2.000			2760.000		

Total MQs: 17618.000 + others = 17618.000

FURTHER CALCULATIONS

Established Initial APQ 23200

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID 123315 — Date Submitted 29-APR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
OXYMORPHONE (FOR CONVERSION)

Name and Address of Registrant
(b)(4)

Schedule/List Number: 2
Drug Code: 9652-A
Quota Year: 2016
DEA Registration Number: (b)(4),(b)(7)(E)

Contact Person (b)(6)
Email Address (b)(4),(b)(6)
Fax. No
Phone No. (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	11,300,000.0	9,659,822.0	0.0	11,100,000.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	3,012,092.0	0.0	335,745.0	335,745.0
b.In-Process Material.....	0.0	0.0	864,000.0	864,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	3,012,092.0	0.0	1,199,745.0	1,199,745.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	11,100,255.0	11,100,255.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	11,100,255.0	11,100,255.0
Acquisition/Production				
a.Domestic Sources.....	138.0	0.0	11,100,000.0	11,100,000.0
	138.0	0.0	11,100,000.0	11,100,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield
NOROXYMORPHONS (FOR CONVERSION)	9668-A	4,333,939	6,481,716	11,100,255	67.08

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant | Explanation of Transfer

Date of Destruction | Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID 123212 | Date Submitted: 28-APR-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
OXYMORPHONE (FOR CONVERSION)

Schedule/List Number: 2
Drug Code: 9652-A
Quota Year: 2016

Name and Address of Registrant
(b)(4)

DEA Registration Number: (b)(4);(b)(7)(E)

Contact Person: (b)(6)
Email Address: (b)(4);(b)(6)

Tax. No
Phone No.: (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA 2014	2015	2016	Quota Requested
	2,751,000.0	2,266,000.0	0.0	3,756,000.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	434,479.0	0.0	1,940,000.0	1,940,000.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	434,479.0	0.0	1,940,000.0	1,940,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	1,661,443.0	0.0	3,420,000.0	3,420,000.0
b Exports.....	0.0	0.0	0.0	0.0
	1,661,443.0	0.0	3,420,000.0	3,420,000.0
Acquisition/Production				
a.Domestic Sources.....	1,867,641.0	0.0	3,756,000.0	3,756,000.0
	1,867,641.0	0.0	3,756,000.0	3,756,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose 2013	2014	2016	% Yield

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks

Production losses estimated at 13,000 grams 1,000 grams for lab support of manufacturing efforts

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 123600 | Date Submitted: 13-MAY-15

Name of Basic Class or List 1 Chemical (only 1 per DEA-189)
OXYMORPHONE (FOR CONVERSION)

Schedule/List Number: 2
Drug Code: 9652-A
Quota Year: 2016

Name and Address of Registrant
(b)(4)

DEA Registration Number: (b)(4),(b)(7)(E)

Contact Person: (b)(6)
Email Address: (b)(4),(b)(6)

Fax. No
Phone No.: (b)(6)

NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).

Quota History	Quotas Previously Issued by DEA			
	2014	2015	2016	Quota Requested
	0.001	0.0	0.0	2,760,000.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	0.0	0.0	0.0	0.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
Disposition(Sale)/Utilization	0.0	0.0	2,760,000.0	2,760,000.0
a.Domestic.....	0.0	0.0	0.0	0.0
b Exports.....	0.0	0.0	2,760,000.0	2,760,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	2,760,000.0	2,760,000.0
	0.0	0.0	2,760,000.0	2,760,000.0

If the Purpose is to Manufacture Another Substance(s), Furnish the Following Information:

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2013	2014	2016	
Naloxone HCl	9000-0	0	0	1,200,000	40.00

Product Development Dosage Form	Strength	Units/Batch	# of Batches	Batch Purpose	Est. Quantity	Est. Completion Time

Transfer Registrant | Explanation of Transfer

Date of Destruction | Explanation

Packaging Product Name	Strength	Units/Pkg	# of Pkgs	Purpose	Total Quantity

Remarks

Oxymorphone is the starting material for the manufacture of Noroxymorphone and subsequently Naloxone HCl Dihydrate for Sale. Currently (b)(4) purchases Oxymorphone from a third party. This quota will be used to validate (b)(4) process for the manufacture of Oxymorphone. (b)(4) is required by FDA to validate a sufficient # of batches to ensure repeatability prior to commercial distribution. The resulting oxymorphone will be used in place of purchased oxymorphone as soon as it is approved for use. It is anticipated the oxymorphone will be approved for use in the year 2017. Naloxone Hydrochloride Dihydrate made from (b)(4) Oxymorphone will be available for sale in late 2017 or early 2018.

Basic Class: [illegible]

Total PQ Requested: 3,861,848,862

2016 Initial APQ Worksheets

FDA Est: .084

IMS Est: .008

Company	DEA Num	2016 Requested MQ	2016 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CPR 50% Invent
(b)(4);(b)(7)(E)		5.000	5.000	0.000	1,480,825.084	0.000	0.000	0.007	0.000	4.000	0.000	1.000	1.007	3.735	1.000	1.007	0.243
		20.000	0.000	0.000	1,480,825.084	0.000	0.000	0.000	10.000	20.000	0.000	70.000	-20.000	0.000	20.000	-20.000	30.000
		30.000	60.000	0.000	1,480,825.084	0.000	24.665	213.731	0.000	20.000	0.000	178.730	253.731	205.296	203.423	278.424	-207.665
		34,600.000	142,550.000	608.000	1,480,825.084	0.000	1,588.131	23,505.000	0.000	34,600.000	0.000	0.000	131,374.000	124,548.000	1,588.131	137,052.131	-83,749.000
		715,000.000	817,142.000	304,079.000	1,480,825.084	0.205	792,987.828	265,847.000	0.000	645,250.000	0.000	166,838.000	237,730.000	683,241.750	861,800.828	1,030,708.828	937,758.385
		1,130,000.000	1,800,000.000	649,560.000	1,480,825.084	0.404	1,360,064.521	774,718.000	0.000	1,119,000.000	0.000	471,154.000	1,255,853.000	1,781,039.250	2,033,118.521	2,816,837.521	1,095,377.952
		5,000.000	3,000.000	16,228.825	1,480,825.084	0.038	148,831.272	36,417.445	0.000	5,000.000	0.000	0.000	24,417.445	79,563.084	148,831.272	161,646.717	148,831.645
		2,388,000.000	1,243,980.000	615,008.000	1,480,825.084	0.348	1,343,031.962	369,770.000	0.000	1,420,000.000	0.000	564,000.000	223,750.000	1,232,812.900	1,807,031.962	1,568,771.962	1,286,023.453
		575,000.000	379,378.000	8,301.000	1,480,825.084	0.004	16,431.553	417,660.000	0.000	527,500.000	0.000	168,000.000	268,821.000	597,315.750	204,431.553	265,352.553	-153,536.000
MQ Totals:		4,765,740.000	3,866,117.000														

2016 Final Initial APQ:	6,200,000.000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	6,766,000.000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	6,252,000.000

Basic Class: 9193-9

2015 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Ingredient	DEA Num	2015 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2015 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2015 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using SPR 50% Invent
(b)(4);(b)(7)(E)		2.000	2.000	0.000	0.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500	1.500	1.500	1.500	-1.000
		2.000	2.000														

2015 Final Initial APQ: 2.000

2015 Final Revised APQ: 0.000

FDA Est (2015 Initial APQ * 1 + FDA Est): 2.000

IMS Est (2015 Initial APQ * 1 + IMS Est): 2.000

Basic Class: 9739-0

2016 Initial APQ Worksheets

Target PQ Requested: 3,365.000

FDA Est:
845 Est:

Company	DEA Num	2016 Requested MQ	2016 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2014 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	2015 Projected Exports	2015 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent
(b)(4);(b)(7)(E)		5.000	5.000	0.000	459.789	0.000	0.000	0.000	0.000	1.000	0.000	8.000	4.000	3.750	8.000	4.000	-3.750
		1,820.000	1,820.000	459.000	459.789	0.999	2,350.942	2,065.000	0.000	1,820.000	0.000	2,464.000	2,555.000	2,606.250	4,624.942	4,415.942	1,351.179
		600.000	0.000	0.000	459.789	0.000	0.000	483.845	0.000	0.000	0.000	0.000	483.845	363.859	0.000	483.845	-483.845
		5.000	5.000	0.789	459.789	0.002	4.084	0.015	0.000	5.000	0.000	1.000	0.015	3.764	5.056	4.078	0.300
MQ Totals:		2,430.000	1,830.000														

2015 Final Initial APQ:	3,000.000
2015 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	3,000.000
845 Est: (2015 Initial APQ * 1 + 845 Est):	3,000.000
2016 Proposed Initial APQ:	3,000.000
with 25% buffer:	3,750.000

Basic Class: 8740-0

Total PQ Requested: 865,226

2018 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Rule	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Base	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2013 Projected Exports	2015 Projected Sales	2016 Projected Exports	2015 Projected Inventory	2015 DEA Projected Inventory	Adj Annlt Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent
(b)(4);(b)(7)(E)		8,000,000	8,000,000	51,700	1,853,700	0.017	11,376	995,935	0.000	8,000,000	0.000	695,000	695,000	1,488,935	1,007,376	1,007,376	-731,680
		20,000	0.000	0.000	1,853,700	0.000	0.000	0.000	10,000	20,000	0.000	20,000	-30,000	0.000	20,000	-30,000	20,000
		2,000	2,000	0.000	1,853,700	0.000	0.000	0.000	0.000	0.500	0.000	1,500	1,500	1,500	1,500	1,500	-1,000
		600,000	583,000	401,000	1,853,700	0.216	143,904	223,000	300,000	565,000	0.000	251,000	-82,000	404,500	284,904	81,904	387,631
		2,500,000	2,500,000	1,421,000	1,853,700	0.767	509,840	2,341,000	1,000,000	2,492,000	0.000	2,126,000	746,000	3,630,750	2,637,840	1,255,840	919,432
MQ Totals:		4,122,000	4,085,000														

2018 Final Initial APQ: 1,004,000
2018 Final Revised APQ: 0.000
FDA Est: (2015 Initial APQ * 1 = FDA Est): 1,004,000
IMS Est: (2015 Initial APQ * 1 = IMS Est): 1,004,000

SUFENTANIL

Basic Cases: 5788-9

Total PQ Requested: 25,501,200,000

2016 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2016 Requested MQ	2016 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2016 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 80% Invent
(b)(4);(b)(7)(E)		10,000	10,000	0.000	147,543,000	0.000	0.000	3,857	0.000	3,000	0.000	11,857	11,857	10,488	11,857	11,857	-4,457
		405,530,000	235,010,000	0.000	147,543,000	0.000	0.000	0.000	0.000	405,530,000	0.000	0.000	-170,520,000	176,357,500	0.000	-170,520,000	229,272,500
		1,857,400,000	9,191,000	0.000	147,543,000	0.000	0.000	0.000	0.000	1,857,400,000	0.000	0.000	-1,848,209,000	6,895,250	0.000	-1,848,209,000	1,859,508,750
		130,000,000	40,000,000	0.000	147,543,000	0.000	0.000	0.000	0.000	86,800,000	0.000	43,150,000	-48,000,000	30,000,000	48,150,000	-48,000,000	56,000,000
		3,000,000	0.000	0.000	147,543,000	0.000	0.000	0.000	0.000	500,000	0.000	4,500,000	-500,000	0.000	4,500,000	-500,000	500,000
		1,000,000	1,000,000	0.000	147,543,000	0.000	0.000	0.000	0.000	1,000,000	0.000	0.000	0.000	750,000	0.000	0.000	750,000
		17,806,000,000	4,675,000,000	225,000	147,543,000	0.000	38,846,799	20,267,000	0.000	14,333,000,000	0.000	4,516,000,000	-9,837,733,000	3,521,450,750	4,554,886,799	-9,586,644,201	10,805,000,000
MQ Totals:		20,304,940,000	4,989,211,000														

2016 Final Initial APQ:	10,000,000,000
2016 Final Revised APQ:	0.000
FDA Est: (2016 Initial APQ * 1 + FDA Est):	10,000,000,000
IMS Est: (2016 Initial APQ * 1 + IMS Est):	10,000,000,000
2016 Proposed Initial APQ:	20,400,000,000
with 25% buffer:	25,500,000,000

Note:

(b)(4) is now the sole supplier of the bulk APs

(b)(4) has bought the brand rights (April 2015) and began an aggressive marketing campaign

TAPENTADOL

(b)(4)

April, 2015

The following tables outline the calculations performed in order to estimate the 2016 quota requirements for (b)(4),(b)(7)(E)

Note: The quota amounts listed in the tables represent the amount required for production to meet commercial demand. The actual requested amount will be 1-2 kgs higher. (b)(4) annually requests small quantities of manufacturing quota for their plant support efforts. When production encounters challenges, the R&D group may have to repeat the manufacturing process on lab scale. Quota consumption is required since this is not development work but running the validated process on a smaller scale.

Table I: 2015 Tapentadol Manufacturing Quota (kgB)
Assumes Additional Quota will be granted in 2015

2015 Tapentadol Inventory Calculations WT	Initial 2015 Grant	Additional 2015 Grant
2014 Ending Inventory	0.0	0.0
Non saleable material	0.0	0.0
2014 Available End. Inv.	**0**	**0**
2015 API Quota	1,293	4,675
2015 Dispositions:		
Sales	3,731	3,731
Processing Losses		
2015 Ending Inventory	**-2,438**	**944**
Converted to % Yearend	**-130.7%**	**50.6%**

Table II: 2015 Tapentadol Yearend Calculation

(b)(4)	Dispositions	kg base
2014 Estimated Dispositions to (b)(4)		0
2015 Estimated Dispositions to (b)(4) for (b)(4) (b)(4)		1,941
2015 Estimated Dispositions to (b)(4) for (b)(4)		1,790
Average		1,866
½ Average		933

CONFIDENTIAL BUSINESS INFORMATION

Table III: 2016 Tapentadol Manufacturing Quota (kgB)

2016 Tapentadol Inventory Calculations WT	
2015 Ending Inventory	944
Non saleable material	0.0
2015 Available End. Inv.	**944**
2016 API Quota	17,905
2016 Dispositions:	
Sales	14,333
Processing Losses	[redacted]
2016 Ending Inventory	**4,516**
Converted to % Yearend	**50.0%**

Table IV: 2016 Tapentadol Yearend Calculation

(b)(4) Dispositions	kg base
2015 Estimated Dispositions to (b)(4)	3,731
2016 Estimated Dispositions to (b)(4) for (b)(4)	2,793
2016 Estimated Dispositions to (b)(4) for (b)(4)	11,540
Average	9,032
½ Average	4,516

2016 Manufacturing Quota Submission Supporting Tables – (b)(4);(b)(7)(E)
Tapentadol (9780)
April 2015

Table V: 2015 Projected Tapentadol Process Loss Information for (b)(4) Demand (kgB)

	PROCESS LOSSES BASED ON 2014 YIELDS FOR CURRENT GRANT					ESTIMATE WITH ADDITIONAL QUOTA		
Description	Input to Step	Process Yield	MW	Net output of step	Loss by step	Input to Step	Output of Step	Loss by step
Tapentadol for Sale (b)(4)								
T2955 to T3028 (Tapentadol Methyl Ether Hydrobromide)	1,269	81.00%	1.258	1,293		3,318	3,382	
Tapentadol Procurement from (b)(4)								
T3028 to Tapentadol Base	3,731	91.20%		3,403	(328)			
Tapentadol Base to Tapentadol HCl	3,403	93.10%		3,168	(235)			
Total					(563)			
Tapentadol Procurement from Geel								
T3028 to Tapentadol Base	3,569	87.30%		3,116	(453)	0	0	0
Tapentadol Base to Tapentadol HCl	3,116	92.30%		2,876	(240)	0	0	0
Total					(693)			

Table VI: 2016 Projected Tapentadol Process Loss Information for (b)(4) Demand (kgB)

2016 Process Loss Calculations for (b)(4) API					
Description	Input to Step	Process Yield	MW	Net output of step	Loss by step
Tapentadol for Sale (b)(4)					
T2955 to T3028 (Tapentadol Methyl Ether Hydrobromide)	11,540	81.00%	1.258	11,761	
Tapentadol Procurement from (b)(4)					
T3028 to Tapentadol Base	11,761	86.00%		10,115	(1,647)
Tapentadol Base to Tapentadol HCl	10,115	93.00%		9,407	(708)
Total					(2,355)
Tapentadol Procurement from (b)(4)					
T3028 to Tapentadol Base	0	87.30%		0	0
Tapentadol Base to Tapentadol HCl	0	93.00%		0	0
Total					0

CONFIDENTIAL BUSINESS INFORMATION

Table VII: 2015/2016 Projected Tapentadol Depomed Requirements (kg HCl)

	DEA Quota 2015 (Kg)			DEA Quota 2016 (Kg)	
	eng-reg	Validation	Clinical	eng-reg	Validation
ER	1204.89				1248.12
IR	615.00				1509.55
			96.24		
Total	1916.13			2757.67	

Table VIII: 2015 Projected Tapentadol Process Loss Information for Depomed Demand (kgB)

	Depomed API Requirements				
Description	**Input to Step**	**Process Yield**	**MW**	**Net output of step**	**Loss by step**
Tapentadol for Sale (b)(4)					
T2955 to T3028 (Tapentadol Methyl Ether Hydrobromide)	1,904	81.00%	1.258	1,941	
Tapentadol Procurement from (b)(4)					
T3028 to Tapentadol Base	1,941	91.20%		1,770	(171)
Tapentadol Base to Tapentadol HCl	1,770	93.10%		1,648	(122)
Total					

Table IX: 2016 Projected Tapentadol Process Loss Information for Depomed Demand (kgB)

	Depomed API Requirements				
Description	**Input to Step**	**Process Yield**	**MW**	**Net output of step**	**Loss by step**
Tapentadol for Sale (b)(4)					
T2955 to T3028 (Tapentadol Methyl Ether Hydrobromide)	2,741	81.00%	1.258	2,793	
Tapentadol Procurement from (b)(4)					
T3028 to Tapentadol Base	2,793	91.20%		2,547	(246)
Tapentadol Base to Tapentadol HCl	2,547	93.10%		2,372	(176)
Total					(422)

CONFIDENTIAL BUSINESS INFORMATION

2016 Manufacturing Quota Submission Supporting Tables – (b)(4);(b)(7)(E)
Tapentadol (9780)
April 2015

Thank you in advance for considering this request. If you require any additional information, please do not hesitate to contact me at (b)(6)

Best regards,

(b)(6)

Director, Controlled Substance Compliance

CONFIDENTIAL BUSINESS INFORMATION

Basic Class: 8153-0

Total PQ Requested: 13,403,125,000

2018 Initial APQ Worksheets

FDA Est:

845 Est:

Company	DEA Base	2016 Requested MQ	2016 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2016 Projected Exports	2016 Projected Sales	2016 Projected Exports	2016 Projected Inventory	2016 DEA Projected Inventory	Adj Avail Calc	Calc Using Company Intent	Calc Using Dea Intent	Calc Using CFR Min Invent
(b)(4);(b)(7)(E)		5,000	5,000	0.000	40,348,013,118	0.000	0.000	0.000	0.000	4,000	0.000	1,000	1,002	3,752	1,000	1,002	0.248
		2,107,000,000	700,612,000	156,000,000	40,348,013,118	0.004	32,824,899	189,710,000	0.000	1,100,000,000	0.000	0.000	-309,475,000	870,141,300	32,824,899	-153,053,001	-446,547,248
		20,000	0.000	0.000	40,348,013,118	0.000	0.000	0.000	10,000	20,000	0.000	20,000	-30,000	0.000	20,000	-30,000	30,000
		25,000	25,000	3,094	40,348,013,118	0.000	1,043	30,843	0.000	10,000	0.000	83,844	65,845	38,858	64,857	65,858	-56,901
		9,395,250,000	9,721,817,000	586,636,000	40,348,013,118	0.015	367,579,073	453,623,000	0.000	6,340,230,000	0.000	0.000	-1,207,080,000	3,268,826,000	367,579,822	-1,008,370,878	3,195,443,029
		1,000,000,000	0.000	0.000	40,348,013,118	0.000	0.000	0.000	0.000	500,000,000	0.000	526,000,000	-494,910,000	3,817,000	525,000,000	-494,910,000	494,910,000
		27,000,000,000	25,000,000,000	12,812,436,000	40,348,013,118	0.318	8,318,647,541	3,826,000,000	0.000	20,000,854,000	0.000	7,409,854,000	4,838,382,000	22,877,004,000	11,726,451,541	8,825,000,541	9,543,357,477
		2,000,000	1,000,000	7,024	40,348,013,118	0.000	2,368	1,526	0.000	2,000,000	0.000	0.000	-999,474	751,145	2,368	-998,108	1,251,474
		10,001,000,000	6,000,000,000	3,023,816,000	40,348,013,118	0.198	2,000,445,378	2,342,000,000	0.000	8,001,000,000	0.000	4,000,000,000	3,261,000,000	8,462,100,000	6,707,445,378	5,000,445,378	3,216,358,725
		35,000,000,000	12,799,361,000	18,383,000,000	40,348,013,118	0.460	6,358,044,218	9,025,000,000	0.000	35,000,000,000	0.000	7,000,000,000	-13,175,615,000	18,268,268,718	13,358,084,218	-8,914,830,782	24,709,328,031
		27,614,000,000	10,000,000,000	0.000	40,348,013,118	0.000	0.000	0.000	0.000	23,194,000,000	0.000	0.000	-12,114,000,000	7,500,000,000	0.000	-12,114,000,000	14,614,000,000
MQ Totals:		100,068,280,000	82,129,744,000														

2018 Final Initial APQ:	100,000,000,000
2018 Final Revised APQ:	0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	100,000,000,000
845 Est: (2018 Initial APQ * 1 + 845 Est):	100,000,000,000

2016 Proposed Established Annual Assessment of Needs and Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of each basic class of schedule I and II controlled substances and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- The attached Federal Register notice, prepared for your signature, proposes to establish calendar year 2016 aggregate production quotas (APQ) for each basic class of schedule I and II controlled substances and assessment of annual needs (AAN) for the list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for which the United States has medical, scientific, industrial, export, and reserve stock requirements.

- As stated in the 2013 Federal Register Notices, DEA continues to add an additional 25% to the APQ for schedule II substances and schedule I substances that are used to produce drugs that have a medical need (specifically, difenoxin, GHB and tetrahydrocannabinols) in an effort to prevent potential drug shortage issues.

- The Federal Drug Administration (FDA) responded on May 6, 2015, to DEA's annual letter which requests information on new, continuing, and discontinued drug products containing schedule II substances. This information was considered in the analysis for the current proposed values.

- Quota applications received as of May 26, 2015 are considered, however, applications can be received throughout the year and those received during the comment period will be considered when DEA establishes the 2016 AAN & APQ values.

- An expedited review and publication is requested to ensure an uninterrupted supply of schedule I and II controlled substances and the list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for medical, scientific, industrial, and export requirements of the U.S.

- Although each quota year is considered separate and independent of previous years, the following points provide brief explanations of noteworthy changes for some the proposed AAN & APQ values:

Schedule I substances

- The APQ for **marihuana** is proposed as a decrease from 2015, but not zero because to accommodate bulk manufacturers with synthesis route for manufacturing API for cannabidiol for research and product development activities, ultimately leading to FDA approved products and commercial sales.

Schedule II substances

- The APQ for **codeine (for sale)** is proposed as an increase, while the APQ for **hydrocodone (for sale)** is proposed as a decrease based on registrant applications received as of May 26, 2015 and IMS Health prescription data, which shows an increase in prescription sales that appears to coincide with the rescheduling of FDA approved hydrocodone products from schedule III to schedule II.

- The APQ for **tapentadol** is proposed as an increase to accommodate the change in synthesis of the bulk API from importing from a foreign source to domestic manufacturing.

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-420N]

Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to establish the 2016 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on or objections to this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59pm Eastern Time on the last day of the comment period.

The Administrator may hold a public hearing on one or more issues raised by the comments received in response to this notice. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the *Federal Register*. After consideration of any comments and after a

hearing, if one is held, the Administrator will publish in the *Federal Register* a final order establishing the 2016 aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–420N" on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want publicly available in the first paragraph of your comment and identify what information you want redacted.

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http://www.regulations.gov may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as personal.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and to establish the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

Analysis for Proposed 2016 Aggregate Production Quotas and Assessment of Annual Needs

The proposed year 2016 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2016 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These proposals include estimated imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include estimated imports of controlled substances for use in industrial processes.

In determining the proposed 2016 aggregate production quotas and assessment of annual needs, the Administrator has taken into account the criteria that is required to be considered in accordance with 21 U.S.C. 826(a), 21 CFR 1303.11 (aggregate production quotas for controlled substances), and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The Administrator estimates the aggregate production quotas and assessment of annual needs for 2016 by considering the following factors: (1) total net disposal of each class or chemical by all manufacturers and chemical importers during the current and two preceding years; (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for each class or chemical as indicated by procurement and chemical import quotas requested in accordance with 21 CFR 1303.12, 1315.32, and 1315.34; and (5) other factors affecting

the medical, scientific, research, and industrial needs of the United States, lawful export requirements, and reserve stocks, as the Administrator finds relevant.

Other factors the Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed 2016 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessments of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

The Administrator also specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be of concern if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the Administrator proposes to include in all schedule II aggregate production quotas, and certain schedule I aggregate production quotas (difenoxin, gamma-hydroxybutyric acid, and tetrahydrocannabinols), an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The proposed aggregate production quotas reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The Administrator expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in

substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the Administrator. The Administrator does not anticipate utilizing the reserve in the absence of these circumstances.

The Administrator, therefore, proposes to establish the 2016 aggregate production quotas for the following basic classes of schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Proposed 2016 Quotas (g)
Schedule I	
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	25
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	25
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	25
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45

1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	25
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-*n*-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-*N*-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-*N*-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-*N*-methylcathinone (3-FMC)	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-*N*-methylcathinone (4-FMC)	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25

4-Methylaminorex	25
4-Methyl-*N*-ethylcathinone (4-MEC)	25
4-Methyl-*N*-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-*N*,*N*-diisopropyltryptamine	25
5-Methoxy-*N*,*N*-dimethyltryptamine	25
Acetyl-*alpha*-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-*N*-oxide	305

Desomorphine	25
Diethyltryptamine	25
Difenoxin	11,000
Dihydromorphine	3,000,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	40
Marihuana	200,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-*N*-oxide	350
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA)	15
N,*N*-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	25
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24

N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Phenomorphan	2
Pholcodine	5
Psilocybin	30
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	25
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	25
Tetrahydrocannabinols	511,250
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,950,000
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	15,000,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	200,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	63,900,000
Dextropropoxyphene	45
Dihydrocodeine	226,375
Diphenoxylate (for conversion)	31,250
Diphenoxylate (for sale)	1,337,500

Ecgonine	125,000
Ethylmorphine	3
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	235,000
Hydrocodone (for sale)	88,500,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	30
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	5,450,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	87,500,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	30,000,000
Oxycodone (for conversion)	6,250,000
Oxycodone (for sale)	139,150,000
Oxymorphone (for conversion)	29,000,000

Oxymorphone (for sale)	7,750,000
Pentobarbital	38,125,000
Phenazocine	6
Phencyclidine	50
Phenmetrazine	3
Phenylacetone	50
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	25,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	100,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	22,400,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Administrator further proposes that the aggregate production quotas for all other basic classes of schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2016 aggregate production quotas and assessment of annual needs as necessary.

Dated:

Chuck Rosenberg,
Acting Administrator.

A:_____

AX:_____

OC:_____

OD:_____

CCR:_____CCO:_____CC:_____

ODX:_____

ODXL:_____

ODW:_____

$ODW_{analyst}$:_____

ODQ: _____

ODEQ (b)(6)

DFN: 630-07-Federal Register

SBF-CM # ODEQ-15-

SUPPLEMENTARY INFORMATION:

Background

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this authority to the Administrator of the DEA. 28 CFR 0.100(b).

On January 30, 2015, the DEA published in the *Federal Register* a final order to temporarily place three synthetic cannabinoids, N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA), and [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201), into schedule I of the CSA (80 FR 5042), making all regulatory controls pertaining to schedule I controlled substances applicable to AB-CHMINACA, AB-PINACA, and THJ-2201, including the requirement to obtain a manufacturing quota pursuant to 21 CFR part 1303.

The 2015 aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201 represent those quantities that may be manufactured in the United States in 2015 to provide for the estimated scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks.

On March 20, 2015, the DEA published a notice titled, "Controlled Substances: 2015 Proposed Aggregate Production Quotas for Three Temporarily Controlled Synthetic Cannabinoids" in the *Federal Register* (80 FR 15034). That notice proposed the 2015 aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201.

Interested persons were invited to comment on or object to the proposed aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201 on or before April 20, 2015. No comments were received.

Analysis for 2015 Established Aggregate Production Quotas

In determining the 2015 aggregate production quotas for N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA), and [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201), the DEA has taken into consideration the factors set forth at 21 CFR 1303.11, pursuant to 21 U.S.C. 826(a), and other relevant factors, including 2015 export requirements, industrial use, applications for quotas, as well as information on research and product development requirements.

Pursuant to 21 U.S.C. 826 and in accordance with 21 CFR 1303.11, the Acting Administrator hereby establishes the 2015 aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201, expressed in grams of anhydrous acid or base, as follows:

Basic Class—schedule I	Established 2015 Quota (g)
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA)	15
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15

In accordance with 21 CFR 1303.13, upon consideration of the relevant factors, the Acting Administrator may adjust the 2015 aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201 as needed.

Dated:

Chuck Rosenberg,
Acting Administrator.

A:____
AX:_____
OC:_____
OD:_____
CCR:_____CCO:_____CC:_____
ODX:_____
ODXL:_____
ODW:_____
$ODW_{analyst}$:_____
ODQ: _____
ODEQ (b)(6) _____
ODEQ: (b)(6) 5-6-2015, 5-11-2015,5/19-2015,6/2/2015

DFN: 630-07-Federal Register

SBF-CM # ODEQ-15-753

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–420N]

Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to establish the 2016 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on or objections to this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 17, 2015. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

The Administrator may hold a public hearing on one or more issues raised by the comments received in response to this notice. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the Federal Register. After consideration of any comments and after a hearing, if one is held, the Administrator will publish in the Federal Register a final order establishing the 2016 aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–420N" on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and to establish the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

Analysis for Proposed 2016 Aggregate Production Quotas and Assessment of Annual Needs

The proposed year 2016 aggregate production quotas and assessment of annual needs represent those quantities

of schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2016 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These proposals include estimated imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include estimated imports of controlled substances for use in industrial processes.

In determining the proposed 2016 aggregate production quotas and assessment of annual needs, the Administrator has taken into account the criteria that is required to be considered in accordance with 21 U.S.C. 826(a), 21 CFR 1303.11 (aggregate production quotas for controlled substances), and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The Administrator estimates the aggregate production quotas and assessment of annual needs for 2016 by considering the following factors: (1) Total net disposal of each class or chemical by all manufacturers and chemical importers during the current and two preceding years; (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for each class or chemical as indicated by procurement and chemical import quotas requested in accordance with 21 CFR 1303.12, 1315.32, and 1315.34; and (5) other factors affecting the medical, scientific, research, and industrial needs of the United States, lawful export requirements, and reserve stocks, as the Administrator finds relevant.

Other factors the Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed 2016 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessments of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

The Administrator also specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be of concern if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the Administrator proposes to include in all schedule II aggregate production quotas, and certain schedule I aggregate production quotas (difenoxin, gamma-hydroxybutyric acid, and tetrahydrocannabinols), an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The proposed aggregate production quotas reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The Administrator expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the Administrator. The Administrator does not anticipate utilizing the reserve in the absence of these circumstances.

The Administrator, therefore, proposes to establish the 2016 aggregate production quotas for the following basic classes of schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Proposed 2016 quotas (g)
Schedule I	
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	25
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	25
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	25
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30

Basic class	Proposed 2016 quotas (g)
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	25
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-*n*-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-*Trimethoxyamphetamine*	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-*N*-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-*N*-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-*N*-methylcathinone (3-FMC)	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-*N*-methylcathinone (4-FMC)	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-*N*-ethylcathinone (4-MEC)	25
4-Methyl-*N*-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	88
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-*N*,*N*-diisopropyltryptamine	25
5-Methoxy-*N*,*N*-dimethyltryptamine	25
Acetyl-*alpha*-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-*N*-oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	11,000
Dihydromorphine	3,000,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	40

Basic class	Proposed 2016 quotas (g)
Marihuana	200,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-*N*-oxide	350
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA)	15
N,*N*-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	25
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Phenomorphan	2
Pholcodine	5
Psilocybin	30
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	25
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	25
Tetrahydrocannabinols	511,250
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,950,000
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	15,000,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	200,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	53,900,000
Dextropropoxyphene	45
Dihydrocodeine	226,375
Diphenoxylate (for conversion)	31,250
Diphenoxylate (for sale)	1,337,500
Ecgonine	125,000
Ethylmorphine	3
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	235,000
Hydrocodone (for sale)	88,500,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	30
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	5,450,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19

Basic class	Proposed 2016 quotas (g)
Methadone (for sale)	31,875,000
Methadone intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	87,500,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	30,000,000
Oxycodone (for conversion)	6,250,000
Oxycodone (for sale)	139,150,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	38,125,000
Phenazocine	6
Phencyclidine	50
Phenmetrazine	3
Phenylacetone	50
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	25,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	100,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	22,400,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Administrator further proposes that the aggregate production quotas for all other basic classes of schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2016 aggregate production quotas and assessment of annual needs as necessary.

Dated: July 13, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015-17561 Filed 7-16-15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration: Meda Pharmaceuticals, Inc.

ACTION: Notice of registration.

SUMMARY: Meda Pharmaceuticals, Inc. applied to be registered as an importer of a certain basic class of controlled substance. The Drug Enforcement Administration (DEA) grants Meda Pharmaceuticals, Inc. registration as an importer of this controlled substance.

SUPPLEMENTARY INFORMATION: By notice dated March 20, 2015, and published in the Federal Register on March 27, 2015, 80 FR 16426, Meda Pharmaceuticals, Inc., 705 Eldorado Street, Decatur, Illinois 62523 applied to be registered as an importer of a certain basic class of controlled substance. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Meda Pharmaceuticals, Inc. to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above-named company is granted registration as an importer of nabilone (7379) a basic class of controlled substance listed in schedule II.

Drug	Company	Comment	Amount	Response	Proposed APQ	Revised APQ	Change
5-Flouro-PB-22	(b)(4)	increase APQ	5	APQ sufficient	25	25	-
AB-CHMINACA		increase APQ	5	APQ sufficient	15	15	-
AB-FUBINACA		increase APQ	5	APQ sufficient	25	25	-
AB-PINACA		increase APQ	5	APQ sufficient	15	15	-
acetyl fentanyl		increase APQ	5	insufficient APQ; adjust accordingly	-	100	100
acetyl fentanyl		increase APQ	50	see above	see above	see above	
ADB-PINACA		increase APQ	5	APQ sufficient	25	25	-
amphetamine (for sale)		increase APQ	3,904,000	insufficient APQ; adjust accordingly	37,500,000	39,705,000	2,205,000
codeine (for sale)		increase APQ	30,501,000	APQ sufficient	63,900,000	63,900,000	-
codeine (for sale)		increase APQ	16,700,000	see above	see above	see above	
gamma hydroxybutyric acid		increase APQ	30,000	APQ sufficient	70,250,000	70,250,000	-
levorphanol		increase APQ	5,100	APQ sufficient	7,125	7,125	-
marihuana		increase APQ	11,000	insufficient APQ; adjust accordingly	200,000	658,000	458,000
methylphenidate		increase APQ	44,279,000	insufficient APQ; adjust accordingly	87,500,000	96,750,000	9,250,000
methylphenidate		increase APQ	7,200,000	see above	see above	see above	
nabilone		increase APQ	2,500	APQ sufficient	18,750	18,750	-
oxymorphone (for conversion)		increase APQ	3,756,000	APQ sufficient	29,000,000	29,000,000	-
oxymorphone (for sale)		increase APQ	2,386,000	APQ sufficient	7,750,000	7,750,000	-
PB-22		increase APQ	5	APQ sufficient	25	25	-
THJ-2201		increase APQ	5	APQ sufficient	15	15	-
							-
							-
							-

Number of registrants/entities commenting: 4
Number of drugs commented on: 20 (minus 3 duplicates) 17

CMEA Chemical	Company	Comment	Amount	Response	Proposed AAN	Revised AAN	Change

Number of registrants/entities commenting: 0
Number of List 1 chemicals commented on: 0

Additional Drug Considerations:

Drug	Company	Response	Proposed	Revised	Change
marihuana	(b)(4)	mentioned in their 2015 request that they would need at least 40kg more in 2016	see above	see above	
hydromorphone	(b)(4)	has validation requirements of 1,062kgs	7,000,000	8,250,000	1,250,000
hydrocodone (for sale)		Down shift in Prescription demand continues in 2015	88,500,000	88,500,000	-
					-
					-
					-
					-

Additional Chemical Considerations:

Drug	Response	Proposed	Revised	Change
				-
				-
				-

(b)(4)

April, 2015

The following tables outline the calculations performed in order to estimate the 2016 quota requirements for (b)(4);(b)(7)(E)

Note: The quota amounts listed in the tables represent the amount required for production to meet commercial demand. The actual requested amount will be 1-2 kgs higher. (b)(4) annually requests small quantities of manufacturing quota for their plant support efforts. When production encounters challenges, the R&D group may have to repeat the manufacturing process on lab scale. Quota consumption is required since this is not development work but running the validated process on a smaller scale.

Table I: 2015 Hydrocodone for Sale Manufacturing Quota (kgB)
Assumes Additional Quota will be granted in 2015

	Initial 2015 Grant	Additional 2015 Grant
2014 Ending Inventory	5,452	5,452
Non saleable material	120	120
2014 Available End. Inv.	**5,332**	**5,332**
2015 API Quota (Procure)	26,999	26,999
2015 API Quota (Manufacture)	2,937	9,000
2015 Dispositions:		
Sales	26,881	26,881
Processing Losses	(4,080)	(5,327)
2015 Ending Inventory	**4,307**	**9,122**
Converted to % Yearend	**18.3%**	**38.7%**

not granted as of 8-25-15

Table II: 2015 Hydrocodone for Sale Yearend Calculation

	kgs, base
2014 Dispositions	20,276
2015 Estimated Dispositions	26,881
Average	23,579
50% Inventory Allowance	11,789

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Table III: 2016 Hydrocodone for Sale Manufacturing Quota (kgB)

2016 Inventory Calculations	Total
2015 Ending Inventory	9,122
Non saleable material	0
2015 Available End. Inv.	**9,122**
2016 API Quota (Procure)	20,500
2016 API Quota (Manufacture)	9,000
2016 Dispositions:	
Sales	23,209
Processing Losses	[redacted] (2,239)
2016 Ending Inventory	**13,175**
Converted to % Yearend	**52.6%**

Table IV: 2016 Hydrocodone for Sale Yearend Calculation

	kgs, base
2015 Estimated Dispositions	26,881
2016 Estimated Dispositions	23,209
Average	25,045
50% Inventory Allowance	12,523

Table V: 2015 Projected Hydrocodone Process Loss Information (kgB)

	PROCESS LOSSES BASED ON 2014 YIELDS FOR CURRENT GRANT				ESTIMATE WITH ADDITIONAL QUOTA		
Description	**Input to Step**	**Process Yield**	**Net output of step**	**Loss by step**	**Input to Step**	**Output of Step**	**Loss by step**
Hydrocodone for Sale - MQ							
CPS Thebaine to Crude hydrocodone (CHB)	3,357	87.5%	2,937		6,929	6,063	
CHB to purified hydrocodone base (PHB)	2,937	94.0%	2,761	(176)	6,063	5,699	(364)
PHB to hydrocodone bitartrate (HBT)	2,789	84.6%	2,359	(429)	5,699	4,822	(878)
HBT to HBT Finished Good API	2,855	99.9%	2,852	(3)	4,822	4,816	(6)
				(609)			(1,247)
Hydrocodone for Sale - PQ							
PHB to hydrocodone bitartrate (HBT)	27,912	88.5%	24,697	(3,215)	0	0	0
HBT to HBT Finished Good API	26,927	99.1%	26,671	(255)	0	0	0
Reprocessing of OOS HBT							
				(3,471)			0

Table VI: 2016 Projected Hydrocodone Process Loss Information (kgB)

2016 Process Loss Calculations				
Description	**Input to Step**	**Process Yield**	**Net output of step**	**Loss by step**
Hydrocodone for Sale - MQ				
CPS Thebaine to Crude hydrocodone	10,286	87.5%	9,000	
Crude hydrocodone to purified hydrocodone base	9,000	94.0%	8,460	(540)
purified hydrocodone base to hydrocodone bitartrate	8,460	84.6%	7,157	(1,303)
HBT to HBT FG	7,157	99.9%	7,149	(9)
Total MQ				(1,851)
Hydrocodone for Sale - PQ				
purified hydrocodone base to hydrocodone bitartrate	20,500	99.1%	20,306	(194)
HBT to HBT FG	20,306	99.1%	20,113	(193)
Total PQ				(387)

CONFIDENTIAL BUSINESS INFORMATION

2016 Manufacturing Quota Submission Supporting Tables – (b)(4);(b)(7)(E)
Hydrocodone for Sale (9193)
April 2015

The CPS ATA is needed to produce hydrocodone, oxycodone and thebaine. The 2016 requirement is captured on the 2016 Oxycodone document. Thank you in advance for considering this request. If you require any additional information, please do not hesitate to contact me at (b)(6)

Best regards,

(b)(6)

Director, Controlled Substance Compliance

Basic Class: 9050-B
Total PQ Requested: 48,444,641.755

2016 Establish APQ Worksheets

FDA Est: N/A
IMS Est: .276

Company	DEA Num	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	25,658,269.319	0.000	0.000	1.600	0.000	5.000	4.950	-0.350	5.000
		20.000	0.000	0.000	25,658,269.319	0.000	0.000	.0.000	10.000	20.000	0.000	30.000	20.000
		100.000	100.000	33.828	25,658,269.319	0.000	54.641	42.664	0.000	20.000	108.998	-29.363	100.000
		628,000.000	628,000.000	0.000	25,658,269.319	0.000	0.000	0.000	0.000	628,000.000	471,000.000	157,000.000	471,000.000
		296,000.000	296,000.000	241,282.000	25,658,269.319	0.009	389,731.596	247,156.000	0.000	197,210.000	467,367.000	215,218.495	215,218.495
		15,000,000.000	13,363,697.000	8,779,625.000	25,658,269.319	0.342	14,180,350.902	3,813,299.000	918,340.000	16,395,120.000	12,882,747.000	21,202,826.877	12,882,747.000
		1,000.000	1,000.000	4.158	25,658,269.319	0.000	6.732	501.534	0.000	1,000.000	1,126.151	-243.119	1,000.000
		30,501,000.000	21,767,000.000	15,938,397.000	25,658,269.319	0.621	25,744,561.618	4,380,520.000	0.000	25,472,000.000	19,810,640.000	36,946,919.523	21,767,000.000
		8,460,000.000	3,543,589.000	699,547.000	25,658,269.319	0.027	1,129,945.744	7,548.000	0.000	8,215,000.000	2,663,352.750	4,963,192.436	4,963,192.436
MQ Totals:	-	54,886,125.000	39,599,391.000										40,300,282.925

2015 Final Initial APQ:	39,600,000.000
2016 Final Revised APQ:	51,120,000.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	39,600,000.000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	50,521,680.000

2016 Proposed Initial APQ:	51,120,000.000
2016 Proposed Initial APQ w/ 25% buffer:	63,900,000.000
2016 Established APQ:	51,120,000.000
2016 Established APQ w/ 25% buffer:	63,900,000.000

Basic Class: 9193-B

Total PQ Requested: 88,865,535.608

2016 Establish APQ Worksheets

FDA Est: - 077

IMS Est: - 127

Company	DEA Num	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	48,367,669.915	0.000	0.000	0.051	0.000	4.000	3.766	0.199	5.000
		164,700.000	74,550.000	10.000	48,367,669.915	0.000	18.377	0.000	0.000	164,700.000	55,912.500	108,810.471	108,810.471
		20.000	20.000	6.735	48,367,669.915	0.000	12.377	66.422	0.000	6.000	64.817	-57.951	20.000
		486,000.000	140,502.000	19,105.000	48,367,669.915	0.000	35,109.365	23,030.000	0.000	486,000.000	122,649.000	401,480.206	401,480.206
		5,900.000	5,900.000	5,300.180	48,367,669.915	0.000	8,740.170	1,673.047	0.000	5,900.000	5,679.765	11,977.158	5,900.000
		3,770,000.000	2,239,596.000	1,901,901.000	48,367,669.915	0.039	3,495,134.030	3,139,601.000	0.000	3,653,000.000	4,034,397.750	3,202,619.537	3,202,619.537
		20,600,000.000	20,261,503.000	17,263,135.000	48,367,669.915	0.357	31,724,559.059	7,668,468.000	12,200.000	18,650,610.000	20,947,476.250	35,653,913.573	20,600,000.000
		9,002,000.000	2,939,000.000	1,659,638.000	48,367,669.915	0.034	3,050,293.610	643,389.000	0.000	7,149,000.000	2,686,791.750	8,114,227.688	2,686,791.750
		25,852,000.000	26,132,000.000	26,895,112.000	48,367,669.915	0.556	49,425,296.682	2,771,666.000	0.000	20,902,000.000	21,677,899.500	59,912,754.852	25,852,000.000
		6,832,000.000	1,638,539.000	575,108.000	48,367,669.915	0.012	1,056,879.168	3,703,945.000	0.000	5,833,000.000	4,006,863.000	2,221,249.707	4,006,863.000
		8,000,000.000	8,120,276.000	46,154.000	48,367,669.915	0.001	68,492.673	3,796,282.000	0.000	8,100,000.000	8,937,418.500	-3,675,872.906	8,000,000.000
MQ Totals:		74,912,625.000	61,551,691.000					21,746,320.529					65,064,469.964

2015 Final Initial APQ:	79,700,000.000
2015 Final Revised APQ:	79,700,000.000
FDA Est: (2015 Initial APQ * 1 + FDA Est):	73,563,100.000
IMS Est: (2015 Initial APQ * 1 + IMS Est):	69,545,220.000

2016 Proposed Initial APQ:	70,600,000.000	
2016 Proposed Initial APQ w/ 25% buffer:	88,500,000.000	
2016 Established APQ:	70,600,000.000	proposed value is slightly less than avg between FDA & IMS estimates
2016 Established APQ w/ 25% buffer:	88,500,000.000	

Basic Class: 9150-0

2016 Initial APQ Worksheets

Total PQ Requested: 2,761,568.166

FDA Est: -.037
IMS Est: -.07

Company	DEA Num	2016 Requested MQ	2015 Revised MQ	2014 Sales	2014 DEA MQ Sales	% of 2014 Sales	Share of 2016 Total PQ	2014 Inventory	2015 Projected Exports	2015 Projected Sales	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	4,046,947.268	0.000	0.000	0.000	0.000	4.000	3.750	0.250	5.000
		108,600.000	57,525.000	0.000	4,046,947.268	0.000	0.000	0.000	0.000	106,600.000	43,143.750	63,656.250	63,656.250
		20.000	0.000	0.000	4,046,947.268	0.000	0.000	0.000	10.000	20.000	0.000	30.000	20.000
		20.000	30.000	0.066	4,046,947.268	0.000	0.045	48.527	0.000	5.000	58.895	-65.971	20.000
		57,950.000	74,173.000	23,991.000	4,046,947.268	0.006	16,371.051	12,356.000	0.000	57,950.000	64,906.750	10,418.064	57,950.000
		691,468.000	574,137.000	485,479.122	4,046,947.268	0.120	331,276.713	246,677.853	5,900.000	576,223.000	593,111.140	348,938.286	593,111.140
		445,000.000	522,452.000	393,568.000	4,046,947.268	0.097	268,564.127	76,932.000	0.000	373,800.000	449,538.000	240,734.159	445,000.000
		620,000.000	1,180,000.000	756,785.000	4,046,947.268	0.187	517,782.012	665,995.000	0.000	839,215.000	1,384,490.250	-94,552.464	620,000.000
		1,000.000	0.000	0.000	4,046,947.268	0.000	0.000	0.000	0.000	1,000.000	0.000	1,000.000	1,000.000
		2,256,000.000	2,621,000.000	2,173,238.000	4,046,947.268	0.537	1,482,960.746	517,097.000	0.000	2,232,000.000	2,353,572.750	1,602,678.932	2,256,000.000
		1,062,000.000	0.000	0.000	4,046,947.268	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1,062,000.000
		1,900,000.000	500,000.000	105,048.000	4,046,947.268	0.026	71,682.973	2,718.000	887,500.000	898,900.000	377,038.500	1,276,285.717	1,276,285.717
MQ Totals:		7,340,263.000	6,529,322.000										6,577,048.106

2015 Final Initial APQ: 5,600,000.000
2015 Final Revised APQ: 0.000
FDA Est: (2015 Initial APQ * 1 + FDA Est): 5,393,360.000
IMS Est: (2015 Initial APQ * 1 + IMS Est): 5,206,680.000

Note (b)(4) equest is actual for validation (pd efforts) but does not list batch size requirements

2015 Proposed Initial APQ: 5,600,000.000
2015 Proposed Initial APQ w/ 25% buffer: 7,000,000.000
2015 Established APQ: 6,600,000.000 rounded up MQ estimates because of (b)(4) -alidation efforts
2015 Established APQ w/ 25% buffer: 8,250,000.000

(b)(4)

August 12, 2015

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, Virginia 22152

RE: Docket No. DEA–420N
Noramco Comment to Federal Register Vol. 80, No. 137 / Friday, July 17, 2015 Notices Pages 42540–42544 FR Doc No: 2015–17561

Dear DEA Federal Register Representative:

(b)(4) herewith comment to a portion of the above referenced Federal Register proposal. Specifically, (b)(4) believes that 2016 Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for the listed drug codes below may not be adequate for the medical, scientific, research and industrial needs of the United States.

Drug	Drug Code
Amphetamines	1100
Methylphenidate	1724
Codeine	9050
Oxymorphone for Conversion	9652
Oxymorphone	9652

Regards,

(b)(6)

Director, Controlled Substance Compliance

(b)(6)

(b)(4)

August 14, 2015

Dr. Christine. A. Sannerud
Chief
Drug & Chemical Evaluation Section
DEA Headquarters
8701 Morrissette Drive
Springfield, VA 22152

RE: **2016 Initial Aggregate Quota Requests for** (b)(4);(b)(7)(E)

(b)(4) requests these manufacturing quotas be addressed as part of the initial aggregate process. Please consider these requests at this time.

9821 Acetyl Fentanyl

(b)(4) submitted an application to add the 9821 acetyl fentanyl drug class to its manufacturing registration. Once the DEA drug class is granted, (b)(4) will submit a manufacturing application request for 50 g AA of acetyl fentanyl manufacturing quota for 2016. (b)(4) requests that DEA consider the 50 g AA future request as part of the aggregate determination process.

9050 Codeine (for sale)

(b)(4) requests 16,700,000 g AA of codeine (for sale) manufacturing quota (Reference #124222 on August 13, 2015) for 2016 (See Exhibit A)

2010 Gamma Hydroxybutyric Acid

(b)(4) requests 30,000 g AA of gamma hydroxybutyric acid manufacturing quota (Reference #124225 on August 13, 2015) for 2016 (See Exhibit B).

9220 Levorphanol

(b)(4) requests 5,100 grams AA of levorphanol manufacturing quota (Reference #124223 on August 13, 2015) for 2016 (See Exhibit C).

1724 Methylphenidate

(b)(4) requests 7,200,000 grams AA of methylphenidate manufacturing quota (Reference #124221 on August 13, 2015) for 2016 (See Exhibit D).

Sincerely,

(b)(6)

Supervisor, Controlled Substances Compliance

(b)(4)

Office phone (b)(6)

Cellular (b)(6)

(b)(4)

Additional Codeine Quota Request
Supplemental Information

Exhibit A

	8/13/2015							
	MB	9050 Codeine Sales						
		(b)(4);(b)(7)(E)						
		Grams Base Class (AA)		AA grams	AA grams	AA grams CY 2015	AA grams Salt Kg	
Type	Registration	Customer	Code	2013 Act	2014 Act	Est.Total	2016 Est	Percent
(32)	Inventory	Bulk Controlled Substances		2,511,455	1,819,241	3,596,606	3,901,486	
(33)		In-Process Material		2,659,828	1,994,058	2,000,000	2,000,000	
(34)		Total Inventory		5,171,283	3,813,299	5,596,606	5,901,486	
E	(b)(4);(b)(7)(E)		1561	5,288,713	3,857,701	7,897,000	7,215,000	43.6%
E			1561	0	0	644,000	0	3.6%
E			1548	2,311,212	1,309,410	2,432,239	3,106,520	13.4%
E			1548	0	0	1,598,400	740,000	8.8%
E			1548	0	0	379,620	0	2.1%
E			1548	0	0	627,520	444,000	0.0%
E			1548	400,619	333,000	466,200	296,000	0.0%
E			1548	740,000	888,000	592,000	592,000	3.3%
E			1548	0	156,880	370,000	74,000	2.0%
E			1548	0	222,000	308,832	444,000	1.7%
E			1548	55,500	107,300	238,280	148,000	1.3%
E			1548	0	0	71,780	370,000	0.4%
E			1548	525,400	99,900	0	0	0.0%
E			1548	166,500	333,000	0	0	0.0%
		Others		695,420	515,167	52,667	1,747,260	0.3%
E	(b)(4);(b)(7)(E)		1580	356,696	373,235	356,000	300,000	2.0%
	Disposition	Domestic		10,540,061	8,195,593	16,034,537	15,476,780	88.5%
		India	1550	0	518,000	1,902,540	777,000	
		All Other Export		1,648,720	176,453	186,376	141,340	
		Export		1,648,720	694,453	2,088,916	918,340	11.5%
(35)		Total Sales		12,188,781	8,890,046	18,123,453	16,395,120	
(36)	Acquisition	Codeine (for Sale) Production		12,259,098	6,971,723	19,906,760	16,700,000	
(37)		Quota previously granted		(13,900,000)	(13,145,613)	(13,364,000)	(15,000,000)	
(38)		Codeine (for Sale) quota needed				6,542,760	1,700,000	
							50% Rule	
							6,705,039	

Contains Confidential and Proprietary Information

(b)(4)

Additional GHB Quota Request
Supplemental Information

Exhibit B

	8/13/2015							
	SZ	2010 Gamma Hydroxybutyric Acid						
		(b)(4);(b)(7)(E)						
		Grams Base Class (AA)				AA grams	AA grams	
				AA grams	AA grams	CY 2015	AA grams	
Type	Registration	Customer	Code	2013 Act	2014 Act	Est.Total	2016 Est	Percent
(01)	Inventory	Bulk Controlled Substances		0	0	0	15,000	
(02)		In-Process Material		0	0	0	0	
(03)		Total Inventory		0	0	0	15,000	
	(b)(4);(b)(7)(E)			0	0	5,000	15,000	66.7%
		* Internal Use		0	0	2,500	0	33.3%
	Disposition	Domestic		0	0	7,500	15,000	
		Export		0	0	0	0	0.0%
(04)		Total Sales		0	0	7,500	15,000	
(05)	Acquisiton	Net Production		0	0	7,500	30,000	
(06)		Quota previously granted		0	0	0	0	
(07)		**Gamma Hydroxybutyric Acid Quota Requested**				**7,500**	**30,000**	

Contains Confidential and Proprietary Information

(b)(4)

Additional Levorphanol Quota Request
Supplemental Information

Exhibit C

	8/13/2015							
	MB	9220 Levorphanol Sales						
		(b)(4);(b)(7)(E)						
		Grams Base Class (AA)				AA grams	AA grams	
				AA grams	AA grams	CY 2015	AA grams	
Type	Registration	Customer	Code	2013 Act	2014 Act	Est.Total	2016 Est	Percent
(01)	Inventory	Bulk Controlled Substances		41	117	567	1,549	
(02)		In-Process Material		1	0	0	0	
(03)		Total Inventory		42	117	567	1,549	
	(b)(4);(b)(7)(E)		0545	1,587	2,910	1,450	2,610	73.2%
			0545	0	46	58	58	2.9%
			0545	110	70	0	29	0.0%
		Other		346	29	144	29	7.2%
		* Internal Use	0545	630	312	243	232	12.3%
	Disposition	Domestic		2,673	3,367	1,895	2,958	
		Export		0	58	87	1,160	4.4%
(04)		Total Sales		2,673	3,425	1,982	4,118	
(05)	Acquisiton	Net Levorphanol Production		2,545	3,595	2,432	5,100	
(06)		Quota previously granted		(3,100)	(1,598)	(2,732)	(4,500)	
(07)		**Levorphanol Quota Requested**				**0**	**600**	
							50% Rule	
							1,525	

Contains Confidential and Proprietary Information

(b)(4)

Additional Methylphenidate Quota Request
Supplemental Information

Exhibit D

	8/13/2015							
	MB	1724 Methylphenidate Sales (b)(4);(b)(7)(E)						
		Grams Base Class (AA)				AA grams		
Type	Registration	Customer	Code	AA grams 2013 Act	AA grams 2014 Act	CY 2015 Est.Total	AA grams 2016 Est	Percent
(01)	Inventory	Bulk Controlled Substances		4,052,684	2,899,423	2,070,380	2,217,490	
(02)		In-Process Material		2,238,698	650,562	1,500,000	1,500,000	
(03)		Total Inventory		6,291,382	3,549,985	3,570,380	3,717,490	
E	(b)(4);(b)(7)(E)		0570	6,071,830	4,640,656	5,487,954	3,273,810	66.5%
E			8335	391,500	1,694,455	0	0	0.0%
E			8335	0	0	1,556,217	696,000	18.9%
E			1571	0	276,660	0	0	0.0%
E			1571	1,781,835	609,000	696,000	696,000	8.4%
		All Others		1,343,925	158,190	203,667	1,926,180	2.5%
E	(b)(4);(b)(7)(E)		7654	0	569,710	246,000	400,000	3.0%
	Disposition	Domestic		9,589,090	7,948,670	8,189,838	6,991,990	99.2%
		Export HCl	1571	108,505	32,416	64,380	60,900	
		Export Base	7654	0	300	0	0	
		Export		108,505	32,716	64,380	60,900	0.8%
(04)		Total Sales		9,697,595	7,981,387	8,254,218	7,052,890	
(05)	Acquisition	Net Production		12,969,532	5,206,730	8,274,613	7,200,000	
(06)		Quota previously granted		(13,044,576)	(10,460,037)	(12,563,564)	0	
(07)		Methylphenidate Quota Requested					7,200,000	
							50% Rule	
							3,795,457	

Contains Confidential and Proprietary Information

Substance	2012 Kg	2013 Kg	% Change	2014 Kg	% Change	EST 2015 Kg	% Change
AMPHETAMINE *	**22,664.555**	**22,574.791**	**-0.40%**	**24,622.361**	**9.07%**	**26,649.411**	**8.23%**
COCAINE	**43.833**	**38.880**	**-11.30%**	**35.481**	**-8.74%**	**36.383**	**2.54%**
CODEINE	22,756.728	21,747.588	-4.43%	21,716.915	-0.14%	27,707.091	27.58%
DIHYDROCODEINE	**75.021**	**35.987**	**-52.03%**	**3.314**	**-90.79%**	**19.854**	**499.08%**
DIPHENOXYLATE	413.016	411.425	-0.39%	385.932	-6.20%	386.709	0.20%
DRONABINOL	**108.128**	**111.177**	**4.76%**	**117.394**	**5.59%**	**113.150**	**-3.62%**
EPHEDRINE	1,972.090	2,079.301	5.44%	2,234.629	7.47%	2,174.679	-2.68%
FENTANYL	**515.025**	**471.712**	**-8.41%**	**472.441**	**0.15%**	**520.881**	**10.25%**
HYDROCODONE	**63,179.515**	**61,710.790**	**-2.32%**	**56,372.635**	**-8.65%**	**49,189.077**	**-12.74%**
HYDROMORPHONE	**1,913.040**	**1,927.636**	**0.76%**	**1,834.406**	**-4.84%**	**1,705.705**	**-7.02%**
LEVORPHANOL	1.544	2.314	49.87%	2.691	16.29%	2.895	7.57%
LISDEXAMFETAMINE	**14,001.470**	**13,652.692**	**-2.49%**	**14,245.693**	**4.34%**	**15,024.879**	**5.47%**
MEPERIDINE	1,880.965	1,522.736	-19.04%	1,243.493	-18.34%	1,117.645	-10.12%
METHADONE	**6,777.086**	**5,805.070**	**-14.34%**	**5,251.161**	**-9.54%**	**4,882.985**	**-7.01%**
METHAMPHETAMINE	14.399	13.192	-8.38%	11.910	-9.72%	11.285	-5.24%
METHYLPHENIDATE **	**21,759.744**	**20,137.904**	**-7.45%**	**20,175.671**	**0.19%**	**20,681.878**	**2.51%**
MORPHINE	28,706.443	26,272.879	-8.48%	24,603.452	-6.35%	23,849.454	-3.06%
NALBUPHINE	**63.599**	**41.766**	**-34.33%**	**40.868**	**-2.15%**	**34.177**	**-16.37%**
NALOXONE	433.684	481.367	10.99%	522.199	8.48%	275.425	-47.26%
NALTREXONE	**646.518**	**743.593**	**15.02%**	**927.244**	**24.70%**	**1,515.728**	**63.47%**
Noroxymorphone products (sum)	1,143.801	1,266.726	10.75%	1,490.310	17.65%	1,825.330	22.48%
OPIUM	**80.986**	**77.417**	**-4.41%**	**76.702**	**-0.92%**	**75.906**	**-1.04%**
OXYCODONE	**66,704.849**	**60,357.506**	**-9.52%**	**58,911.473**	**-2.40%**	**59,605.015**	**1.18%**
OXYMORPHONE	**1,958.281**	**1,863.432**	**-4.84%**	**1,930.455**	**3.60%**	**1,961.302**	**1.60%**
PENTAZOCINE	698.430	565.292	-19.06%	422.871	-25.19%	333.411	-21.16%
PENTOBARBITAL	**46.612**	**24.226**	**-48.03%**	**16.541**	**-31.72%**	**17.406**	**5.23%**
PHENYLPROPANOLAMINE		2.966	#DIV/0!	1.058	-64.34%	2.751	160.14%
PSEUDOEPHEDRINE***	**187,867.353**	**186,436.285**	**-0.76%**	**181,452.065**	**-2.67%**	**189,236.703**	**4.29%**
REMIFENTANIL	1.105	1.158	4.75%	1.225	5.83%	1.309	6.89%
SECOBARBITAL	**15.670**	**12.040**	**-23.17%**	**11.470**	**-4.73%**	**11.500**	**0.26%**
SUFENTANIL	0.051	0.047	-8.82%	0.041	-11.40%	0.042	2.91%
TAPENTADOL	**6,388.449**	**5,989.766**	**-6.24%**	**5,645.768**	**-5.74%**	**5,614.405**	**-0.56%**

2015 Data based on Jan - Jun 2015 data

* corrected based on historical IMS data for d,l and d

** added dexmethylphenidate to methylphenidate

*** corrected based on IMS capture of OTC market

IMS DATA 2012 - June 2015 with 2015 annual (est)

2016 Establish Adjusted Aggregate Production Quotas and Annual Assessment of Needs

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish the production amount of each basic class of Schedule I and II controlled substances and for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- DEA regulations allow the Administrator to revise the established annual aggregate production quota (APQ) and assessment of annual needs (AAN) after review of pertinent information provided from various sources including DEA-registered manufacturers and the Food and Drug Administration (FDA).

- The attached Federal Register notice, prepared for your signature, reflects the calendar year 2016 established aggregate production quotas (APQ) for schedules I and II controlled substances and assessment of annual needs (AAN) for the list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for which the United States has medical, scientific, industrial, export and reserve stock requirements.

- As stated in the 2013 Federal Register Notices, DEA continues to add an additional 25% to the APQ for schedule II substances and those schedule I substances that are used to produce drugs that have a medical need (specifically, GHB and tetrahydrocannabinols) to prevent potential drug shortage issues.

- Although DEA and FDA have signed an MOU for the transfer of information between the agencies, FDA did not respond to DEA's August 13, 2015 request for information and clarification regarding methylphenidate which is utilized in ADHD medications domestically and abroad. The request was based on DEA's knowledge of FDA's success in a court challenge regarding their recent downgrade of 2 manufacturers' generic equivalents of the brand. Therefore, the APQ for methylphenidate is based on manufacturers' data and recent shifts in the visible market.

- Expeditious review and publication of this notice is necessary to ensure an uninterruptable supply of schedule I and II controlled substances as well as list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for the legitimate medical, scientific, industrial, and export requirements of the U.S.

- The following points provide brief explanations of the changes from the proposed revised AAN & APQ values:

List I Chemicals:

- No changes

Controlled Substances:

- OD is recommending an increase in the APQs for **amphetamine (for sale)** and **hydromorphone.** The increases are based on increased product development and validation effort requirements by bulk manufacturers.

- OD is recommending an increase in the APQ for **marihuana**. The increase is based on the requirements from bulk manufacturers to supply cannabidiol or other marihuana extracts to dosage-form manufacturers conducting product development activities with the objective of receiving FDA approval of their products.

- OD is recommending an increase in the APQ for **methylphenidate.** The increase is based on the FDA downgrading the efficacy rating for two generic manufacturers of the brand Concerta® . This change is to allow the remaining authorized generic and brand manufacturers to supply the entire domestic market.

- OD is recommending an increase in the APQ for **N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl).** The increase is based on its newly established temporary control status as a schedule I controlled substance and the need for reference standards.

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-420F]

Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final Order.

SUMMARY: This final order establishes the initial 2016 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

EFFECTIVE DATE: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled

Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. This responsibility has been delegated to the Administrator of the DEA through 28 CFR 0.100(b).

Background

The 2016 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured in the United States in 2016 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment

and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes.

On July 17, 2015, a notice titled, "Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Proposed Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016" was published in the *Federal Register*. 80 FR 42540. This notice proposed the 2016 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2016 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before August 17, 2015.

Comments Received

Twenty comments were received from four DEA-registered manufacturers within the published comment period regarding 17 different schedule I and II controlled substances. The DEA did not receive any comments regarding the proposed assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Commenters stated that the proposed aggregate production quotas for [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201), amphetamine (for sale), codeine (for sale), gamma hydroxybutric acid, levorphanol, marihuana, methylphenidate, *N*-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA), *N*-(1-Amino-3-methyl-1-

oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl), nabilone, oxymorphone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-Flouro-PB-22), and Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

Determination of 2016 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2016 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the 2015 manufacturing quotas, current 2015 sales and inventories, anticipated 2016 export requirements, industrial use, additional applications for 2016 quotas, as well as information on research and product development requirements. Based on this information, the DEA has determined that adjustments to the proposed aggregate production quotas for codeine (for sale), hydromorphone, marihuana, methylphenidate, and *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl) are warranted. This final order reflects those adjustments.

Regarding [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201), amphetamine (for sale), gamma hydroxybutric acid, levorphanol, *N*-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA),

N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA), nabilone, oxymorphone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-Flouro-PB-22), and Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22), the DEA has determined that the proposed aggregate production quotas are sufficient to provide for the 2016 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these aggregate production quotas at the same amounts as proposed.

As described in the previously published notice proposing the 2016 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all established schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The established aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to

maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforescen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2016 aggregate production quotas for the following schedule I and II controlled substances and the 2016 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Established 2016 Quotas (g)
Schedule I	
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	25
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	25
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45

1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	25
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-*n*-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-*N*-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-*N*-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-*N*-methylcathinone (3-FMC)	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2

4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-*N*-methylcathinone (4-FMC)	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-*N*-ethylcathinone (4-MEC)	25
4-Methyl-*N*-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-*N*,*N*-diisopropyltryptamine	25
5-Methoxy-*N*,*N*-dimethyltryptamine	25
Acetyl-*alpha*-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betamethadol	4
Betaprodine	2

Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-*N*-oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	11,000
Dihydromorphine	3,000,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	40
Marihuana	658,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-*N*-oxide	350
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA)	15
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100
N,*N*-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	25

N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Phenomorphan	2
Pholcodine	5
Psilocybin	30
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	50
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	50
Tetrahydrocannabinols	511,250
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,950,000
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	15,000,000
Amphetamine (for sale)	39,705,000
Carfentanil	19
Cocaine	200,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	63,900,000
Dextropropoxyphene	45
Dihydrocodeine	226,375

Dihydroetorphine	3
Diphenoxylate (for conversion)	31,250
Diphenoxylate (for sale)	1,337,500
Ecgonine	125,000
Ethylmorphine	3
Etorphine hydrochloride	3
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	235,000
Hydrocodone (for sale)	88,500,000
Hydromorphone	8,250,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	30
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	5,450,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	30,000,000
Oxycodone (for conversion)	6,250,000

Oxycodone (for sale)	139,150,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	38,125,000
Phenazocine	6
Phencyclidine	50
Phenmetrazine	3
Phenylacetone	50
Racemethorphan	3
Racemorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	25,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	100,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	22,400,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Administrator also establishes aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2016 aggregate production quotas and assessment of annual needs as needed.

Dated:

Chuck Rosenberg,
Acting Administrator

A:_____

AX:_____

OC:_____

OD:_____

CCR:_____CCO:_____CC:_____

ODX:_____

ODXL:_____

ODW:_____

ODW analyst:_____

ODQ: _____

ODEQ: (b)(6)

DFN: 630-07 Federal Register

SBF-CM # ODQ-16-108

cannot guarantee that we will be able to do so.

CALIFORNIA

Monterey County

Aeneas Sardine Packing Company Cannery, 300 Cannery Row, Monterey, 15000739

COLORADO

Routt County

Hayden Co-Operative Elevator Company, 198 E. Lincoln Ave., Hayden, 15000740

DISTRICT OF COLUMBIA

District of Columbia

Capitol Hill Historic District (Boundary Increase II), Squares 752, 753, 777, 788 bounded by 2nd, 4th & F Sts. NE., Washington, 15000741

Davis, Colonel William Robert, House, 3020 Albemarle St. NW., Washington, 15000742

Young, Browne, Phelps and Springarn Educational Campus Historic District, (Public School Buildings of Washington, DC MPS) 2500 Benning Rd. NE., 704, 820, & 850 26th St. NE., Washington, 15000743

GEORGIA

Stephens County

Toccoa Downtown Historic District (Boundary Increase), 118 W. Doyle St., Toccoa, 15000744

IOWA

Carroll County

Manning Commercial Historic District, (Iowa's Main Street Commercial Architecture MPS) 217–411, 413–507, 302–326 Main, 717–723 3rd, 303 Center & 825 5th Sts., Manning, 15000745

Henry County

Benjamin Chapel and Richwoods Cemetery, 1936 Franklin Ave., Trenton, 15000746

Boyle, Hugh and Matilda, House and Cemetery Historic District, 3225 Lexington Ave., Lowell, 15000747

Edwards, Joseph A. and Lydia A., House, 1735 Salem Rd., Salem, 15000748

Garretson, Owen A. and Emma J., House, 1878 335th St., Salem, 15000750

Linn County

Cedar Rapids 2nd Avenue SE. Automobile Row Historic District, Roughly 2nd to 3rd Aves., SE., from 6th to 8th Sts., SE., Cedar Rapids, 15000749

Monroe Elementary School Historic District, 3200 Pioneer Ave., SE., Cedar Rapids, 15000751

Montgomery County

Ellis, William and Amanda J., Farmstead Historic District, 1134 I Ave., Elliott, 15000752

NEW YORK

Essex County

Helen Hill Historic District, Prescott Place, Helen & Front Sts., Sheppard, Franklin & Clinton Aves., Saranac Lake, 15000754

OHIO

Hamilton County

William Howard Taft National Historic Site (Boundary Increase and Additional Documentation, 2038 Auburn Ave., Cincinnati, 15000753

A request to move has been made for the following resource:

INDIANA

Clay County

Indiana State Highway Bridge 46–11–1316, IN 46 over Eel R., Bowling Green, 00000211

In the interest of preservation a three day comment period has been requested for the following resource:

WISCONSIN

Ozaukee County

SENATOR (steam screw) Shipwreck, (Great Lakes Shipwreck Sites of Wisconsin MPS) Address Restricted, Port Washington, 15000738

Authority: 60.13 of 36 CFR part 60

Dated: September 16, 2015.

Roger Reed,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2015–25375 Filed 10–5–15; 8:45 am]

BILLING CODE 4312–51–P

JOINT BOARD FOR THE ENROLLMENT OF ACTUARIES

Meeting of the Advisory Committee; Meeting

AGENCY: Joint Board for the Enrollment of Actuaries

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Executive Director of the Joint Board for the Enrollment of Actuaries gives notice of a closed teleconference meeting of the Advisory Committee on Actuarial Examinations.

DATES: The meeting will be held on October 30, 2015, from 8:30 a.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Patrick W. McDonough, Executive Director of the Joint Board for the Enrollment of Actuaries, 703–414–2173.

SUPPLEMENTARY INFORMATION:

Notice is hereby given that the Advisory Committee on Actuarial Examinations will hold a teleconference meeting on October 30, 2015, from 8:30 a.m. to 5:00 p.m. The meeting will be closed to the public.

The purpose of the meeting is to discuss topics and questions that may be recommended for inclusion on future Joint Board examinations in actuarial mathematics, pension law and methodology referred to in 29 U.S.C. 1242(a)(1)(B).

A determination has been made as required by section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. App., that the subject of the meeting falls within the exception to the open meeting requirement set forth in Title 5 U.S.C. 552b(c)(9)(B), and that the public interest requires that such meeting be closed to public participation.

Dated: September 21, 2015.

Patrick W. McDonough,

Executive Director, Joint Board for the Enrollment of Actuaries.

[FR Doc. 2015–25342 Filed 10–5–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–420F]

Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2016 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Effective October 6, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. 21

U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. This responsibility has been delegated to the Administrator of the DEA through 28 CFR 0.100(b).

Background

The 2016 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine that may be manufactured in the United States in 2016 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes.

On July 17, 2015, a notice titled, "Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Proposed Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016" was published in the **Federal Register**. 80 FR 42540. This notice proposed the 2016 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2016 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before August 17, 2015.

Comments Received

Twenty comments were received from four DEA-registered manufacturers within the published comment period regarding 17 different schedule I and II controlled substances. The DEA did not receive any comments regarding the proposed assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Commenters stated that the proposed aggregate production quotas for [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ–2201), amphetamine (for sale), codeine (for sale), gamma hydroxybutric acid, levorphanol, marihuana, methylphenidate, *N*-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB–PINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB–FUBINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB–CHMINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB–PINACA), *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl), nabilone, oxymorphone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-Flouro-PB–22), and Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB–22) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

Determination of 2016 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2016 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the 2015 manufacturing quotas, current 2015 sales and inventories, anticipated 2016 export requirements, industrial use, additional applications for 2016 quotas, as well as information on research and product development requirements. Based on this information, the DEA has determined that adjustments to the proposed aggregate production quotas for codeine (for sale), hydromorphone, marihuana, methylphenidate, and *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide (acetyl fentanyl) are warranted. This final order reflects those adjustments.

Regarding [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ–2201), amphetamine (for sale), gamma hydroxybutric acid, levorphanol, *N*-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB–PINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB–FUBINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB–CHMINACA), *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB–PINACA), nabilone, oxymorphone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-Flouro-PB–22), and Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB–22), the DEA has determined that the proposed aggregate production quotas are sufficient to provide for the 2016 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these aggregate production quotas at the same amounts as proposed.

As described in the previously published notice proposing the 2016 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all established schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The established aggregate production quotas will reflect these included amounts. This action will not affect the ability of

manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2016 aggregate production quotas for the following schedule I and II controlled substances and the 2016 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2016 quotas (g)
Schedule I	
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144)	25
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ–2201)	15
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	25
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH–073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C–P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I–NBOMe; 2C–I–NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	25
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-*n*-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-*N*-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-*N*-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-*N*-methylcathinone (3–FMC)	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	25
4-Fluoro-*N*-methylcathinone (4–FMC)	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-*N*-ethylcathinone (4–MEC)	25
4-Methyl-*N*-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-*N*,*N*-diisopropyltryptamine	25
5-Methoxy-*N*,*N*-dimethyltryptamine	25
Acetyl-*alpha*-methylfentanyl	2

Basic class	Established 2016 quotas (g)
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-*N*-oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	11,000
Dihydromorphine	3,000,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	40
Marihuana	658,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-*N*-oxide	350
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB–PINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB–FUBINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB–CHMINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB–PINACA)	15
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100
N,N-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	25
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Phenomorphan	2
Pholcodine	5
Psilocybin	30
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	50
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB–22; QUPIC)	50
Tetrahydrocannabinols	511,250
Thiofentanyl	2
Tilidine	25

Basic class	Established 2016 quotas (g)
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,950,000
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	15,000,000
Amphetamine (for sale)	39,705,000
Carfentanil	19
Cocaine	200,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	63,900,000
Dextropropoxyphene	45
Dihydrocodeine	226,375
Dihydroetorphine	3
Diphenoxylate (for conversion)	31,250
Diphenoxylate (for sale)	1,337,500
Ecgonine	125,000
Ethylmorphine	3
Etorphine hydrochloride	3
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	235,000
Hydrocodone (for sale)	88,500,000
Hydromorphone	8,250,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	30
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	5,450,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	30,000,000
Oxycodone (for conversion)	6,250,000
Oxycodone (for sale)	139,150,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	38,125,000
Phenazocine	6
Phencyclidine	50
Phenmetrazine	3
Phenylacetone	50
Racemethorphan	3
Racemorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	25,500,000
Thebaine	125,000,000

Basic class	Established 2016 quotas (g)
List I Chemicals	
Ephedrine (for conversion)	100,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	22,400,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Administrator also establishes aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2016 aggregate production quotas and assessment of annual needs as needed.

Dated: September 30, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015-25373 Filed 10-5-15; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

[F.C.S.C. Meeting and Hearing Notice No. 09-15]

Sunshine Act Meeting

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR 503.25) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings as follows:

Thursday, October 15, 2015: 10 a.m.—Issuance of Proposed Decisions in claims against Libya.

Status: Open

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Patricia M. Hall, Foreign Claims Settlement Commission, 600 E Street NW., Suite 6002, Washington, DC 20579. Telephone: (202) 616-6975.

Brian M. Simkin,

Chief Counsel.

[FR Doc. 2015-25500 Filed 10-2-15; 4:15 pm]

BILLING CODE 4410-BA-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On September 29, 2015, the Department of Justice lodged a proposed consent decree with the United States District Court for the Eastern District of Michigan in the lawsuit entitled *United States* v. *Guardian Industries Corp.*, Civil Action No. 2:15-cv-13426.

The United States filed this lawsuit under the Clean Air Act. The complaint seeks injunctive relief and civil penalties for violations of the Clean Air Act's Prevention of Significant Deterioration requirements at eight float glass manufacturing furnaces owned and operated by the defendant, Guardian Industries Corp., in Kingsburg, California; DeWitt, Iowa; Carleton, Michigan; Geneva, New York; Floreffe, Pennsylvania; Richburg, South Carolina; and Corsicana, Texas. The consent decree requires the defendant to perform injunctive relief, which includes complying with emission limitations that are comprised of numerical or work practice standards that together apply continuously at all times. The defendant will also pay a $312,000 civil penalty and perform a $150,000 wood burning appliance replacement mitigation project in the San Joaquin Valley area in California.

The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Guardian Industries Corp.*, D.J. Ref. No. 90-5-2-1-11128. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044-7611.

During the public comment period, the proposed consent decree may be examined and downloaded at this Justice Department Web site: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed consent decree upon written request and payment of reproduction costs. Please mail your request and payment to:

Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for $24.25 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $19.50.

Maureen M. Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015-25339 Filed 10-5-15; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

179th Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in Section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 179th open meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans (also known as the ERISA Advisory Council) will be held on November 3-4, 2015.

The meeting will take place in C5320 Room 6, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210 on November 3, from 1 p.m. to approximately 5:00 p.m. On

Molecule	2013 KG	2014 KG	% chg	2015 KG	% chg	est. 2016 KG	% chg
AMPHETAMINE*	**23,850.324**	**26,286.338**	**10.21%**	**28,781.821**	**9.49%**	**30,517.931**	**6.03%**
COCAINE	34.627	31.631	-8.65%	30.527	-3.49%	27.583	-9.64%
CODEINE	**15,613.921**	**15,843.674**	**1.47%**	**20,257.91**	**27.86%**	**21,012.94**	**3.73%**
DIFENOXIN	.187	.056	-70.00%		-100.00%		#DIV/0!
DIHYDROCODEINE	35.475	3.403	-90.41%	22.281	554.75%	22.784	2.26%
DIPHENOXYLATE	373.241	352.308	-5.61%	352.954	0.18%	349.543	-0.97%
DRONABINOL	120.358	128.18	6.50%	130.851	2.08%	128.57	-1.74%
FENTANYL	361.043	354.528	-1.80%	335.363	-5.41%	319.397	-4.76%
HYDROCODONE	**36,678.845**	**35,451.338**	**-3.35%**	**31,723.148**	**-10.52%**	**30,855.332**	**-2.74%**
HYDROMORPHONE	1,797.363	1,732.504	-3.61%	1,575.059	-9.09%	1,510.81	-4.08%
LEVORPHANOL	1.862	2.196	17.93%	2.158	-1.73%	1.453	-32.67%
LISDEXAMFETAMINE	**8,308.34**	**8,682.564**	**4.50%**	**9,249.049**	**6.52%**	**9,833.118**	**6.31%**
MEPERIDINE	1,418.809	1,168.501	-17.64%	1,016.846	-12.98%	887.269	-12.74%
METHADONE	5,354.641	4,952.815	-7.50%	4,308.58	-13.01%	3,999.395	-7.18%
METHAMPHETAMINE	11.603	10.589	-8.74%	9.221	-12.92%	7.331	-20.49%
METHYLPHENIDATE**	**18,623.703**	**18,770.777**	**0.79%**	**18,888.757**	**0.63%**	**19,430.554**	**2.87%**
MORPHINE	20,720.216	19,464.979	-6.06%	18,836.94	-3.23%	18,129.334	-3.76%
NABILONE	.038	.04	6.07%	.027	-32.09%	.018	-32.60%
OPIUM	82.183	81.23	-1.16%	81.117	-0.14%	79.946	-1.44%
OXYCODONE	**57,343.022**	**57,195.413**	**-0.26%**	**56,991.066**	**-0.36%**	**55,550.807**	**-2.53%**
OXYMORPHONE	1,740.366	1,827.113	4.98%	1,871.443	2.43%	1,839.972	-1.68%
PENTAZOCINE	506.79	390.019	-23.04%	326.007	-16.41%	296.022	-9.20%
PENTOBARBITAL	22.046	15.052	-31.72%	16.061	6.70%	15.903	-0.98%
REMIFENTANIL	1.054	1.12	6.26%	1.231	9.90%	1.298	5.45%
SECOBARBITAL	11.123	10.589	-4.80%	9.476	-10.51%	4.416	-53.40%
SUFENTANIL	.031	.028	-11.37%	.026	-4.60%	.033	25.89%
TAPENTADOL	5,363.34	5,073.831	-5.40%	5,137.105	1.25%	5,310.589	3.38%

2016 Data based on Jan - Mar 2016 data

* corrected based on historical IMS data for d,l and D

** combined dexmethylphenidate and methylphenidate date

DEA Number	Company	Drug Name	Drug Code	Quota Year	Requested Quota	Current Quota	Increase/Decrease	APQ Available
(b)(4);(b)(7)(E)		COCAINE	9041-0	2016	1.000	0.000	1.000	yes
		CODEINE (FOR CONVERSION)	9050-A	2016	1.000	0.000	1.000	yes
		D,L-AMPHETAMINE	1100-A	2016	1,500.000	0.000	1,500.000	no
		D,L-AMPHETAMINE	1100-A	2016	2.000	0.000	2.000	yes
		D,L-AMPHETAMINE	1100-A	2016	11,314,982.000	6,345,984.000	4,968,998.000	no
		D-AMPHETAMINE (FOR SALE)	1100-B2	2016	1,500.000	0.000	1,500.000	no
		D-AMPHETAMINE (FOR SALE)	1100-B2	2016	12,859,842.000	8,185,423.000	4,674,419.000	no
		DIHYDROCODEINE	9120-0	2016	1.000	0.000	1.000	
		DIHYDROETORPHINE	9334-0	2016	1.000	0.000	1.000	
		ECGONINE	9180-0	2016	1.000	0.000	1.000	yes
		ETHYLMORPHINE	9190-0	2016	1.000	0.000	1.000	
		ETORPHINE HCL	9059-0	2016	1.000	0.000	1.000	
		HYDROCODONE (FOR CONVERSION)	9193-A	2016	1.000	0.000	1.000	yes
		HYDROCODONE (FOR SALE)	9193-B	2016	139,880.000	5,680.000	134,200.000	
		HYDROMORPHONE	9150-0	2016	2.000	0.000	2.000	yes
		ISOMETHADONE	9226-0	2016	1.000	0.000	1.000	
		L-AMPHETAMINE	1100-C	2016	1.000	0.000	1.000	yes
		LEVO-ALPHACETYLMETHADOL (LAAM)	9648-0	2016	1.000	0.000	1.000	
		LEVOMETHORPHAN	9210-0	2016	1.000	0.000	1.000	
		LEVORPHANOL	9220-0	2016	1.000	0.000	1.000	
		LISDEXAMFETAMINE	1205-0	2016	2.000	0.000	2.000	
		L-METHAMPHETAMINE	1105-C	2016	1.000	0.000	1.000	
		MARIJUANA	7360-A	2016	1.000	0.000	1.000	
		MEPERIDINE	9230-0	2016	1.000	0.000	1.000	yes
		MEPERIDINE-INTERMEDIATE-A	9232-0	2016	1.000	0.000	1.000	
		MEPERIDINE-INTERMEDIATE-B	9233-0	2016	3.000	0.000	3.000	
		MEPERIDINE-INTERMEDIATE-C	9234-0	2016	1.000	0.000	1.000	
		METHADONE	9250-0	2016	1.000	0.000	1.000	yes
		METHADONE-INTERMEDIATE	9254-0	2016	1.000	0.000	1.000	yes
		METHYLPHENIDATE	1724-0	2016	9,600,000.000	7,200,000.000	2,400,000.000	
		METHYLPHENIDATE	1724-0	2016	2.000	0.000	2.000	yes
		METHYLPHENIDATE	1724-0	2016	6,785,330.000	5,219,330.000	1,566,000.000	4566,000
		METHYLPHENIDATE	1724-0	2016	600,000.000	0.000	600,000.000	
		MORPHINE (FOR CONVERSION)	9300-A	2016	1.000	0.000	1.000	yes

Pending HQ requests 6-3-16

(b)(4);(b)(7)(E)

MORPHINE (FOR CONVERSION)	9300-A	2016	2,357,143.000	757,143.000	1,600,000.000	
NABILONE	7379-0	2016	1.000	0.000	1.000	Yes
NOROXYMORPHONE (FOR CONVERSION)	9668-A	2016	2,545,747.000	1,315,747.000	1,230,000.000	
NOROXYMORPHONE (FOR SALE)	9668-B	2016	103,117.000	15,960.000	87,157.000	
OXYCODONE (FOR CONVERSION)	9143-A	2016	1.000	0.000	1.000	yes
OXYCODONE (FOR SALE)	9143-B	2016	30,814,693.000	22,814,693.000	8,000,000.000	no
OXYMORPHONE (FOR CONVERSION)	9652-A	2016	1.000	0.000	1.000	yes
OXYMORPHONE (FOR SALE)	9652-B	2016	1,991,000.000	1,232,812.000	758,188.000	
PENTOBARBITAL	2270-0	2016	49,000.000	0.000	49,000.000	
PHENYLACETONE	8501-0	2016	1.000	0.000	1.000	
RACEMETHORPHAN	9732-0	2016	1.000	0.000	1.000	
RACEMORPHAN	9733-0	2016	1.000	0.000	1.000	
SUFENTANIL	9740-0	2016	730.000	600.000	130.000	
THEBAINE	9333-0	2016	1.000	0.000	1.000	yes

Pending MD requests 6-3-16

Request ID	Status	Assigned Date	Staff Review Date	Staff ID	Date Submitted	Quota Type	DEA Number	Company	Drug Name	Drug Code	Quota Year	Requested Quota	Current Quota	Increase/Decrease	APQ Available
127682	Pending	31-MAY-16	31-MAY-16	(b)(6)	25-MAY-16	MAN	(b)(4);(b)(7)(E)		D,L-AMPHETAMINE	1100-A	2016	1,500.000	0.000	1,500.000	no
126143	Pending	19-APR-16	31-MAY-16		29-MAR-16	MAN			D,L-AMPHETAMINE	1100-A	2016	11,314,982.000	6,345,984.000	4,968,998.000	no
127861	Pending	31-MAY-16	31-MAY-16		25-MAY-16	MAN			D-AMPHETAMINE (FOR SALE)	1100-B2	2016	1,500.000	0.000	1,500.000	no
126144	Pending	19-APR-16	31-MAY-16		29-MAR-16	MAN			D-AMPHETAMINE (FOR SALE)	1100-B2	2016	12,859,842.000	8,185,423.000	4,674,419.000	no
127623	Pending	31-MAY-16	02-JUN-16		20-MAY-16	MAN			ETHYLMORPHINE	9190-0	2016	1.000	0.000	1.000	no
127631	Pending	31-MAY-16	02-JUN-16		20-MAY-16	MAN			LEVOMETHORPHAN	9210-0	2016	1.000	0.000	1.000	no
127646	Pending	31-MAY-16	02-JUN-16		20-MAY-16	MAN			RACEMETHORPHAN	9732-0	2016	1.000	0.000	1.000	no

2016 Revised APQ
Worksheets

Basic Class: 9170-A
PQ Total(CM+PD): 0.000

FDA Est:
IMS Est:

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		10,000.000	10,000.000	13,020.000	13,020.000	1.000	0.000	270.000	0.000	-270.000	2,985.000	0.000
MQ Totals:		10,000.000	10,000.000	13,020.000				270.000	0.000	-270.000		0.000

Final Initial APQ:	25,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-10,270.000
2015 Initial APQ:	0.001
FDA Est = 2015 APQ * (1 + FDA Est):	0.001
IMS Est = 2015 APQ * (1 + IMS Est):	0.001
Proposed Revised:	15,000.000
with 25% buffer:	18,750.000

CFR 50%: -7,015.000

2016 Revised APQ Worksheets

Basic Class: 9193-A
PQ Total(CM+PD): 1,000,000

FDA Est: -.088 based on hydromorphone
IMS Est: -.091

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2016 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		187,515.000	92,760.000	98,000.000	98,000.000	1.000	1.000000	389.000	0.000	911.000	25,361.000	0.000
		20.000	20.000	0.000	98,000.000	0.000	0.000	0.000	10.000	10.000	10.000	0.000
		1.000	0.000	0.000	98,000.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,000.000	1,000.000	0.000	98,000.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		188,536.000	93,800.000	98,000.000				389.000	10.000	921.000		0.000

Final Initial APQ:	188,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-92,669.000
2015 Initial APQ:	110,000.000
FDA Est = 2015 APQ * (1 + FDA Est):	100,320.000
IMS Est = 2015 APQ * (1 + IMS Est):	100,001.000
Proposed Revised:	100,000.000
with 25% buffer:	125,000.000

CFR 50%: -68,439.000

NOTE:
(b)(4) quota was based on (b)(4) pd work, however, (b)(4) has not applied for quota as of 6-3-16

2016 Revised APQ
Worksheets

Basic Class: 9193-S
PQ Total(CM+PD): 71,376,461,000

FDA Est: -.144
IMS Est: -.027

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	4.000	0.000	36,853,357.688	0.000	0.000	0.051	0.000	-0.051	-0.051	0.000
		164,700.000	55,913.000	5,785.000	36,853,357.688	0.000	11,165.476	117,905.000	0.000	-103,389.881	-102,506.904	0.000
		20.000	20.000	7.460	36,853,357.688	0.000	14.448	66.401	0.000	-47.618	-46.470	0.000
		486,000.000	122,649.000	7,219.428	36,853,357.688	0.000	13,982.368	41,907.931	0.000	-23,730.852	-22,625.114	0.000
		139,680.000	5,680.000	28.600	36,853,357.688	0.000	55.779	1,673.047	0.000	-1,600.534	-1,596.123	0.000
		3,228,000.000	3,228,000.000	0.000	36,853,357.688	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		842,000.000	842,000.000	1,377,583.000	36,853,357.688	0.037	2,668,060.608	3,951,192.000	0.000	-482,712.950	-271,720.241	0.000
		20,800,000.000	20,800,000.000	14,458,675.000	36,853,357.688	0.393	28,057,738.380	6,707,342.000	12,200.000	27,779,917.895	29,998,749.726	0.000
		25,852,000.000	21,877,900.000	18,427,523.000	36,853,357.688	0.500	35,689,565.436	4,389,739.000	0.000	42,027,086.066	44,849,473.545	0.000
		9,002,000.000	6,844,396.000	521,592.000	36,853,357.688	0.014	1,010,203.503	2,011,901.000	0.000	-698,636.446	-818,748.621	0.000
		6,832,000.000	4,006,863.000	170,470.000	36,853,357.688	0.005	330,161.105	4,204,518.000	0.000	-3,775,338.563	-3,749,199.116	0.000
		8,000,000.000	8,000,000.000	1,856,294.000	36,853,357.688	0.050	3,595,213.696	1,822,837.000	0.000	2,850,890.805	3,135,203.620	0.000
MQ Totals:		75,346,685.000	64,563,424.000	36,853,357.688				25,229,131.430	12,200.000	67,572,467.870		0.000

Final Initial APQ: 70,800,000.000

Final Revised APQ: 0.000

MQ Need=PQ* 1.6 - Revised MQ - Inventory: 17,252,136.070
2015 Initial APQ: 79,700,000.000
FDA Est = 2016 APQ * (1 + FDA Est): 60,519,200.000
IMS Est = 2016 APQ * (1 + IMS Est): 68,762,826.000

CFR 50%: 6,621,360.242

NOTE:
(b)(4) has a pending request for 138,000.000

Proposed Revised: 66,800,000.000
with 25% buffer: 86,000,000.000

2016 Revised APQ
Worksheets

Basic Class: 9150-0
PQ Total(CM+PD): 2,595,407.000

FDA Est: -.088
IMS Est: -.091

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	4.000	0.000	3,211,426.354	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		106,800.000	43,144.000	3,961.000	3,211,426.354	0.001	3,201.197	35,040.000	0.000	-30,878.444	-30,048.254	0.000
		20.000	20.000	0.000	3,211,426.354	0.000	0.000	0.000	10.000	10.000	10.000	0.000
		20.000	20.000	8.692	3,211,426.354	0.000	7.025	39.097	0.000	-29.965	-28.143	0.000
		57,950.000	57,950.000	24,164.468	3,211,426.354	0.008	18,529.213	34,034.872	0.000	-8,646.895	-3,582.239	0.000
		2.000	0.000	0.000	3,211,426.354	0.000	0.000	1.014	0.000	-1.014	-1.014	0.000
		70,761.000	70,361.000	43,466.651	3,211,426.354	0.014	35,128.830	67,486.082	0.000	-21,818.503	-12,708.382	0.000
		691,468.000	593,111.000	493,801.543	3,211,426.354	0.154	399,079.985	241,629.413	5,900.000	283,074.568	385,570.954	0.000
		445,000.000	445,000.000	297,642.000	3,211,426.354	0.093	240,547.982	32,075.000	0.000	280,637.377	343,020.478	0.000
		820,000.000	820,000.000	576,481.000	3,211,426.354	0.180	465,899.777	405,070.000	0.000	200,599.710	321,424.971	0.000
		1,000.000	1,000.000	0.000	3,211,426.354	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		2,256,000.000	2,256,000.000	1,714,735.000	3,211,426.354	0.534	1,385,812.638	368,836.000	0.000	1,432,720.427	1,792,113.545	0.000
		1,062,000.000	636,000.000	0.000	3,211,426.354	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,900,000.000	377,038.000	57,166.000	3,211,426.354	0.018	46,200.355	229,429.000	567,500.000	498,131.451	510,112.943	0.000
MQ Totals:		7,411,026.000	5,299,648.000	3,211,426.354				1,413,540.478	573,410.000	2,633,798.622		0.000

Final Initial APQ:	6,600,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-2,820,177.978
2015 Initial APQ:	5,600,000.000
FDA Est = 2015 APQ * (1 + FDA Est):	5,107,200.000
IMS Est = 2015 APQ * (1 + IMS Est):	5,090,960.000
Proposed Revised:	5,600,000.000
with 25% buffer:	7,000,000.000

CFR 50%: -2,666,173.140

2016 Revised APQ Worksheets

Basic Class: 9230-0
PQ Total(GM+PD): 1,607,142.000

FDA Est: -.156
IMS Est: -.127

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	4.000	0.000	1,018,940.677	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,950,000.000	1,950,000.000	786,514.000	1,018,940.677	0.772	1,240,542.959	1,178,362.000	0.000	434,323.647	368,925.199	0.000
		20.000	20.000	0.000	1,018,940.677	0.000	0.000	0.000	10.000	10.000	10.000	0.000
		5.000	5.000	2.677	1,018,940.677	0.000	4.222	0.730	0.000	4.759	5.217	0.000
		1.000	0.000	0.000	1,018,940.677	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		830,000.000	505,805.000	232,424.000	1,018,940.677	0.228	366,594.818	159,305.000	0.000	317,268.264	357,044.823	0.000
MQ Totals:		2,780,031.000	2,455,834.000	1,018,940.677				1,337,667.730	10.000	751,606.870		0.000

Final Initial APQ:	4,360,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-1,382,808.730
2015 Initial APQ:	5,000,000.000
FDA Est = 2015 APQ * (1 + FDA Est):	4,220,000.000
IMS Est = 2015 APQ * (1 + IMS Est):	4,363,000.000
Proposed Revised:	3,706,000.000
with 25% buffer:	4,632,500.000

CFR 50%: -1,529,559.061

2016 Revised APQ Worksheets

Basic Class: 9630-0
PQ Total(CM+PD): 1,061,327.000

FDA Est:
IMS Est:

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 60% Invent	Final MQ
(b)(4);(b)(7)(E)		44,000.000	44,000.000	39,054.000	198,740.000	0.197	208,559.247	25,916.000	0.000	245,209.021	244,544.558	0.000
		140,000.000	140,000.000	159,686.000	198,740.000	0.803	852,767.753	228,909.000	0.000	878,689.079	876,972.192	0.000
		60,000.000	15,000.000	0.000	198,740.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		244,000.000	199,000.000	198,740.000				254,827.000	0.000	1,124,898.100		0.000

Final Initial APQ: 550,000.000

Final Revised APQ: 0.000

MQ Need=PQ* 1.5 - Revised MQ - Inventory: 1,138,153.500
2015 Initial APQ: 550,000.000
FDA Est = 2015 APQ * (1 + FDA Est): 550,000.000
IMS Est = 2015 APQ * (1 + IMS Est): 550,000.000

CFR 50%: 922,516.750

Proposed Revised: 300,000.000
with 25% buffer: 375,000.000

2016 Revised APQ Worksheets

Basic Class: 9143-A
PQ Total(CM+PQ): 600.000

FDA Est: .114 from oxymorphone data
IMS Est: -.017

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		10,000	10,000	0.000	2,194,982.015	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1.000	0.000	0.000	2,194,982.015	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		800,000.000	666,667.000	559,900.000	2,194,982.015	0.255	153.049	0.000	0.000	198.964	140,168.311	0.000
		2,000,000.000	2,000,000.000	1,635,070.000	2,194,982.015	0.745	446.948	845,183.000	0.000	-845,601.968	-436,856.815	0.000
		1,000.000	1,000.000	0.000	2,194,982.015	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		2,801,011.000	2,667,677.000	2,194,970.000				845,183.000	0.000	-845,403.004		0.000

Final Initial APQ: 5,000,000.000

Final Revised APQ: 0.000

MQ Need=PQ* 1.5 - Revised MQ - Inventory: -3,512,960.000
2015 Initial APQ: 6,680,000.000
FDA Est = 2015 APQ * (1 + FDA Est): 7,442,856.000
IMS Est = 2015 APQ * (1 + IMS Est): 6,567,776.000

CFR 50%: -2,964,357.500

Proposed Revised: 4,000,000.000
with 25% buffer: 5,000,000.000

2016 Revised APQ
Worksheets

Basic Class: 9652-A
PQ Total[(CM+PD): 2,883,506.000

FDA Est: .078- from noroxymorphone data
IMS Est: .113

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2015 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		1.000	0.000	0.000	12,086,269.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		380,000.000	380,000.000	0.000	12,086,269.000	0.000	0.000	283,481.000	0.000	-283,481.000	-283,481.000	0.000
		11,100,000.000	10,004,189.000	10,343,436.000	12,086,269.000	0.856	1,783,065.648	962,629.000	0.000	1,355,456.332	3,652,162.050	0.000
		3,756,000.000	3,234,359.000	1,742,633.000	12,086,269.000	0.144	300,440.360	999,065.000	0.000	-608,492.532	-187,806.300	0.000
		2,000.000	750.000	0.000	12,086,269.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		2,760,000.000	1,993,556.000	0.000	12,086,269.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		17,998,001.000	15,612,834.000	12,086,269.000				2,245,075.000	0.000	463,482.800		0.000

Final Initial APQ:	23,200,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-14,732,650.000
2015 Initial APQ:	23,200,000.000
FDA Est = 2015 APQ * (1 + FDA Est):	25,009,600.000
IMS Est = 2015 APQ * (1 + IMS Est):	25,828,560.000
Proposed Revised:	20,000,000.000
with 25% buffer:	25,000,000.000

CFR 50%: -12,231,959.250

2016 Revised APQ Worksheets

Basic Class: 9652-B
PQ Total(CM+PD): 3,415,276.000

FDA Est: .114
IMS Est: .024

Company	DEA Num	2016 MQ Request	2015 MQ	2015 Sales	2013 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2015 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	4.000	0.000	1,934,368.547	0.000	0.000	0.007	0.000	-0.007	-0.007	0.000
		20.000	20.000	0.000	1,934,368.547	0.000	0.000	0.000	10.000	10.000	10.000	0.000
		30.000	30.000	40.090	1,934,368.547	0.000	70.782	177.111	0.000	-85.094	-78.611	0.000
		34,690.000	34,690.000	38.457	1,934,368.547	0.000	67.899	23,193.231	0.000	-23,104.963	-23,098.743	0.000
		715,000.000	662,242.000	294,222.000	1,934,368.547	0.152	519,471.807	126,969.000	0.000	546,344.349	593,926.258	0.000
		1,120,000.000	1,120,000.000	1,102,608.000	1,934,368.547	0.570	1,947,093.229	929,269.000	0.000	1,810,952.198	1,789,299.536	0.000
		1,991,000.000	1,232,812.000	534,694.000	1,934,368.547	0.276	944,043.811	263,281.000	0.000	863,975.854	1,050,447.264	0.000
		5,000.000	3,000.000	0.000	1,934,368.547	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		525,000.000	284,525.000	2,566.000	1,934,368.547	0.001	4,539.472	318,081.000	0.000	-312,171.386	-311,756.409	0.000
MQ Totals:		4,390,745.000	3,337,326.000	1,934,368.547				1,653,950.349	10.000	2,785,921.051		0.000

Final Initial APQ: 6,200,000.000

Final Revised APQ: 0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory: 131,540.651
2015 Initial APQ: 6,200,000.000
FDA Est = 2015 APQ * (1 + FDA Est): 6,908,040.000
IMS Est = 2015 APQ * (1 + IMS Est): 6,350,660.000

CFR 50%: -238,566.712

Proposed Revised: 5,000,000.000
with 25% buffer: 6,250,000.000

2016 Revised APQ
Worksheets

Basic Class: 9732-0
PQ Total(CM+PD): 0.000

FDA Est:
IMS Est:

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2015 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		2,000	2,000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		3,000	2,000	0.000				0.000	0.000	0.000		0.000

Final Initial APQ:	2,000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-2,000
2015 Initial APQ:	2,000
FDA Est = 2015 APQ * (1 + FDA Est):	2,000
IMS Est = 2015 APQ * (1 + IMS Est):	2,000
Proposed Revised:	4,000
with 25% buffer:	5,000

CFR 50%: -2,000

Basic Class	Established 2016 Quotas (g)	Proposed Revised 2016 Quotas (g)
Temporarily Scheduled Substances		
beta-Hydroxythiofentanyl	N/A	30
Butyryl fentanyl	N/A	30
Schedule I		
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15	no change
1-(1-Phenylcyclohexyl)pyrrolidine	10	no change
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	no change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	no change
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45	no change
1-Benzylpiperazine	25	no change
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45	no change
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45	no change
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45	no change
1-Methyl-4-phenyl-4-propionoxypiperidine	2	no change
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45	no change
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45	no change
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45	no change
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45	no change
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45	no change
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45	no change
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45	no change
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30	no change
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30	no change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30	no change
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30	no change
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30	no change
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25	no change
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	no change
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25	no change
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30	no change
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15	no change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change
2,5-Dimethoxy-4-n-propylthiophenethylamine	25	no change
2,5-Dimethoxyamphetamine	25	no change
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30	no change
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30	no change
3,4,5-Trimethoxyamphetamine	25	no change
3,4-Methylenedioxyamphetamine (MDA)	55	no change
3,4-Methylenedioxymethamphetamine (MDMA)	50	no change
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	no change
3,4-Methylenedioxy-N-methylcathinone (methylone)	50	no change
3,4-Methylenedioxypyrovalerone (MDPV)	35	no change
3-FMC; 3-Fluoro-N-methylcathinone	25	no change
3-Methylfentanyl	2	no change
3-Methylthiofentanyl	2	no change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	no change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	no change
4-FMC; Flephedrone	25	no change
4-Methoxyamphetamine	150	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change

4-MEC; 4-Methyl-N-ethylcathinone	25	no change
4-Methyl-N-methylcathinone (mephedrone)	45	no change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25	no change
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53	40
5-Fluoro-UR144, XLR11	25	no change
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change
5-Methoxy-N,N-diisopropyltryptamine	25	no change
5-Methoxy-N,N-dimethyltryptamine	25	no change
AB-PINACA	15	no change
Acetyl-alpha-methylfentanyl	2	no change
Acetyldihydrocodeine	2	no change
Acetylmethadol	2	no change
AB-FUBINACA	N/A	30
Allylprodine	2	no change
alpha-Ethyltryptamine	25	no change
alpha-Methylfentanyl	2	no change
alpha-Methylthiofentanyl	2	no change
alpha-Methyltryptamine (AMT)	25	no change
alpha-Pyrrolidinobutiophenone (α-PBP)	25	no change
alpha-Pyrrolidinopentiophenone (α-PVP)	25	no change
Alphacetylmethadol	2	no change
Alphameprodine	2	no change
Alphamethadol	2	no change
Aminorex	25	no change
APINCA, AKB48	25	no change
Benzylmorphine	2	no change
beta-Hydroxy-3-methylfentanyl	2	no change
beta-Hydroxyfentanyl	2	no change
Betacetylmethadol	2	no change
Betameprodine	2	no change
Betamethadol	4	no change
Betaprodine	2	no change
Bufotenine	3	no change
Butylone	25	no change
Cathinone	70	30
Codeine methylbromide	5	no change
Codeine-N-oxide	305	no change
Desomorphine	25	no change
Diethyltryptamine	25	no change
Difenoxin	11,000	no change
Dihydromorphine	3,000,000	2,000,000
Dimethyltryptamine	35	no change
Dipipanone	5	no change
Fenethylline	5	no change
gamma-Hydroxybutyric acid	70,250,000	no change
Heroin	50	no change
Hydromorphinol	2	no change
Hydroxypethidine	2	no change
Ibogaine	5	no change
Lysergic acid diethylamide (LSD)	40	no change
Marihuana	658,000	no change
Mescaline	25	no change
Methaqualone	10	no change
Methcathinone	25	no change
Methyldesorphine	5	no change

Methyldihydromorphine	2	no change
Morphine methylbromide	5	no change
Morphine methylsulfonate	5	no change
Morphine-N-oxide	350	no change
N,N-Dimethylamphetamine	25	no change
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	50	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	50	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15	no change
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100	no change
N-Ethyl-1-phenylcyclohexylamine	5	no change
N-Ethylamphetamine	24	no change
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Naphyrone	25	no change
Noracymethadol	2	no change
Norlevorphanol	52	no change
Normethadone	2	no change
Normorphine	40	no change
Para-fluorofentanyl	5	no change
Parahexyl	5	no change
Pentedrone	25	no change
Pentylone	25	no change
Phenomorphan	2	no change
Pholcodine	5	no change
Psilocybin	30	no change
Psilocyn	50	no change
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	50	25
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	50	25
Tetrahydrocannabinols	511,250	no change
Thiofentanyl	2	no change
Tilidine	25	no change
Trimeperidine	2	no change
UR-144	25	no change
Schedule II		
1-Phenylcyclohexylamine	5	no change
1-Piperidinocyclohexanecarbonitrile	5	no change
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,950,000	2,250,000
Alfentanil	17,750	no change
Alphaprodine	3	no change
Amobarbital	25,125	no change
Amphetamine (for conversion)	15,000,000	no change
Amphetamine (for sale)	39,705,000	45,000,000
Carfentanil	19	no change
Cocaine	200,000	no change
Codeine (for conversion)	50,000,000	no change
Codeine (for sale)	63,900,000	no change
Dextropropoxyphene	19	no change
Dihydrocodeine	226,375	no change
Dihydroetorphine	3	no change
Diphenoxylate (for conversion)	31,250	18,750
Diphenoxylate (for sale)	1,337,500	no change
Ecgonine	125,000	no change
Ethylmorphine	3	5
Etorphine hydrochloride	3	no change
Fentanyl	2,300,000	no change
Glutethimide	3	no change
Hydrocodone (for conversion)	235,000	177,500

Hydrocodone (for sale)	88,500,000	86,000,000
Hydromorphone	8,250,000	7,000,000
Isomethadone	5	no change
Levo-alphacetylmethadol (LAAM)	4	no change
Levomethorphan	30	33
Levorphanol	7,125	no change
Lisdexamfetamine	29,750,000	23,750,000
Meperidine	5,450,000	4,632,500
Meperidine Intermediate-A	6	no change
Meperidine Intermediate-B	11	no change
Meperidine Intermediate-C	6	no change
Metazocine	19	no change
Methadone (for sale)	31,875,000	no change
Methadone Intermediate	34,375,000	no change
Methamphetamine	2,061,375	no change
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]		
Methylphenidate	96,750,000	84,375,000
Morphine (for conversion)	91,250,000	no change
Morphine (for sale)	62,500,000	no change
Nabilone	18,750	no change
Noroxymorphone (for conversion)	17,500,000	no change
Noroxymorphone (for sale)	1,475,000	625,000
Opium (powder)	112,500	no change
Opium (tincture)	687,500	375,000
Oripavine	30,000,000	no change
Oxycodone (for conversion)	6,250,000	5,000,000
Oxycodone (for sale)	139,150,000	no change
Oxymorphone (for conversion) 25,000,000	29,000,000	~~no change~~
Oxymorphone (for sale)	7,750,000	6,250,000
Pentobarbital	38,125,000	no change
Phenazocine	6	no change
Phencyclidine	50	no change
Phenmetrazine	3	no change
Phenylacetone	50	no change
Racemethorphan	3	5
Racemorphan	3	no change
Remifentanil	3,750	no change
Secobarbital	215,003	no change
Sufentanil	6,255	no change
Tapentadol	25,500,000	no change
Thebaine	125,000,000	no change
List I Chemicals		
Ephedrine (for conversion)	100,000	50,000
Ephedrine (for sale)	4,000,000	no change
Phenylpropanolamine (for conversion)	22,400,000	15,000,000
Phenylpropanolamine (for sale) N/C	8,500,000	~~8,500,000~~ N/C
Pseudoephedrine (for conversion)	7,000	zero 50
Pseudoephedrine (for sale)	224,500,000	200,000,000

2016 Proposed Adjusted Aggregate Production Quotas and Assessment of Annual Needs

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA), who has re-delegated this responsibility to the Deputy Administrator of the DEA.

- The attached Federal Register (FR) notice, prepared for your signature, proposes to adjust the calendar year 2016 aggregate production quotas (APQ) for each basic class of schedule I and II controlled substances and assessment of annual needs (AAN) for the list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for which the United States has medical, scientific, industrial, export, and reserve stock requirements.

- As stated in the 2013 FR Notice, DEA continues to add an additional 25% to the APQ for schedule II substances and those schedule I substances that are used to produce drugs that have a medical need (specifically, GHB, difenoxin, and tetrahydrocannabinols) to prevent potential drug shortage issues.

- The Food and Drug Administration (FDA) responded to DEA's annual letter on May 12, 2016, which provides information on new, continuing, and discontinued drug products containing schedule II substances. Therefore, this information is considered in the analysis for the current proposed adjustments.

- Expeditious review and publication of this notice is necessary to ensure an uninterruptable supply of schedule I and II controlled substances as well as list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for the legitimate medical, scientific, industrial, and export requirements of the U.S.

- The following points provide brief explanations of the changes from the initial AAN & APQ values:

Schedule I substances

- The APQs for **AH-7921, beta-Hydroxythiofentanyl, and Butyryl Fentanyl** were increased from zero due to these substances being controlled or temporarily controlled after the publication of the 2016 Established APQ FR on October 6, 2015. The manufacturing of these substances will be used for analytical standards, reference, and research material.

- The APQs for **Cathinone, Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22),** and **Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)** were decreased due to the decline in the manufacture of diagnostic kits and reference standards by manufacturers, as well as reduced research requests from schedule I researchers for these substances.

- The APQ for **Dihydromorphine** was decreased based on the decline in the production of hydromorphone for which dihydromorphine is an intermediate controlled substance.

Schedule II substances

- The APQ for **4-Anilino-n-phenethyl-4-piperidine (ANPP)** was decreased based on the decline in the production of fentanyl for which ANPP is a starting material.

- The APQ for **Amphetamine (for sale)** was increased based on FDA, IMS Health, and manufacturing data showing an increase in the domestic market and product development efforts for new generic drug products.

- The APQ for **Diphenoxylate (for conversion)** was decreased based on the new brand holder and their contract manufacturer awaiting FDA approval to re-enter the market with the drug product Motefen for which diphenoxylate (for conversion) is the starting material.

- The APQs for **Ethylmorphine, Levomethorphan,** and **Racemethorphan** were increased due to increased registrant requirements. The manufacturing of these substances will be used for analytical standards, reference, and research material.

- The APQs for **Hydrocodone (for conversion), Hydrocodone (for sale), Hydromorphone, Meperidine, Oxycodone (for conversion),** and **Oxymorphone (for sale)** were all decreased based on FDA and IMS Health data showing a steep decline in domestic utilization. This decline may be related to the efforts of the DEA and CDC to inform the public of the opiate epidemic.

- The APQ for **Lisdexamfetamine** was decreased based on the exportation of Vyvanse in lower quantities than previously forecasted by both the brand holder and contract manufacturer. Lisdexamfetamine is not an internationally controlled substance, consequently the brand holder's forecast of export expectations were considered until actual export data from the contract manufacturer could be obtained.

- The APQ for **Methylphenidate** was decrease based on IMS Health data showing the market stabilizing at a lower threshold then either the FDA or the brand holder manufacturer predicted after FDA downgraded the rating of 2 generic products as not equivalent to Concerta in 2014.

- The APQs for **Oxymorphone (for conversion)** and **Noroxymorphone (for sale)** were decreased based on a major manufacturer awaiting FDA approval for a new drug product.

- The APQ for **Opium Tincture** was decreased due to a major manufacturer exiting the market. No other manufacturer currently shows interest in acquiring the available market share.

List 1 chemicals

- The AANs for **Ephedrine (for conversion), Phenylpropanolamine (for conversion), Pseudoephedrine (for conversion),** and **Pseudoephedrine (for sale)** were decreased based on IMS Health data and actual received importer and manufacturer quota applications.

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-420P]

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to adjust the 2016 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the *Federal Register*. After consideration of any comments or objections, or

after a hearing, if one is held, the Administrator will publish in the *Federal Register* a final order establishing the 2016 adjusted aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-420P" on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to http://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that

comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority and Background

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

The DEA established the 2016 aggregate production quotas for substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on October 6, 2015 (80 FR 60400). That notice stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Analysis for Proposed Adjusted 2016 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2016 aggregate production quotas and assessment of annual needs for certain schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2016 to provide for the estimated medical,

scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the proposed adjustment, the Acting Administrator has taken into account the criteria in accordance with 21 CFR 1303.13 (adjustment of aggregate production quotas for controlled substances) and 21 CFR 1315.13 (adjustment of the assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The DEA determined whether to propose an adjustment of the aggregate production quotas and assessment of annual needs for 2016 by considering: (1) changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, and changes in the rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for the class; (2) whether any increased demand for that class or chemical, the national and/or individual rates of net disposal of that class or chemical are temporary, short term, or long term; (3) whether any increased demand for that class or chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota; (4) whether any decreased demand for that class or chemical will result in excessive inventory accumulation by all persons registered to handle that class or chemical; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Acting Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

The Acting Administrator also considered updated information obtained from 2015 year-end inventories, 2015 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to the DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the Acting Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed adjusted 2016 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 established assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

As described in the previously published notice establishing the 2016 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers, 21 CFR 1303.24, may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all proposed adjusted schedule II controlled substance aggregate production quotas, and certain proposed adjusted schedule I controlled substance aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting adjusted established aggregate production

quotas will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Acting Administrator, therefore, proposes that the year 2016 aggregate production quotas for the two temporarily scheduled substances be established, and to adjust the 2016 aggregate production quotas for certain schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Established 2016 Quotas (g)	Proposed Revised 2016 Quotas (g)
Temporarily Scheduled Substances		
beta-Hydroxythiofentanyl	N/A	30
Butyryl fentanyl	N/A	30
Schedule I		
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15	no change
1-(1-Phenylcyclohexyl)pyrrolidine	10	no change
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	no change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	no change
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-	45	no change

200)		
1-Benzylpiperazine	25	no change
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45	no change
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45	no change
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45	no change
1-Methyl-4-phenyl-4-propionoxypiperidine	2	no change
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45	no change
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45	no change
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45	no change
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45	no change
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45	no change
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45	no change
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45	no change
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30	no change
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30	no change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30	no change
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30	no change
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30	no change
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25	no change
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	no change
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25	no change
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30	no change
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15	no change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change
2,5-Dimethoxy-4-n-propylthiophenethylamine	25	no change
2,5-Dimethoxyamphetamine	25	no change
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30	no change
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30	no change
3,4,5-Trimethoxyamphetamine	25	no change
3,4-Methylenedioxyamphetamine (MDA)	55	no change
3,4-Methylenedioxymethamphetamine (MDMA)	50	no change
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	no change
3,4-Methylenedioxy-N-methylcathinone (methylone)	50	no change
3,4-Methylenedioxypyrovalerone (MDPV)	35	no change

3-FMC; 3-Fluoro-N-methylcathinone	25	no change
3-Methylfentanyl	2	no change
3-Methylthiofentanyl	2	no change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	no change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	no change
4-FMC; Flephedrone	25	no change
4-Methoxyamphetamine	150	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-MEC; 4-Methyl-N-ethylcathinone	25	no change
4-Methyl-N-methylcathinone (mephedrone)	45	no change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25	no change
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53	40
5-Fluoro-UR144, XLR11	25	no change
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change
5-Methoxy-N,N-diisopropyltryptamine	25	no change
5-Methoxy-N,N-dimethyltryptamine	25	no change
AB-PINACA	15	no change
Acetyl-*alpha*-methylfentanyl	2	no change
Acetyldihydrocodeine	2	no change
Acetylmethadol	2	no change
AH-7921	N/A	30
Allylprodine	2	no change
alpha-Ethyltryptamine	25	no change
alpha-Methylfentanyl	2	no change
alpha-Methylthiofentanyl	2	no change
alpha-Methyltryptamine (AMT)	25	no change
alpha-Pyrrolidinobutiophenone (α-PBP)	25	no change
alpha-Pyrrolidinopentiophenone (α-PVP)	25	no change
Alphacetylmethadol	2	no change
Alphameprodine	2	no change
Alphamethadol	2	no change
Aminorex	25	no change
APINCA, AKB48	25	no change
Benzylmorphine	2	no change
beta-Hydroxy-3-methylfentanyl	2	no change
beta-Hydroxyfentanyl	2	no change
Betacetylmethadol	2	no change
Betameprodine	2	no change

Betamethadol	4	no change
Betaprodine	2	no change
Bufotenine	3	no change
Butylone	25	no change
Cathinone	70	30
Codeine methylbromide	5	no change
Codeine-N-oxide	305	no change
Desomorphine	25	no change
Diethyltryptamine	25	no change
Difenoxin	11,000	no change
Dihydromorphine	3,000,000	2,000,000
Dimethyltryptamine	35	no change
Dipipanone	5	no change
Fenethylline	5	no change
gamma-Hydroxybutyric acid	70,250,000	no change
Heroin	50	no change
Hydromorphinol	2	no change
Hydroxypethidine	2	no change
Ibogaine	5	no change
Lysergic acid diethylamide (LSD)	40	no change
Marihuana	658,000	no change
Mescaline	25	no change
Methaqualone	10	no change
Methcathinone	25	no change
Methyldesorphine	5	no change
Methyldihydromorphine	2	no change
Morphine methylbromide	5	no change
Morphine methylsulfonate	5	no change
Morphine-N-oxide	350	no change
N,N-Dimethylamphetamine	25	no change
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	50	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	50	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15	no change
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100	no change
N-Ethyl-1-phenylcyclohexylamine	5	no change
N-Ethylamphetamine	24	no change

N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Naphyrone	25	no change
Noracymethadol	2	no change
Norlevorphanol	52	no change
Normethadone	2	no change
Normorphine	40	no change
Para-fluorofentanyl	5	no change
Parahexyl	5	no change
Pentedrone	25	no change
Pentylone	25	no change
Phenomorphan	2	no change
Pholcodine	5	no change
Psilocybin	30	no change
Psilocyn	50	no change
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	50	25
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	50	25
Tetrahydrocannabinols	511,250	no change
Thiofentanyl	2	no change
Tilidine	25	no change
Trimeperidine	2	no change
UR-144	25	no change
Schedule II		
1-Phenylcyclohexylamine	5	no change
1-Piperidinocyclohexanecarbonitrile	5	no change
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,950,000	2,250,000
Alfentanil	17,750	no change
Alphaprodine	3	no change
Amobarbital	25,125	no change
Amphetamine (for conversion)	15,000,000	no change
Amphetamine (for sale)	39,705,000	45,000,000
Carfentanil	19	no change
Cocaine	200,000	no change
Codeine (for conversion)	50,000,000	no change
Codeine (for sale)	63,900,000	no change
Dextropropoxyphene	19	no change
Dihydrocodeine	226,375	no change
Dihydroetorphine	3	no change
Diphenoxylate (for conversion)	31,250	18,750
Diphenoxylate (for sale)	1,337,500	no change
Ecgonine	125,000	no change

Ethylmorphine	3	5
Etorphine hydrochloride	3	no change
Fentanyl	2,300,000	no change
Glutethimide	3	no change
Hydrocodone (for conversion)	235,000	177,500
Hydrocodone (for sale)	88,500,000	86,000,000
Hydromorphone	8,250,000	7,000,000
Isomethadone	5	no change
Levo-alphacetylmethadol (LAAM)	4	no change
Levomethorphan	30	33
Levorphanol	7,125	no change
Lisdexamfetamine	29,750,000	23,750,000
Meperidine	5,450,000	4,632,500
Meperidine Intermediate-A	6	no change
Meperidine Intermediate-B	11	no change
Meperidine Intermediate-C	6	no change
Metazocine	19	no change
Methadone (for sale)	31,875,000	no change
Methadone Intermediate	34,375,000	no change
Methamphetamine	2,061,375	no change
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]		
Methylphenidate	96,750,000	84,375,000
Morphine (for conversion)	91,250,000	no change
Morphine (for sale)	62,500,000	no change
Nabilone	18,750	no change
Noroxymorphone (for conversion)	17,500,000	no change
Noroxymorphone (for sale)	1,475,000	625,000
Opium (powder)	112,500	no change
Opium (tincture)	687,500	375,000
Oripavine	30,000,000	no change
Oxycodone (for conversion)	6,250,000	5,000,000
Oxycodone (for sale)	139,150,000	no change
Oxymorphone (for conversion)	29,000,000	25,000,000
Oxymorphone (for sale)	7,750,000	6,250,000
Pentobarbital	38,125,000	no change
Phenazocine	6	no change
Phencyclidine	50	no change
Phenmetrazine	3	no change
Phenylacetone	50	no change
Racemethorphan	3	5

Racemorphan	3	no change
Remifentanil	3,750	no change
Secobarbital	215,003	no change
Sufentanil	6,255	no change
Tapentadol	25,500,000	no change
Thebaine	125,000,000	no change
List I Chemicals		
Ephedrine (for conversion)	100,000	50,000
Ephedrine (for sale)	4,000,000	no change
Phenylpropanolamine (for conversion)	22,400,000	15,000,000
Phenylpropanolamine (for sale)	8,500,000	no change
Pseudoephedrine (for conversion)	7,000	40
Pseudoephedrine (for sale)	224,500,000	200,000,000

The Acting Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Acting Administrator may adjust the 2016 aggregate production quotas and assessment of annual needs as needed.

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Acting Administrator will issue and publish in the *Federal Register* a final order establishing any adjustment of 2016 aggregate production quota for each basic class of controlled substances in schedules I and II and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, 21 CFR 1303.13(c) and 1315.13(f).

Dated:

Chuck Rosenberg,
Acting Administrator.

A: _____
CPC: _____
OC: _____
CCR: _____
OD: _____
OD/R: _____

ODX: _____
OD/RX: _____

ODXA: _____

ODW: _____

ODW Analyst: _____

ODQ: _____

ODQ: (b)(6) _____ Date: 6-21-2016

S:\ODQ\Federal Register\2016 (DEA-420P) Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

SBF-CM # ODQ-16-874

DFN# 630-07- Federal Register

Michigan, the State in which he seeks registration. Because he does not meet this prerequisite for obtaining a DEA registration, I will deny his application on this basis.

Material Falsification

Pursuant to section 304(a)(1), the Attorney General is also authorized to suspend or revoke a registration "upon a finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter." 21 U.S.C. 824(a)(1). It is well established that the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered in deciding whether to grant or deny an application under section 303. *See The Lawsons, Inc.*, 72 FR 74334, 74337 (2007); *Anthony D. Funches*, 64 FR 14267, 14268 (1999); *Alan R. Schankman*, 63 FR 45260 (1998); *Kuen H. Chen*, 58 FR 65401, 65402 (1993).

Thus, the allegation that Applicant materially falsified his application is properly considered in this proceeding. *See Samuel S. Jackson*, 72 FR 23848, 23852 (2007). Moreover, just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application. *The Lawsons*, 72 FR 74338; *cf. Bobby Watts, M.D.*, 58 FR 46995 (1993).

Here, the Government's evidence shows that upon being served with an Order to Show Cause and Immediate Suspension of Registration which alleged that he had prescribed controlled substances in violation of the CSA, Applicant surrendered his registration. GXs 3 & 4. Moreover, on the Voluntary Surrender form, Applicant acknowledged that he was doing so "[i]n view of my alleged failure to comply with the Federal requirements pertaining to controlled substances." GX 4. Yet days later, Applicant applied for a new registration and provided a "no" answer to the question: "[h]as the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?" GX 1, at 1, 3.

Applicant's answer was false as he had clearly surrendered his registration for cause. His false answer was also material as "it 'ha[d] a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed." *Kungys* v. *United States*, 485 U.S. 759, 770 (1988) (quoting *Weinstock* v. *United States*, 231 F.2d 699, 701 (D.C. Cir. 1956)) (other citation omitted); see also *United States* v. *Wells*, 519 U.S. 482, 489 (1997) (quoting *Kungys*, 485 U.S. at 770). As the Supreme Court has further explained, "it has never been the test of materiality that the misrepresentation or concealment would *more likely than not* have produced an erroneous decision, or even that it would *more likely than not* have triggered an investigation, but rather, whether the misrepresentation or concealment was predictably capable of affecting, *i.e.*, had a natural tendency to affect, the official decision." *Kungys*, 485 U.S. at 771. While the evidence must be "clear, unequivocal, and convincing," the "ultimate finding of materiality turns on an interpretation of the substantive law." *Id.* at 772 (int. quotations and citations omitted).

Applicant's false answer to the question of whether he had ever surrendered his federal registration was clearly "capable of affecting" the decision of whether to grant his application. As the evidence shows, Applicant surrendered his registration in response to allegations that he violated the CSA and DEA regulations by prescribing controlled substances that were in schedules for which he lacked authorization, as well as allegations that he issued prescriptions that lacked a legitimate medical purpose. GX 3, at 2 (Sept. 24, 2012 Immediate Suspension Order) (citing 21 U.S.C. 822(b) and 841(a)(1); 21 CFR 1301.12(a) and 1306.04(a)). Notably, under the public interest standard, the Agency is required to consider both the Applicant's "experience in dispensing . . . controlled substances" and his "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances." 21 U.S.C. 823(f)(2) & (4). *See also Shannon L. Gallentine, D.P.M.*, 76 FR 45864, 45866 (2011).

Thus, notwithstanding that the Agency did not grant his application, his false answer was still material as it was capable of influencing the decision as to whether to grant his application. *See United States* v. *Alemany Rivera*, 781 F.2d 229, 234 (1st Cir. 1985) ("It makes no difference that a specific falsification did not exert influence so long as it had the capacity to do so."); *United States* v. *Norris*, 749 F.2d 1116, 1121 (4th Cir. 1984) ("There is no requirement that the false statement influence or effect the decision making process of a department of the United States Government."). Accordingly, I conclude that Applicant materially falsified his September 2012 application for registration. This provides a further reason to deny his pending application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Mikhayl Soliman, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective immediately.

Dated: July 15, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–17394 Filed 7–21–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–420P]

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to adjust the 2016 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 22, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will publish in the

Federal Register a final order establishing the 2016 adjusted aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–420P" on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority and Background

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

The DEA established the 2016 aggregate production quotas for substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on October 6, 2015 (80 FR 60400). That notice stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Analysis for Proposed Adjusted 2016 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2016 aggregate production quotas and assessment of annual needs for certain schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2016 to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the proposed adjustment, the Acting Administrator has taken into account the criteria in accordance with 21 CFR 1303.13 (adjustment of aggregate production quotas for controlled substances) and 21 CFR 1315.13 (adjustment of the assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The DEA determined whether to propose an adjustment of the aggregate production quotas and assessment of annual needs for 2016 by considering: (1) Changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, and changes in the rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for the class; (2) whether any increased demand for that class or chemical, the national and/or individual rates of net disposal of that class or chemical are temporary, short term, or long term; (3) whether any increased demand for that class or chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota; (4) whether any decreased demand for that class or chemical will result in excessive inventory accumulation by all persons registered to handle that class or chemical; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Acting Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

The Acting Administrator also considered updated information obtained from 2015 year-end inventories, 2015 disposition data submitted by quota applicants,

estimates of the medical needs of the United States, product development, and other information made available to the DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the Acting Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed adjusted 2016 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 established assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

As described in the previously published notice establishing the 2016 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers, 21 CFR 1303.24, may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all proposed adjusted schedule II controlled substance aggregate production quotas, and certain proposed adjusted schedule I controlled substance aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting adjusted established aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Acting Administrator, therefore, proposes that the year 2016 aggregate production quotas for the two temporarily scheduled substances be established, and to adjust the 2016 aggregate production quotas for certain schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2016 quotas (g)	Proposed revised 2016 quotas (g)
Temporarily Scheduled Substances		
beta-Hydroxythiofentanyl	N/A	30.
Butyryl fentanyl	N/A	30.
Schedule I		
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ–2201)	15	no change.
1-(1-Phenylcyclohexyl)pyrrolidine	10	no change.
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	no change.
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	no change.
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change.
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200)	45	no change.
1-Benzylpiperazine	25	no change.
1-Butyl-3-(1-naphthoyl)indole (JWH–073)	45	no change.
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45	no change.
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45	no change.
1-Methyl-4-phenyl-4-propionoxypiperidine	2	no change.
1-Pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678)	45	no change.
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45	no change.
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45	no change.
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45	no change.
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45	no change.
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45	no change.
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45	no change.
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30	no change.
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30	no change.
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30	no change.
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C–P)	30	no change.
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	30	no change.
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36).	25	no change.
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30	no change.
2-(4-Chloro-2,5-dimethoxyphonyl)-N-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82).	25	no change.
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30	no change.
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I–NBOMe; 2C–I–NBOMe; 25I; Cimbi-5).	15	no change.
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change.
2,5-Dimethoxy-4-n-propylthiophenethylamine	25	no change.
2,5-Dimethoxyamphetamine	25	no change.

Basic class	Established 2016 quotas (g)	Proposed revised 2016 quotas (g)
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30	no change.
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30	no change.
3,4,5-Trimethoxyamphetamine	25	no change.
3,4-Methylenedioxyamphetamine (MDA)	55	no change.
3,4-Methylenedioxymethamphetamine (MDMA)	50	no change.
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	no change.
3,4-Methylenedioxy-N-methylcathinone (methylone)	50	no change.
3,4-Methylenedioxypyrovalerone (MDPV)	35	no change.
3–FMC; 3-Fluoro-N-methylcathinone	25	no change.
3-Methylfentanyl	2	no change.
3-Methylthiofentanyl	2	no change.
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	no change.
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	25	no change.
4–FMC; Flephedrone	25	no change.
4-Methoxyamphetamine	150	no change.
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change.
4-Methylaminorex	25	no change.
4–MEC; 4-Methyl-N-ethylcathinone	25	no change.
4-Methyl-N-methylcathinone (mephedrone)	45	no change.
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25	no change.
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68	50.
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog).	53	40.
5-Fluoro-UR144, XLR11	25	no change.
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change.
5-Methoxy-N,N-diisopropyltryptamine	25	no change.
5-Methoxy-N,N-dimethyltryptamine	25	no change.
AB–PINACA	15	no change.
Acetyl-*alpha*-methylfentanyl	2	no change.
Acetyldihydrocodeine	2	no change.
Acetylmethadol	2	no change.
AH–7921	N/A	30.
Allylprodine	2	no change.
alpha-Ethyltryptamine	25	no change.
alpha-Methylfentanyl	2	no change.
alpha-Methylthiofentanyl	2	no change.
alpha-Methyltryptamine (AMT)	25	no change.
alpha-Pyrrolidinobutiophenone (α-PBP)	25	no change.
alpha-Pyrrolidinopentiophenone (α-PVP)	25	no change.
Alphacetylmethadol	2	no change.
Alphameprodine	2	no change.
Alphamethadol	2	no change.
Aminorex	25	no change.
APINCA, AKB48	25	no change.
Benzylmorphine	2	no change.
beta-Hydroxy-3-methylfentanyl	2	no change.
beta-Hydroxyfentanyl	2	no change.
Betacetylmethadol	2	no change.
Betameprodine	2	no change.
Betamethadol	4	no change.
Betaprodine	2	no change.
Bufotenine	3	no change.
Butylone	25	no change.
Cathinone	70	30.
Codeine methylbromide	5	no change.
Codeine-N-oxide	305	no change.
Desomorphine	25	no change.
Diethyltryptamine	25	no change.
Difenoxin	11,000	no change.
Dihydromorphine	3,000,000	2,000,000.
Dimethyltryptamine	35	no change.
Dipipanone	5	no change.
Fenethylline	5	no change.
gamma-Hydroxybutyric acid	70,250,000	no change.
Heroin	50	no change.
Hydromorphinol	2	no change.
Hydroxypethidine	2	no change.
Ibogaine	5	no change.
Lysergic acid diethylamide (LSD)	40	no change.
Marihuana	658,000	no change.

Basic class	Established 2016 quotas (g)	Proposed revised 2016 quotas (g)
Mescaline	25	no change.
Methaqualone	10	no change.
Methcathinone	25	no change.
Methyldesorphine	5	no change.
Methyldihydromorphine	2	no change.
Morphine methylbromide	5	no change.
Morphine methylsulfonate	5	no change.
Morphine-N-oxide	350	no change.
N,N-Dimethylamphetamine	25	no change.
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB–PINACA)	50	no change.
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB–FUBINACA)	50	no change.
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB–CHMINACA)	15	no change.
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100	no change.
N-Ethyl-1-phenylcyclohexylamine	5	no change.
N-Ethylamphetamine	24	no change.
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change.
Naphyrone	25	no change.
Noracymethadol	2	no change.
Norlevorphanol	52	no change.
Normethadone	2	no change.
Normorphine	40	no change.
Para-fluorofentanyl	5	no change.
Parahexyl	5	no change.
Pentedrone	25	no change.
Pentylone	25	no change.
Phenomorphan	2	no change.
Pholcodine	5	no change.
Psilocybin	30	no change.
Psilocyn	50	no change.
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB–22; 5F–PB–22)	50	25.
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB–22; QUPIC)	50	25.
Tetrahydrocannabinols	511,250	no change.
Thiofentanyl	2	no change.
Tilidine	25	no change.
Trimeperidine	2	no change.
UR–144	25	no change.
Schedule II		
1-Phenylcyclohexylamine	5	no change.
1-Piperidinocyclohexanecarbonitrile	5	no change.
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,950,000	2,250,000.
Alfentanil	17,750	no change.
Alphaprodine	3	no change.
Amobarbital	25,125	no change.
Amphetamine (for conversion)	15,000,000	no change.
Amphetamine (for sale)	39,705,000	45,000,000.
Carfentanil	19	no change.
Cocaine	200,000	no change.
Codeine (for conversion)	50,000,000	no change.
Codeine (for sale)	63,900,000	no change.
Dextropropoxyphene	19	no change.
Dihydrocodeine	226,375	no change.
Dihydroetorphine	3	no change.
Diphenoxylate (for conversion)	31,250	18,750.
Diphenoxylate (for sale)	1,337,500	no change.
Ecgonine	125,000	no change.
Ethylmorphine	3	5.
Etorphine hydrochloride	3	no change.
Fentanyl	2,300,000	no change.
Glutethimide	3	no change.
Hydrocodone (for conversion)	235,000	177,500.
Hydrocodone (for sale)	88,500,000	86,000,000.
Hydromorphone	8,250,000	7,000,000.
Isomethadone	5	no change.
Levo-alphacetylmethadol (LAAM)	4	no change.
Levomethorphan	30	33.
Levorphanol	7,125	no change.
Lisdexamfetamine	29,750,000	23,750,000.
Meperidine	5,450,000	4,632,500.
Meperidine Intermediate-A	6	no change.

Basic class	Established 2016 quotas (g)	Proposed revised 2016 quotas (g)
Meperidine Intermediate-B	11	no change.
Meperidine Intermediate-C	6	no change.
Metazocine	19	no change.
Methadone (for sale)	31,875,000	no change.
Methadone Intermediate	34,375,000	no change.
Methamphetamine	2,061,375	no change.
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]		
Methylphenidate	96,750,000	84,375,000.
Morphine (for conversion)	91,250,000	no change.
Morphine (for sale)	62,500,000	no change.
Nabilone	18,750	no change.
Noroxymorphone (for conversion)	17,500,000	no change.
Noroxymorphone (for sale)	1,475,000	625,000.
Opium (powder)	112,500	no change.
Opium (tincture)	687,500	375,000.
Oripavine	30,000,000	no change.
Oxycodone (for conversion)	6,250,000	5,000,000.
Oxycodone (for sale)	139,150,000	no change.
Oxymorphone (for conversion)	29,000,000	25,000,000.
Oxymorphone (for sale)	7,750,000	6,250,000.
Pentobarbital	38,125,000	no change.
Phenazocine	6	no change.
Phencyclidine	50	no change.
Phenmetrazine	3	no change.
Phenylacetone	50	no change.
Racemethorphan	3	5.
Racemorphan	3	no change.
Remifentanil	3,750	no change.
Secobarbital	215,003	no change.
Sufentanil	6,255	no change.
Tapentadol	25,500,000	no change.
Thebaine	125,000,000	no change.
List I Chemicals		
Ephedrine (for conversion)	100,000	50,000.
Ephedrine (for sale)	4,000,000	no change.
Phenylpropanolamine (for conversion)	22,400,000	15,000,000.
Phenylpropanolamine (for sale)	8,500,000	no change.
Pseudoephedrine (for conversion)	7,000	40.
Pseudoephedrine (for sale)	224,500,000	200,000,000.

The Acting Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Acting Administrator may adjust the 2016 aggregate production quotas and assessment of annual needs as needed.

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Acting Administrator will issue and publish in the **Federal Register** a final order establishing any adjustment of 2016 aggregate production quota for each basic class of controlled substances in schedules I and II and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, 21 CFR 1303.13(c) and 1315.13(f).

Dated: July 14, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–17371 Filed 7–21–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Charter Renewal

AGENCY: Justice Department.

ACTION: Notice of Charter Renewal of the Executive Advisory Board of the National Domestic Communications Assistance Center.

SUMMARY: In accordance with the provisions of the Federal Advisory Committee Act, title 5, United States Code, Appendix, and title 41 of the U.S. Code of Federal Regulations, section 101–6.1015, notice is hereby given that the Charter of the National Domestic Communications Assistance Center (NDCAC) Executive Advisory Board (EAB) has been renewed. The Charter is on file with the General Services Administration. The Attorney General determined that the NDCAC EAB is in the public interest and is necessary in connection with the performance of duties of the United States Department of Justice. These duties can best be performed through the advice and counsel of this group.

The purpose of the EAB is to provide advice and recommendations to the

Drug	Company	Comment	Amount	Response	Proposed APQ	Revised APQ	Change
amphetamine (for sale)	(b)(4)	increase	200,000	increase APQ	45,000,000	50,000,000	5,000,000
etorphine HCl		increase	30	increase APQ	2	40	38
methadone		increase	5,988,481	APQ is sufficient	31,875,000	31,875,000	-
methadone intermediate		increase	3,369,372	APQ is sufficient	34,375,000	34,375,000	-
nabilone		increase	300	increase APQ	18,750	18,875	125
phencyclidine (CI)		increase	5	increase APQ	50	60	10

Number of registrants/entities commenting: 4
Number of drugs commented on: 6

6

CMEA Chemical	Company	Comment	Amount	Response	Proposed AAN	Revised AAN	Change
ephedrine (for sale) via FDA	(b)(4)	increase	22,029		4,000,000	4,000,000	-
pseudoephedrine (for sale)		increase	17,100,000		200,000,000	200,000,000	-

Number of registrants/entities commenting: 2
Number of List I chemicals commented on: 2

Additional Comments:

Drug	Response	Proposed	Revised	Change
All CII	(b)(4) esponded to removal of additional 25% starting in 2017 in both the 2016 and 2017 notice	-	-	

Additional Drug Considerations:

Drug	Response	Proposed	Revised	Change
amphetamine (d,l)	(b)(4) quota correction created increase of 169kg not previously considered	see above		
dextropropoxyphene	new applications while comment period open	19	55	36
levophanol (CII)	(b)(4) quota was limited by Est APQ, see app # 128077	7,125	9,525	2,400
methylphenidate	(b)(4) have pending requests; APQ is sufficient	84,375,000	84,375,000	-
noroxymorphone (for sale)	(b)(4) has pending request; increase APQ	625,000	875,000	250,000
secobarbital	(b)(4) had low yields and requested increase to make one additional batch	215,003	243,380	28,377
thiafentanil (CI)	New temp controlled substance, will be Published as final on Sept 30th; can't add to this FR notice	N/A		

Additional Chemical Considerations:

Chemical	Response	Proposed	Revised	Change
ephedrine (for sale) via FDA	FDA sent email regarding (b)(4) company having the only FDA approved ephedrine product	see above		
				-

** the proposed and revised values include 25% buffer for CII substances

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION, OFFICE OF DIVERSION CONTROL
PENDING QUOTA REQUESTS
RUN DATE: 14-SEP-16
QUOTA YEAR: 2016 DEA NO: * DRUG CODE: * REQUEST NO: * STAFF ID: ALL

Request ID	Status	Assigned Date	Staff Review Date	Staff ID	Date Submitted	Quota Type	DEA Number	Company	Drug Name	Drug Code	Quota Year	Requested Quota	Current Quota	Requested Increase/Decrease	Pending Revision Quota	Granted Increase/Decrease
126410	New			(b)(6)	08-SEP-16	MAN	(b)(4);(b)(7)(E)		CODEINE (FOR CONVERSION)	9050-A	2016	15,000	0 000	15,000		
126232	Pending	22-AUG-16	25-AUG-16		18-AUG-16	MAN			D,L-AMPHETAMINE	1100-A	2016	4,201,497,000	4,001,497 000	200,000,000	4,201,497,000	200,000 000
126102	New	08-AUG-16			05-AUG-16	MAN			D,L-AMPHETAMINE	1100-A	2016	2,550,000,000	1,764,760 000	785,240,000	1,933,527,000	168,767,000
126377	New	02-SEP-16			31-AUG-16	MAN			D,L-AMPHETAMINE	1100-A	2016	10,386,730,000	7,708,984 000	2,677,746 000	10,386,730 00	2,677,746 000
126103	New	08-AUG-16			05-AUG-16	MAN			D-AMPHETAMINE (FOR SALE)	1100-B2	2016	2,900,000 000	2,002,516 000	897,484 000	2,002,516 00	0 000
126378	New	02-SEP-16			31-AUG-16	MAN			D-AMPHETAMINE (FOR SALE)	1100-B2	2016	11,398,160 000	8,185,423 000	3,412,737 000	11,461,658 00	3,276,235 000
											Total	31,636,387 000	23,663,210 000	7,973,177 000		6,322,716 000
126181	Pending	22-AUG-16	25-AUG-16		15-AUG-16	MAN			NABILONE	7379-0	2016	10,300 000	10,000 000	300 000		
126369	New				31-AUG-16	MAN			NOROXYMORPHONE (FOR SALE)	9668-B	2016	380,000 000	142,250 000	237,750 000		
126401	New				07-SEP-16	MAN			PENTOBARBITAL	2270-0	2016	27,000 000	0 000	27,000 000		
126107	Pending	09-AUG-16	07-SEP-16		05-AUG-16	MAN			PENTOBARBITAL	2270-0	2016	48,130 000	0 000	48,130 000		
											Total	75,130 000	0 000	75,130 000		
126351	New	29-AUG-16			26-AUG-16	MAN			SECOBARBITAL	2315-0	2016	194,700 000	137,000 000	57,700 000		

(b)(4)

August 22, 2016

Deputy Administrator
Drug Enforcement Administration
Washington, D.C. 20537

Attn: DEA Federal Register Representative [Docket No. DEA-420P]

This letter constitutes (b)(4) comments on the Proposed Revised Aggregate Production Quotas for 2016, as published in Federal Register on July 22, 2016, FR Volume 81, No. 141, pages 47829-47834. It should be considered to be Confidential Business Information.

In light of the fact that (b)(4) has no knowledge of either the amounts of any available aggregate quotas or DEA's planned allocation of any aggregate, (b)(4) requests that DEA make any adjustments to the aggregate quotas sufficient to satisfy our requests for increased manufacturing quotas, which are outlined below. Because this comment contains confidential business information on our manufacturing quota needs, (b)(4) also requests that DEA treat this entire document as confidential.

All requests below are stated in grams anhydrous base ("AA").

9250 Methadone

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 5,988,481 grams AA of methadone manufacturing quota for 2016, reference DEA online submission number 128318.

9254 Methadone Intermediate

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 3,369,372 grams AA of methadone intermediate manufacturing quota for 2016, reference DEA online submission number 128317.

Contains Confidential and Proprietary Information

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

(b)(4)

Office phone (b)(6)

Cellular (b)(6)

(b)(4);(b)(6)

Contains Confidential and Proprietary Information

(b)(4)

August 22, 2016

Dr. Christine. A. Sannerud
Chief
Drug & Chemical Evaluation Section
DEA Headquarters
8701 Morrissette Drive
Springfield, VA 22152

RE: **Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016**

(b)(4) requests these manufacturing quotas be addressed as part of the revised aggregate process. At this time, please consider these requests including all supporting documentation previously submitted by (b)(4) in conjunction with these requests.

9250 Methadone

(b)(4) requests 5,988,481 grams AA of additional methadone manufacturing quota for 2016. (Reference # 128318 on August 22, 2016) With the 14,011,519 grams already granted, the total is 20,000,000 grams (See Exhibit A page 1 of 2).

9254 Methadone Intermediate

(b)(4) requests 3,369,372 grams AA of additional methadone intermediate manufacturing quota for 2016. (Reference # 128317 on August 22, 2016) With the 17,630,628 grams already granted, the total is 21,000,000 grams (See Exhibit A page 2 of 2).

Sincerely,

(b)(6)
Supervisor, Controlled Substances Compliance
(b)(4)
Office phone (b)(6) Cellular (b)(6)
(b)(4);(b)(6)

(b)(4)

Additional Methadone Quota Request
Supplemental Information

Exhibit A page 1 of 2

	8/22/2016								
	DH/EB	9250 Methadone Sales							
		(b)(4);(b)(7)(E)				Actual	Firm+Forecast		
		Grams Base Class (AA)				AA grams	AA grams	AA grams	
Type	Registration	Customer	Code	AA grams 2014 Act	AA grams 2015 Act	Jan-Jul 2016 Act	Aug-Dec 2016 Est	CY 2016 Est.Total	Percent
(1)	Inventory	Bulk Controlled Substances		1,194,557	699,682			2,489,787	
(2)		In-Process Material		1,494,770	1,890,933			1,800,000	
(3)		Finished Dosage Forms		979	979			1,780	
(4)		Total Inventory		2,690,306	2,591,594			4,291,567	10.1%
E	(b)(4);(b)(7)(E)		6887/9383	7,304,607	9,674,681	6,827,350	5,476,901	12,304,251	72.8%
F			1510	416,656	536,073	232,172	28,035	260,207	1.5%
E			1510	738,700	710,724	1,777,864	1,854,760	3,632,624	21.5%
			1510	0	0	394,715	0	394,715	2.3%
		Others	1510	14,534	22,448	3,057	91,670	94,727	0.6%
		Dextromethadone	8514	0	0	0	220,542	220,542	1.3%
		Methadone Base	3278	0	0	0	0	0	0.0%
(5)	Disposition	Domestic		8,474,497	10,943,926	9,235,158	7,671,908	16,907,066	
(6)		Export		26,144	23,143	0	84,550	84,550	0.5%
(7)		Total Sales		8,500,641	10,967,069	9,235,158	7,756,458	16,991,616	
(8)		Net Production		7,789,075	10,919,334			18,691,589	
(9)	7%	Non-recoverable waste		452,097	335,880			1,308,411	
(10)	Acquisition	Total Quota Production		8,241,172	11,255,214			20,000,000	
(11)		Quota previously granted		(10,155,194)	(14,100,000)			(14,011,519)	
(12)		**Additional Methadone quota needed**						5,988,481	
								50% Rule	
(13)								6,962,748	

50% Rule is 1/2 the average of the last 2 years estimated domestic sales
= 1/2 x (16,907,066 [2014] + 10,943,926 [2014]) / 2 = ... >

Year Production Estimate is (days in year / days YTD) x Actual YTD domestic sales x Waste Factor
= 365/213 * 9,235,158 * 1.07 = 16,933,291 Production for Export * Waste Factor = 84,550 x 1.07 = 90,469

Producton for Inventory Build is (50% rule - Previous End) * Waste Factor
= (6,962,748 - 2,591,594) x 1.07 = 4,677,135

Quota is Year Production Estimate + Production for Inventory Build + Production for Export
= 16,933,291 + 4,677,135 + 90,469 = 21,700,894 [Match with Acquisitions]

(b)(4)

Additional Methadone Quota Request
Supplemental Information

		9254 Methadone Intermediate						
(14)	Inventory	Bulk Controlled Substances	1,054,648	1,548,294			1,346,020	
(15)		In-Process Material	0	2,487,375			2,500,000	
(16)		Total Inventory	1,054,648	4,035,669			3,846,020	
(17)	(8)/97% Disposition	Methadone Intermediate to Methadone	8,035,799	10,500,037			19,269,679	
(17)		Net Production	6,930,437	13,504,960			19,080,031	
(18)	10%	Non-recoverable waste	755,703	1,405,777			1,908,003	
(19)	Acquisition	**Total Methadone Intermediate**	7,686,140	14,910,737			21,000,000	
(18)		Quota previously granted	(11,928,645)	(17,500,000)			(17,630,628)	
(19)		**Additional Methadone Intermediate quota needed**					3,369,372	
(20)	Convert to	Methadone	8,035,799	10,500,037			19,269,679	97%

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Application for Quota Allotment
Manufacturer (DEA Form 189)

Drug Name	Drug Code	Drug Schedule	Quota Year
METHADONE	9250	2	2016

DEA Number	Registrant Name and Address	Date Submitted	Reference Number
(b)(4);(b)(7)(E)		Aug 22, 2016	128318

Quota Allotment Requests by Year	2014 (approved)	2015 (approved)	2016 (request)
	10,155,194.000	14,100,000.000	20,000,000.000

Year-End Inventory Data by Year	2014 (actual)	2015 (actual)	2016 (estimate)
Inventory (as of Dec 31)			
Bulk controlled substance (API)	1,194,557.000	699,685.000	2,469,787.000
In-process material (in all forms)	1,494,770.000	1,890,949.000	1,800,000.000
Finished dosage forms	979.000	979.000	1,780.000
Total Inventory	2,690,306.000	2,591,613.000	4,291,567.000
Dispositions			
Domestic	8,474,496.000	10,943,928.000	16,907,066.000
Exports	26,144.000	23,143.000	84,550.000
Total Dispositions	8,500,640.000	10,967,071.000	16,991,616.000
Acquisitions			
Domestic	8,241,434.000	11,260,827.000	20,000,000.000
Imports	.000	.000	.000
Total Acquisitions	8,241,434.000	11,260,827.000	20,000,000.000

Remarks
Supplemental documentation in support of this request will be emailed separately to ODE.Quota@usdoj.gov.

Current Request by Category				
Commercial Manufacturing	Product Developement	Packaging	Replacements	Transfers
20,000,000.000	.000	.000	.000	.000

Commercial Manufacturing -- Converted Substances (Box 13)					
Drug Name	Drug Code	Amount Used 2014	Amount Used 2015	Amount Estimated 2016	Historical Percentage

Commercial Manufacturing -- Dosage Forms (Box 14)					
Name	Drug Schedule	Market Authority	Amount Used 2014	Amount Used 2015	Amount Estimated 2016

Product Development						
Name	Strength	Units per Batch	Number of Batches	Purpose	Total Quantity	Time to Completion

Application for Quota Allotment
Manufacturer (DEA Form 189)

Drug Name	Drug Code	Drug Schedule	Quota Year
METHADONE-INTERMEDIATE	9254	2	2016

DEA Number	Registrant Name and Address	Date Submitted	Reference Number
(b)(4);(b)(7)(E)		Aug 22, 2016	128317

Quota Allotment Requests by Year	2014 (approved)	2015 (approved)	2016 (request)
	11,926,645.000	17,500,000.000	21,000,000.000

Year-End Inventory Data by Year	2014 (actual)	2015 (actual)	2016 (estimate)
Inventory (as of Dec 31)			
Bulk controlled substance (API)	1,054,648.000	1,548,294.000	1,346,020.000
In-process material (in all forms)	.000	2,487,375.000	2,500,000.000
Finished dosage forms	.000	.000	.000
Total Inventory	1,054,648.000	4,035,669.000	3,846,020.000
Dispositions			
Domestic	50.000	.000	19,269,679.000
Exports	.000	.000	.000
Total Dispositions	50.000	.000	19,269,679.000
Acquisitions			
Domestic	7,666,140.000	14,910,737.000	21,000,000.000
Imports	.000	.000	.000
Total Acquisitions	7,666,140.000	14,910,737.000	21,000,000.000

Remarks
Supplemental documentation in support of this quota request will be emailed separately to ODE.Quota@usdoj.gov.

Current Request by Category				
Commercial Manufacturing	Product Development	Packaging	Replacements	Transfers
21,000,000.000	.000	.000	.000	.000

Commercial Manufacturing -- Convertad Substances (Box 13)					
Drug Name	Drug Code	Amount Used 2014	Amount Used 2015	Amount Estimated 2016	Historical Percentage
METHADONE	9250	8,241,172.000	11,255,214.000	19,269,679.000	97.00%

Commercial Manufacturing -- Dosage Forms (Box 14)					
Name	Drug Schedule	Market Authority	Amount Used 2014	Amount Used 2015	Amount Estimated 2016

Product Development						
Name	Strength	Units per Batch	Number of Batches	Purpose	Total Quantity	Time to Completion

DEA Form: DEA-189	1117-0006	May 31, 2019

Basic Class: .273-0

2016 Revised AI Worksheets

PQ Total(CM+PD): 57.000

FDA Est:

IMS Est:

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	4.000	0.000	8,725.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		20.000	20.000	0.000	8,725.000	0.000	0.000	0.000	10.000	10.000	10.000	0.000
		10.000	10.000	0.000	8,725.000	0.000	0.000	6.086	0.000	-6.086	-6.086	0.000
MQ Totals:		35.000	34.000	0.000				6.086	10.000	3.914		0.000

Final Initial APQ:	36.000
Proposed Revised:	36.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	45.414
2015 Initial APQ:	15.000
FDA Est = 2015 APQ * (1 + FDA Est):	15.000
IMS Est = 2015 APQ * (1 + IMS Est):	15.000

CFR 50%: 31.164

Revised APQ is less 15

Final Revised APQ: 45.000

2016 Revised
Worksheets

Basic Class: 9059-0
PQ Total(CM+PD): 0.000

FDA Est:
IMS Est:

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2015 Total PQ	2015 Inventory	2015 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		1.000	1.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		1.000	1.000	0.000				0.000	0.000	0.000		0.000

Final Initial APQ: 2.000
Proposed Revised: 2.000

MQ Need=PQ* 1.5 - Revised MQ - Inventory: -1.000
2015 Initial APQ: 2.000
FDA Est = 2015 APQ * (1 + FDA Est): 2.000
IMS Est = 2015 APQ * (1 + IMS Est): 2.000

CFR 50%: -1.000

Revised APQ is more [redacted] 2

Internal Comments:

Received letter from (b)(4) requesting to import 30g. Will change 2016 estimate and APQ to reflect that change

Final Revised APQ: 40.000

Basic Class: 250-0

2016 R
Work

PQ Total(CM+FD): 18,132,974.001

FDA Est:
IMS Est:

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2016 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	4.000	0.000	16,267,739.315	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		20.000	20.000	0.000	16,267,739.315	0.000	0.000	0.000	10.000	10.000	10.000	0.000
		10.000	10.000	2.315	16,267,739.315	0.000	2.580	16.452	0.000	-13.097	-12.648	0.000
		265,220.000	223,519.000	16.000	16,267,739.315	0.000	17.835	35,914.000	0.000	-35,690.615	-35,687.707	0.000
		1.000	1.000	0.000	16,267,739.315	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		20,000,000.000	14,011,519.000	10,968,778.000	16,267,739.315	0.674	12,224,213.498	2,591,613.000	64,550.000	13,384,414.545	15,514,808.620	0.000
		8,700,000.000	7,043,932.000	5,300,642.000	16,267,739.315	0.326	5,905,740.090	1,439,230.000	0.000	6,272,132.117	7,101,930.613	0.000
MQ Totals:		28,965,256.000	21,279,005.000	16,267,739.315				4,066,773.452	64,560.000	19,620,652.749		0.000

Final Initial APQ: 25,500,000.000
Proposed Revised: 25,500,000.000

MQ Need=PQ* 1.5 - Revised MQ - Inventory: 1,883,682.550
2015 Initial APQ: 25,500,000.000
FDA Est = 2015 APQ * (1 + FDA Est): 25,500,000.000
IMS Est = 2015 APQ * (1 + IMS Est): 25,500,000.000

CFR 50%: 1,417,373.678

Revised APQ is more [illegible] 25,500.000

(b)(4) comments is for an increase by [illegible] 5,988,481
New MQ total would be [illegible] 27,267,486.00
Revised APQ is not sufficient [illegible] 25,500,00

Also requested the same amount through YERS system

Internal Comments:

(b)(4) request was processed and they were not eligible based on supporting documentation provided for full amount.
Therefore, proposed APQ is sufficient

Final Revised APQ: 31,875,000.000

Basic Class: 9254-0

2016 PQ
Wo.

PQ Total(CM+PQ): 0.000

FDA Est:
IMS Est:

Company	DEA Num	2016 MQ Request	2016 MQ	2015 Sales	2015 Total Sales	% of 2015 Sales	Share of 2016 Total PQ	2015 Inventory	2016 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4),(b)(7)(E)		10.000	10.000	0.000	17,842,811.000	0.000	0.000	9.950	0.000	-9.950	-9.950	0.000
		578,450.000	402,284.000	0.000	17,842,811.000	0.000	0.000	12,157.000	0.000	-12,157.000	-12,157.000	0.000
		1.000	1.000	0.000	17,842,811.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		21,000,000.000	17,630,628.000	10,500,037.000	17,842,811.000	0.588	0.000	4,035,669.000	0.000	-4,035,669.000	-1,410,659.750	0.000
		10,230,000.000	8,824,247.000	7,342,774.000	17,842,811.000	0.412	0.000	1,464,642.000	0.000	-1,464,642.000	371,051.500	0.000
MQ Totals:		31,808,461.000	26,857,170.000	17,842,811.000				5,512,477.950	0.000	-5,512,477.950		0.000

Final Initial APQ:	27,500,000.000
Proposed Revised:	27,500,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-32,369,647.950
2015 Initial APQ:	27,500,000.000
FDA Est = 2015 APQ * (1 + FDA Est):	27,500,000.000
IMS Est = 2015 APQ * (1 + IMS Est):	27,500,000.000

CFR 50%: -27,906,945.200

Revised APQ is more [illegible] 27,500,000

(b)(4) comments is for an increase by 3,369,372
New MQ total would be 30,226,542.00
Revised APQ is not sufficient 27,500,000

Also requested for the same amount through YERS system

Internal Comments:

(b)(4) request was processed and they were not eligible based on supporting documentation provided for full amount.
Therefore, proposed APQ is sufficient

Final Revised APQ: 34,375,000.000

2016 Final Adjusted Aggregate Production Quotas and Annual Assessment of Needs

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish the production amount of each basic class of Schedule I and II controlled substances and for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- DEA regulations allow the Administrator to revise the established annual aggregate production quota (APQ) and assessment of annual needs (AAN) after review of pertinent information provided from various sources including DEA-registered manufacturers and the Food and Drug Administration (FDA).

- The attached Federal Register notice, prepared for your signature, reflects the calendar year 2016 final adjusted aggregate production quotas (APQ) for schedules I and II controlled substances and assessment of annual needs (AAN) for the list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for which the United States has medical, scientific, industrial, export and reserve stock requirements.

- As stated in the 2013 Federal Register Notices, DEA continues to add an additional 25% to the APQ for schedule II substances and those schedule I substances that are used to produce drugs that have a medical need (specifically, GHB and tetrahydrocannabinols) to prevent potential drug shortage issues.

- Expeditious review and publication of this notice is necessary to ensure an uninterruptable supply of schedule I and II controlled substances as well as list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for the legitimate medical, scientific, industrial, and export requirements of the U.S.

- The following points provide brief explanations of the changes from the proposed revised AAN & APQ values:

List I Chemicals:

- No further adjustments

Controlled Substances:

- OD is recommending an increase in the APQs for **Dextropropoxyphene, Etorphine HCl** and **Phencyclidine.** The increase is based on registrant applications and projected demand for reference standards.

- OD is recommending an increase in the APQs for **Amphetamine (for sale), Levorphanol,** and **Noroxymorphone (for sale).** The increase is based on additional new purchase orders and batch size requirements at the bulk manufacturer level.

- OD is recommending an increase in the APQs for **Nabilone** and **Secobarbital.** The increase is based on changes in the manufacturing yields at the bulk manufacturing level.

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-420F]

Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

AGENCY: Drug Enforcement Administration (DEA), Department of Justice (DOJ).

ACTION: Final order.

SUMMARY: This final order establishes the final adjusted 2016 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202)598-6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 306 of the Controlled Substances Act (CSA), (21 U.S.C. 826), requires the Attorney General to establish aggregate production quotas for each basic class of controlled substances listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100.

Background

The DEA published the 2016 established aggregate production quotas for controlled

substances in schedules I and II and for the assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the Federal Register (80 FR 60400) on October 6, 2015. That notice stated that the Administrator would adjust, as needed, the established aggregate production quotas in 2016 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The 2016 proposed adjusted aggregate production quotas for controlled substances in schedules I and II and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the Federal Register on July 22, 2016 (81 FR 47829) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before August 22, 2016.

Comments Received

Four DEA-registered entities submitted timely comments regarding a total of six schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for amphetamine (for sale), etorphine hydrochloride, methadone, methadone intermediate, nabilone, and phencyclidine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks. The DEA received one comment from a DEA registrant regarding the proposed removal of the additional 25% of the estimated medical, scientific, and research needs of the United States for the calendar year 2017 published in the Federal Register on July 22, 2016 (81 FR 47821).

The DEA received one comment from a DEA-registered entity and two comments from non-DEA registered entities for the proposed adjustments to the 2016 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. Comments received proposed that the annual assessment of needs for ephedrine (for sale) and pseudoephedrine (for sale) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the

United States, for export requirements, and for the establishment and maintenance of reserve stocks.

Analysis for Final Adjusted 2016 Aggregate Production Quotas and Assessment of Annual Needs

In determining the final adjusted 2016 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors set forth in 21 CFR 1303.13 and 21 CFR 1315.13 accordance with 21 U.S.C. 826(a), and other relevant factors including the 2015 year-end inventories, initial 2016 manufacturing and import quotas, 2016 export requirements, actual and projected 2016 sales, research and product development requirements, and additional applications received. Based on all of the above, the Administrator has determined that the proposed adjusted 2016 aggregate production quotas and assessment of annual needs for amphetamine (for sale), etorphine hydrochloride, dextropropoxyphene, levorphanol, nabilone, noroxymorphone (for sale), phencyclidine, and secobarbital required additional consideration and hereby further adjusts the 2016 aggregate production quota and assessment of annual needs for these substances. This final order reflects those adjustments.

Regarding ephedrine (for sale), methadone, methadone intermediate, and pseudoephedrine (for sale) the Administrator hereby determines that the proposed adjusted 2016 aggregate production quotas and assessment of annual needs for these substances and List I chemicals as published on July 22, 2016 (81 FR 47829) are sufficient to meet the current 2016 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock. This final order establishes these aggregate production quotas at the same amounts as proposed.

As described in the previously published notice establishing the 2016 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that

inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all proposed revised schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting revised established aggregate production quota will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

Pursuant to the above, the Administrator hereby finalizes the 2016 aggregate production quotas for the following schedule I and II controlled substances and the 2016 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Revised 2016 Quotas (g)
Temporarily Scheduled Substances	
beta-Hydroxythiofentanyl	30
Butyryl fentanyl	30

Schedule I	
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Benzylpiperazine	25
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55

3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-FMC; Flephedrone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Fluoro-UR144, XLR11	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
AB-PINACA	15
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
AH-7921	30
Allylprodine	2
alpha-Ethyltryptamine	25
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Alphacetylmethadol	2
Alphameprodine	2
Alphamethadol	2

Aminorex	25
APINCA, AKB48	25
Benzylmorphine	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betacetylmethadol	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Butylone	25
Cathinone	30
Codeine methylbromide	5
Codeine-N-oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	11,000
Dihydromorphine	2,000,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	40
Marihuana	658,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
N,N-Dimethylamphetamine	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide	50

(ADB-PINACA)	
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Naphyrone	25
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Pentedrone	25
Pentylone	25
Phenomorphan	2
Pholcodine	5
Psilocybin	30
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	25
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	25
Tetrahydrocannabinols	511,250
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
UR-144	25
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	15,000,000
Amphetamine (for sale)	50,000,000

Carfentanil	19
Cocaine	200,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	63,900,000
Dextropropoxyphene	55
Dihydrocodeine	226,375
Dihydroetorphine	3
Diphenoxylate (for conversion)	18,750
Diphenoxylate (for sale)	1,337,500
Ecgonine	125,000
Ethylmorphine	5
Etorphine hydrochloride	40
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	177,500
Hydrocodone (for sale)	86,000,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	33
Levorphanol	9,525
Lisdexamfetamine	23,750,000
Meperidine	4,632,500
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	84,375,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,875
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	875,000

Opium (powder)	112,500
Opium (tincture)	375,000
Oripavine	30,000,000
Oxycodone (for conversion)	5,000,000
Oxycodone (for sale)	139,150,000
Oxymorphone (for conversion)	25,000,000
Oxymorphone (for sale)	6,250,000
Pentobarbital	38,125,000
Phenazocine	6
Phencyclidine	60
Phenmetrazine	3
Phenylacetone	50
Racemethorphan	5
Racemorphan	3
Remifentanil	3,750
Secobarbital	243,380
Sufentanil	6,255
Tapentadol	25,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	50,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	15,000,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	40
Pseudoephedrine (for sale)	200,000,000

Aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Dated:

Chuck Rosenberg,
Acting Administrator.

A: _____
CPC: _____
CCR: _____
OD: _____
OD/R: _____

ODX: _____
OD/RX: _____

ODXA: _____

ODW: _____

ODW Analyst: _____

ODQ: _____

ODQ: (b)(6) 09-16-2016

S:\ODQ\Federal Register\2016 (DEA-420F) Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

SBF-CM# ODQ-16-1143

DFN# 630-07- Federal Register

(as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: October 19, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–25715 Filed 10–24–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1002]

Certain Carbon and Alloy Steel Products; Commission Decision Not To Review an Initial Determination Granting Complainant's Motion To Amend the Complaint and Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ") initial determination ("ID") (Order No. 34), granting a motion of complainant United States Steel Corporation to amend the Complaint and Notice of Investigation to correct the name of respondent "Shougang Group" to "Shougang Corporation."

FOR FURTHER INFORMATION CONTACT: Megan M Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on June 2, 2016, based on a complaint filed by United States Steel Corporation of Pittsburgh, Pennsylvania ("U.S. Steel"), alleging a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337. 81 FR 35381 (June 2, 2016). The notice of investigation named numerous respondents, including Shougang Group and China Shougang International Trade & Engineering Corporation ("Shougang Trade") both of Beijing, China. *Id.* at 35382. The Office of Unfair Import Investigations ("OUII") was also named as a party. *Id.* The alleged violation of section 337 is based upon the importation into the United States, or in the sale of certain carbon and alloy steel products by reason of: (1) a conspiracy to fix prices and control output and export volumes, the threat or effect of which is to restrain or monopolize trade and commerce in the United States; (2) misappropriation and use of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States; or (3) false designation of origin or manufacturer, the threat or effect of which is to destroy or substantially injure an industry in the United States. *Id.* at 35381.

On August 31, 2016, U.S. Steel filed a motion for leave to amend the Complaint and Notice of Investigation to correct the name of respondent "Shougang Group" to "Shougang Corporation." On September 12, 2016, respondent Shougang Trade responded to the motion, identifying an apparent error in the proposed amended Complaint but stating that it does not oppose the motion. No other responses were received.

On September 19, 2016, the ALJ issued the subject ID, granting U.S. Steel's motion pursuant to Commission rule 210.14(b)(1) (19 CFR 210.14(b)(1)). The ID notes that on June 30, 2016, following institution of the investigation, Shougang Trade filed a response to the Complaint, stating that "Shougang Group" is not a legal entity. Shougang Trade also asserted that it is a wholly owned subsidiary of Shougang Corporation. U.S. Steel noted in its motion that the address for Shougang Corporation is the same address that was identified in the Complaint for "Shougang Group." The ALJ found there is good cause to amend the pleadings to correct the name of a misidentified respondent. The ALJ also found that there is no prejudice in identifying Shougang Corporation at this stage of the investigation because Shougang Trade, its wholly owned subsidiary, was properly served the Complaint and Notice of Investigation and has entered an appearance.

No petitions for review were filed and the Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: October 19, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–25716 Filed 10–24–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–420F]

Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016

AGENCY: Drug Enforcement Administration (DEA), Department of Justice (DOJ).

ACTION: Final order.

SUMMARY: This final order establishes the final adjusted 2016 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective October 25, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826),

requires the Attorney General to establish aggregate production quotas for each basic class of controlled substances listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

Background

The DEA published the 2016 established aggregate production quotas for controlled substances in schedules I and II and for the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the **Federal Register** on October 6, 2015, 80 FR 60400. This notice stated that the Administrator would adjust, as needed, the established aggregate production quotas in 2016 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The 2016 proposed adjusted aggregate production quotas for controlled substances in schedules I and II, and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the **Federal Register** on July 22, 2016, (81 FR 47829) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before August 22, 2016.

Comments Received

Four DEA-registered entities submitted timely comments regarding a total of six schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for amphetamine (for sale), etorphine hydrochloride, methadone, methadone intermediate, nabilone, and phencyclidine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks. The DEA received one comment from a non-DEA registered entity requesting the reduction of oxycodone (for sale) to pre-2013 levels. The DEA received one comment from a DEA registrant regarding the proposed removal of the additional 25% of the estimated medical, scientific, and research needs of the United States for the calendar year 2017 published in the **Federal Register** on July 22, 2016 (81 FR 47821).

The DEA received one comment from a DEA-registered entity and two comments from non-DEA registered entities for the proposed adjustments to the 2016 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. Comments received proposed that the annual assessment of needs for ephedrine (for sale) and pseudoephedrine (for sale) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks.

Analysis for Final Adjusted 2016 Aggregate Production Quotas and Assessment of Annual Needs

In determining the final adjusted 2016 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors set forth in 21 CFR 1303.13 and 21 CFR 1315.13 in accordance with 21 U.S.C. 826(a), and other relevant factors including the 2015 year-end inventories, initial 2016 manufacturing and import quotas, 2016 export requirements, actual and projected 2016 sales, research and product development requirements, and additional applications received. Based on all of the above, the Administrator has determined that the proposed adjusted 2016 aggregate production quotas and assessment of annual needs for amphetamine (for sale), etorphine hydrochloride, dextropropoxyphene, levorphanol, nabilone, noroxymorphone (for sale), phencyclidine, and secobarbital required additional consideration, and hereby further adjusts the 2016 aggregate production quotas and assessment of annual needs for these substances. This final order reflects those adjustments.

Regarding ephedrine (for sale), methadone, methadone intermediate, oxycodone (for sale), and pseudoephedrine (for sale) the Administrator hereby determines that the proposed adjusted 2016 aggregate production quotas and assessment of annual needs for these substances and list I chemicals as published on July 22, 2016, (81 FR 47829) are sufficient to meet the current 2016 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock. This final order establishes these aggregate production quotas at the same amounts as proposed.

As described in the previously published notice establishing the 2016 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA included in all final schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting final aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

Pursuant to the above, the Administrator hereby finalizes the 2016 aggregate production quotas for the following schedule I and II controlled substances and the 2016 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Revised 2016 quotas (g)
Temporarily Scheduled Substances	
beta-Hydroxythiofentanyl	30
Butyryl fentanyl	30
Schedule I	
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ–2201)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200)	45
1-Benzylpiperazine	25
1-Butyl-3-(1-naphthoyl)indole (JWH–073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C–P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I–NBOMe; 2C–I–NBOMe; 25I; Cimbi-5)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3–FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	25
4–FMC; Flephedrone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4–MEC; 4-Methyl-N-ethylcathinone	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog)	53
5-Fluoro-UR144, XLR11	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
AB–PINACA	15
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
AH–7921	30

Basic class	Revised 2016 quotas (g)
Allylprodine	2
alpha-Ethyltryptamine	25
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Alphacetylmethadol	2
Alphameprodine	2
Alphamethadol	2
Aminorex	25
APINCA, AKB48	25
Benzylmorphine	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betacetylmethadol	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Butylone	25
Cathinone	30
Codeine methylbromide	5
Codeine-N-oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	11,000
Dihydromorphine	2,000,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	40
Marihuana	658,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
N,N-Dimethylamphetamine	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB–PINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB–FUBINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB–CHMINACA)	15
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Naphyrone	25
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Pentedrone	25
Pentylone	25
Phenomorphan	2
Pholcodine	5
Psilocybin	30
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB–22; 5F–PB–22)	25
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB–22; QUPIC)	25

Basic class	Revised 2016 quotas (g)
Tetrahydrocannabinols	511,250
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
UR–144	25
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	15,000,000
Amphetamine (for sale)	50,000,000
Carfentanil	19
Cocaine	200,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	63,900,000
Dextropropoxyphene	55
Dihydrocodeine	226,375
Dihydroetorphine	3
Diphenoxylate (for conversion)	18,750
Diphenoxylate (for sale)	1,337,500
Ecgonine	125,000
Ethylmorphine	5
Etorphine hydrochloride	40
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	177,500
Hydrocodone (for sale)	86,000,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	33
Levorphanol	9,525
Lisdexamfetamine	23,750,000
Meperidine	4,632,500
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	84,375,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,875
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	875,000
Opium (powder)	112,500
Opium (tincture)	375,000
Oripavine	30,000,000
Oxycodone (for conversion)	5,000,000
Oxycodone (for sale)	139,150,000
Oxymorphone (for conversion)	25,000,000
Oxymorphone (for sale)	6,250,000
Pentobarbital	38,125,000
Phenazocine	6
Phencyclidine	60
Phenmetrazine	3
Phenylacetone	50
Racemethorphan	5
Racemorphan	3

Basic class	Revised 2016 quotas (g)
Remifentanil	3,750
Secobarbital	243,380
Sufentanil	6,255
Tapentadol	25,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	50,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	15,000,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	40
Pseudoephedrine (for sale)	200,000,000

Aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Dated: October 19, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016-25696 Filed 10-24-16; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Program To Prevent Smoking in Hazardous Areas of Underground Coal Mines

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Mine Safety and Health Administration (MSHA) sponsored information collection request (ICR) titled, "Program to Prevent Smoking in Hazardous Areas of Underground Coal Mines," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before November 25, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201605-1219-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-MSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202-395-5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Program to Prevent Smoking in Hazardous Areas of Underground Coal Mines information collection. Regulations 30 CFR 75.1702 prohibits a person from smoking or carrying smoking materials underground or in places where there is a fire or explosion hazard. Regulations 30 CFR 75.1702-1 requires a mine operator to submit a smoking prevention plan to the MSHA for approval. Federal Mine Safety and Health Act of 1977 section 103(h) authorizes this information collection. *See* 30 U.S.C. 813(h).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1219-0041.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on December 31, 2016. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the Federal Register on June 30, 2016 (81 FR 42734).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the Federal Register. In order to help ensure appropriate consideration, comments should mention OMB Control Number

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2009 Initial Quota Worksheet**		9050				
PQ Total:	27,335.906 kg					**FDA Est.:**	-4.20%
Company:	(b)(4)						
Request:	52.000	450.000	18,000.000	14,238.000	1,600.000	34,340.000	requested
Current Year MQ:	100.000	450.000	20,000.000	17,264.000	1,193.000		
Prev. Year's Sales:	-	87.576	17,237.853	6,601.513	809.886		
Total Prev. Year's Sales:	24,742.466	24,742.466	24,742.466	24,742.466	24,742.466		
% of Prev. Year's Sales:	0%	0%	70%	27%	3%		
Share of Next Year's PQs:	-	96.755	19,044.679	7,293.466	894.776		
Prev. Yr. Year-end Inv.:	-	182.016	9,979.766	2,060.394	408.521		
Proj. Exports Current Year:	-	-	865.800	-	-		
Company est. current year sale	-	100.000	23,841.739	7,100.000	1,500.000		
Proj. Exports Next Year:	-	-	1,110.000	-	-		
Company's Proj. Inv. Current Y	-	200.901	8,183.664	0.500	0.383		
DEA's Proj. Inv. Current Year:	100.000	532.016	5,272.227	12,224.394	101.521		
INITIAL MQs							
2/3 calculation	66.667	421.344	19,986.511	12,882.929	1,067.681		
Calc. Using Company's Inv.:	-	(55.768)	21,493.355	10,939.699	1,341.781		
Calc. Using DEA's Inv.:	(100.000)	(386.883)	24,404.792	(1,284.195)	1,240.643		
Calc. w/ CFR 50% inventory	(100.000)	(431.576)	22,215.565	(1,847.660)	1,289.819		
Further Calculation:	100.000	443.000	25,118.000	5,855.000	921.000		
MQ:	100.000	443.000	25,000.000	5,855.000	921.000		
Total Initial MQs:	32,319.000	+ others	3.101	=	32,322.101		

FURTHER CALCULATIONS

Initial

Update numbers below

MQs 2008	39,014.131
Final 2008	39,605.000
Initial APQ	39,605.000

total request for codeine (for sale) = 34496.101 about same as APQ therefore no change

FDA est: APQ last year * est = 37,941.590
grant 2/3

Initial Aggregate Production Quotas for 2009

BASIC CLASS: 2009 Initial Quota Worksheets 9050

Company:	(b)(4)																			
Request:	250				10500			Initial	39000				0				0			
Current Year MQ:	0				7500				43000				7900				10			
Prev. Yr. Year-end Inv.:	0				2,216.182				255.192				3,407.555				0			
Company's Proj. Inv. Current Yr.:	10				2,217.838				1,965.026				571.000				0			
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield
(based on request MQ)	5649	hydrocodon	4,802.0	85%	7,547.170	hydrocodor	4,000.0	53%	32,608.696	hydrocodone	30,000.000	92%	-	hydrocodor	-	81%	0	hydrocodone	0	60%
					-	dihydrocod	-	79%	475.610	dihydrocodei	390.000	82%					0	dihydrocodein	0	75%
					494.505	codeine (sa	450.000	91%												
total need	5649				8,041.675				33,084.305				-				0			
INITIAL MQs																				
total x 50% inventory - prev. YEI	8464.118				9,844.675				47,661.432				(571.000)				0.000			
MQ:	1100.000				6,000.000				41,000.000				7,900.000				10			
Total Initial MQs:	56010	+ others		=	56,010.000															
FURTHER CALCULATIONS																				
						MQs 2008			59,510.000											
						MQs 2009			56,299.000				-							
FDA est for hydrocodone =	8.40%					Final 2008			65,000.000											
Applied to APQ for codeine (for conversion)	70460					Initial APQ			65,000.000											

(b)(4) pilot 4@25, plant 5@200

Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield
(based on initial MQ)	1176	hydrocodon	1,000.0	85%	4,422.642	hydrocodor	2,344.0	53%	24,796.739	hydrocodone	22,813.000	92%	5,555.556	hydrocodor	4,500.00	81%	0	hydrocodone	0	60%
					-	dihydrocod	-	79%	731.707	dihydrocodei	600.000	82%					7	dihydrocodein	5	75%
					494.505	codeine (sa	450.000	91%												
total need	1,176.471				4,917.147				25,528.446				5,555.556				6.667			
total x 50% inventory - prev. YEI	1,754.706				5,157.883				36,327.644				7,762.333				10.000			
2/3 calc./initial assessment	126.670				6,202.230				24,536.253				16,076.867				28.000			

Codeine (for conversion) Initial

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2009 Initial Quota Worksheets**		9273			
PQ Total:	76,590.374 kg				**FDA Est.:**	-1.60%
Company:	(b)(4)					
Request:	0.001	0.002	-	38,000.000	53,000.000	Initial
Current Year MQ:	0.001	0.002	30.000	41,722.000	48,238.000	
Prev. Year's Sales:	-	-	-	43,435.547	35,577.677	
Total Prev. Year's Sales:	79,193.581	79,193.581	79,193.581	79,193.581	79,193.581	
% of Prev. Year's Sales:	0%	0%	0%	55%	45%	
Share of Next Year's PQs:	-	-	-	42,007.758	34,408.188	
Prev. Yr. Year-end Inv.:	-	0.014	-	12,481.620	26,034.539	
Proj. Exports Current Year:	-	-	-	414.000	1,260.000	
Proj. Exports Next Year:	-	-	-	414.000	-	
company est. sales current year	0.001	-	-	58,770.540	62,115.000	
Company's Proj. Inv. Current Yr.:	0.001	-	-	15,058.952	23,000.000	
DEA's Proj. Inv. Current Year:	-	0.016	30.000	(4,980.920)	10,897.539	
INITIAL MQs						
2/3 calculation	0.001	0.011	20.000	36,135.747	49,515.026	
Calc. Using Company's Inv.:	(0.001)	-	-	48,366.685	28,612.281	
Calc. Using DEA's Inv.:	-	(0.016)	(30.000)	68,406.557	40,714.742	
Calc. w/ CFR 50% inventory	0.000	(0.020)	(30.000)	69,166.348	41,447.811	
Further Calculation:	0.001	0.002	30.000	55,121.359	61,000.000	
MQ:	0.001	0.002	30.000	55,121.359	61,000.000	
Total Initial MQs:	116,151.362	+ others	-	=	116,151.362	

FURTHER CALCULATIONS Initial

Update numbers below

(b)(4) 10 @ 0.2, 4 @7 kg (PD)

grant 2/3 and see how market fares between (b)(4)

MQs 2008	89,990.003
MQ 2009 request	91,000.005
Final 2008	106,000.000
Initial APQ	106,000.000

FDA est: APQ last year * est = 104304

91,000.01 total request

Dextromethorphan Hydrobromide Initial

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2009 Initial Quota Worksheets**						
PQ Total:	1,738.358 kg					**FDA Est.:**	3.80%
Company:	(b)(4)						
Request:	516.000	85.000	50.000	925.000	840.000		Initial
Current Year MQ:	55.000	70.000	10.000	500.000	775.000		
Prev. Year's Sales:	31.657	55.116	0.088	351.920	612.775		
Total Prev. Year's Sales:	1,098.926	1,098.926	1,098.926	1,098.926	1,098.926		
% of Prev. Year's Sales:	3%	5%	0%	32%	56%		
Share of Next Year's PQs:	50.077	87.186	0.139	556.692	969.330		
Prev. Yr. Year-end Inv.:	53.524	17.496	-	478.791	155.454		
Proj. Exports Current Year:	-	24.178	-	-	80.488		
estimated sales current year:	31.000	26.178	1.596	533.800	619.148		
Proj. Exports Next Year:	-	65.000	-	-	104.480		
Company's Proj. Inv. Current Yr.:	-	6.500	7.101	287.598	163.519	464.718	
DEA's Proj. Inv. Current Year:	77.524	37.140	8.404	444.991	230.818		
INITIAL MQs							
2/3 calculation	72.349	58.331	6.667	652.527	620.303	1,410.177	
Calc. Using Company's Inv.:	65.100	171.842	(6.920)	436.101	1,201.090		
Calc. Using DEA's Inv.:	(12.424)	141.202	(8.223)	278.708	1,133.791		
calc. w/ CFR 50% inventory	(20.558)	80.058	(7.831)	264.626	1,116.890		
Further Calculation:	63.000	70.000	10.000	500.000	800.000		
MQ:	63.000	70.000	10.000	500.000	800.000		
Total Initial MQs:	1,443.000	+ others	0.003	=	1,443.003		

FURTHER CALCULATIONS			Initial
Update numbers below			
2008 PQ =	1,738.358	MQs 2008	1,410.003
MQ = PQ x 1.3 - YEI =	1,795.147	MQs 2009	2,419.003
		Final 2008	1,428.000
		Initial APQ	1,428.000
Keep APQ same			
FDA est: APQ last year * est =	1482.264		

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2009 Initial Quota Worksheets**		9193						
PQ Total:	69,528.349 kg						**FDA Est.:**	8.40%	
Company:	(b)(4)								
Request:	-	4,802.000	4,000.000	30,000.000	-	40,500.000	-	2,000.000	10,000.000
Current Year MQ:	-	1,000.000	3,939.000	31,043.000	3,100.000	15,400.000	-	-	-
Prev. Year's Sales:	-	-	489.446	22,994.043	14,680.601	5,362.212	-	-	41.103
Total Prev. Year's Sales:	43,567.406	43,567.406	43,567.406	43,567.406	43,567.406	43,567.406	43,567.406	43,567.406	43,567.406
% of Prev. Year's Sales:	0%	0%	1%	53%	34%	12%	0%	0%	0%
Share of Next Year's PQs:	-	-	781.097	36,695.732	23,428.477	8,557.447	-	-	65.595
Prev. Yr. Year-end Inv.:	33.414	-	1,327.736	9,611.341	4,223.634	3,749.927	-	1,291.100	2,747.977
Proj. Exports Current Year:	-	-	-	7.930	-	-	-	-	-
estimated sales current year:	-	55.000	600.324	26,684.083	16,942.000	7,320.000	-	-	2,531.500
Proj. Exports Next Year:	-	-	-	6.100	-	-	-	-	-
Company's Proj. Inv. Current Yr.:	-	6.000	1,014.790	7,381.932	4,715.000	1,650.000	-	1,990.000	900.000
DEA's Proj. Inv. Current Year:	33.414	945.000	4,666.412	13,962.328	(9,618.366)	11,829.927	-	1,291.100	216.477
INITIAL MQs									
2/3 calculation	22.276	666.667	3,511.157	27,102.894	4,882.423	12,766.618	-	860.733	1,831.985
Calc. Using Company's Inv.:	-	(6.000)	0.636	40,328.619	25,742.020	9,474.680	-	(1,990.000)	(814.726)
Calc. Using DEA's Inv.:	(33.414)	(945.000)	(3,650.986)	33,748.223	40,075.386	(705.247)	-	(1,291.100)	(131.203)
Calc. using CFR 50% inventory	(41.768)	(931.250)	(3,871.894)	36,177.505	42,083.553	(240.601)	-	(1,613.875)	(188.602)
Further Calculation:	-	1,000.000	2,344.000	31,000.000	6,000.000	16,000.000	-	-	2,405.000
MQ:	-	1,000.000	2,344.000	31,000.000	6,000.000	16,000.000	-	-	2,405.000
Total Initial MQs:	58,749.000	+ others	0.021	=	58,749.021				

FURTHER CALCULATIONS

Update numbers below

(b)(4) 5 @ 200 DMF

MQs 2008	54,482.021
MQs 2009	91,382.021
Final 2008	55,500.000
Initial APQ	55,000.000

FDA est: APQ * est = 60162

Hydrocodone (sale) Initial

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	2009 Initial Quota Worksheets							
PQ Total:	5221.519		(less packaging/transfer quotas)				FDA Est.:	10.70%
Company:	(b)(4)							
Request:	-	-	156.000	330.000	300.000	1,420.000	1,500.000	-
Current Year MQ:	108.000	-	156.000	90.000	252.000	1,410.000	1,068.000	-
Prev. Year's Sales:	236.240	-	-	-	205.046	932.517	744.721	-
Total Prev. Year's Sales:	2,119.652	2,119.652	2,119.652	2,119.652	2,119.652	2,119.652	2,119.652	2,119.652
% of Prev. Year's Sales:	11%	0%	0%	0%	10%	44%	35%	0%
Share of Next Year's PQs:	581.950	-	-	-	505.107	2,297.148	1,834.535	-
Prev. Yr. Year-end Inv.:	123.230	-	-	10.334	62.122	436.890	305.138	-
Proj. Exports Current Year:	38.500	-	-	-	-	8.900	-	-
company's est. current year sales	358.500	-	25.000	-	210.000	1,129.655	1,189.000	
Proj. Exports Next Year:	-	-	-	-	-	-	-	-
Company's Proj. Inv. Current Yr.:	6.000	-	6.000	-	74.409	467.946	207.000	12.900
DEA's Proj. Inv. Current Year:	(165.770)	-	131.000	100.334	104.122	708.335	184.138	-
INITIAL MQs								
2/3 calculation	154.153	-	104.000	66.889	209.415	1,231.260	915.425	-
Calc. Using Company's Inv.:	866.925	-	(6.000)	-	683.252	2,977.777	2,544.802	(12.900)
Calc. Using DEA's Inv.:	1,038.695	-	(131.000)	(100.334)	653.539	2,737.388	2,567.664	-
Calc. using CFR 50% inventory	600.400	-	39.000	9.583	616.732	2,677.823	2,178.746	-
Further Calculation:	108.000	-	156.000	-	234.000	1,300.000	688.000	-
MQ:	108.000	-	156.000	-	234.000	1,300.000	688.000	-
Total Initial MQs:	2,486.000	+ others	0.021	=	2,486.021			

FURTHER CALCULATIONS

Update numbers below

(b)(4) validation of process 20 lab @0.3, 4 pilot @ 37.5 kg

MQs 2008	3,337.021
MQs 2009	4,202.278
Final 2008	3,340.000
Initial APQ	3,300.000

(b)(4) supplies (b)(4)

(b)(4) sells to (b)(4)

FDA est: APQ * est = 3697.380

Total request is 3,459.021 vs. 3,300 kg APQ = 95% - keep same

Hydromorphone Oral

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2009 Initial Quota Worksheet**		9230				
PQ Total:	4,079.698 kg					**FDA Est.:**	-4.00%
Company:	(b)(4)						
Request:	0.001	3,908.000	0.002	46.000	-	2,400.000	Initial
Current Year MQ:	0.001	3,908.000	0.002	46.000	261.000	1,600.000	
Prev. Year's Sales:	-	2,771.600	-	-	-	1,479.634	
Total Prev. Year's Sales:	4,251.234	4,251.234	4,251.234	4,251.234	4,251.234	4,251.234	
% of Prev. Year's Sales:	0%	65%	0%	0%	0%	35%	
Share of Next Year's PQs:	-	2,659.767	-	-	-	1,419.931	
Prev. Yr. Year-end Inv.:	0.001	941.555	0.002	-	-	1,503.983	
Proj. Exports Current Year:	-	-	-	-	-	74.255	
Company est. sales current yr.	0.001	3,800.213	0.001	-	-	2,157.603	
Proj. Exports Next Year:	-	-	-	-	-	43.500	
Company's Proj. Inv. Current Yr.:	0.001	1,017.000	0.001	-	-	999.000	
DEA's Proj. Inv. Current Year:	0.001	1,049.342	0.003	46.000	261.000	872.125	
INITIAL MQs							
2/3 calculation	0.001	3,233.037	0.003	30.667	174.000	2,069.322	
Calc. Using Company's Inv.:	(0.001)	2,972.650	(0.001)	-	-	1,174.397	
Calc. Using DEA's Inv.:	(0.001)	2,940.308	(0.003)	(46.000)	(261.000)	1,301.272	
calc. using CFR 50% inventory	(0.001)	3,124.765	(0.002)	11.500	65.250	294.935	
Further Calculation:	0.001	3,733.000	0.002	46.000	261.000	2,500.000	
MQ:	0.001	3,733.000	0.002	46.000	261.000	2,500.000	
Total Initial MQs:	6,540.003	+ others		=	6,540.003		

FURTHER CALCULATIONS Initial

Update numbers below

(b)(4) plant runs 4 @.11 kg; 10 lab @ 0.2kg

MQs 2007	5,815.003
MQs 2008	6,354.003
Final 2008	8,600.000
Initial APQ	8,600.000

FSA est: APQ last year * est = 8256

total request is less than current APQ - keep same

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2009 Initial Quota Worksheets**			9250			
PQ Total:	17,188.354		kg			**FDA Est.:**	**14.80%**
Company:	(b)(4)						
Request:	3,196.000	0.004	-	12,000.000	2,900.000	Initial	
Current Year MQ:	3,096.000	0.004	267.000	14,000.000	2,233.000		
Prev. Year's Sales:	2,705.077	0	-	11,236.060	2,237.001		
Total Prev. Year's Sales:	16,178.138	16,178.138	16,178.138	16,178.138	16,178.138		
% of Prev. Year's Sales:	17%	0%	0%	69%	14%		
Share of Next Year's PQs:	2,873.991	-	-	11,937.676	2,376.687		
Prev. Yr. Year-end Inv.:	1,651.419	0.004	-	2,794.036	732.888		
Proj. Exports Current Year:	-	-	-	1,442.306	-		
company est. sales current year	2,931.660	0.002	-	12,904.963	1,713.000		
Proj. Exports Next Year:	-	-	-	1,780.000	-		
Company's Proj. Inv. Current Yr.:	1,829.451	0.004	-	2,500.000	826.940		
DEA's Proj. Inv. Current Year:	1,815.759	0.006	267.000	2,446.767	1,252.888		
INITIAL MQs							
2/3 calculation	3,164.946	0.005	178.000	11,196.024	1,977.259		
Calc. Using Company's Inv.:	1,906.737	(0.004)	-	14,798.979	2,262.753		
Calc. Using DEA's Inv.:	1,920.429	(0.006)	(267.000)	14,852.212	1,836.805		
calc. using CFR 50% Inventory	2,096.790	(0.007)	(267.000)	15,363.637	1,962.998		
Further Calculation:	3,242.000	0.004	267.000	15,897.000	958.000		
MQ:	3,242.000	0.004	267.000	15,897.000	958.000		
Total Initial MQs:	20,364.004		+ others		=	20,364.004	

FURTHER CALCULATIONS

			Initial
Update numbers below			
		MQs 2008	19,596.004
		MQs 2009	18,761.006
		Final 2007	25,000.000
		Initial APQ	25,000.000
FDA est: APQ last year * est =	28700		

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2009 Initial Quota Worksheets**															
	3000															
Company:	(b)(4)															
Request:	3,000.000				-				12,800.000				4,100.000			
Current Year MQ:	1,500.000				350.000				16,000.000				3,000.000			
Prev. Yr. Year-end Inv.:	1,914.350				-				4,339.129				1,055.210			
Company's Proj. Inv. Current Yr.:	-				-				5,000.000				1,100.000			
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield
	4,045.570	methadone	3,196.000	79%	-	methadone	-	50%	12,371.134	methadone	12,000.000	97%	3,152.174	methadone	2,900.000	92%
total need	4,045.570				-				12,371.134				3,152.174			
INITIAL MQs																
total x 50% inventory - prev. YE	6,068.354				-				13,556.701				3,628.261			
MQ:	1,500.000				350.000				16,000.000				2,846.000			
Total Initial MQs:	20,696.000	+ others	0.004	=	20,696.004											

FURTHER CALCULATIONS

Update numbers below

(b)(4) now procures from (b)(4)

MQs 2008	20,850.004
MQs 2009	24,150.004
Final 2008	26,000.000
Initial APQ	26,000.000

last year methadone APQ =	25000	
last year methadone intermediate APQ =	26000	
ratio	1.04	
applied to recommended methadone APQ		1.04%
	26,270.400	

Initial Aggregate Production Quotas for 2009

BASIC CLASS: **2009 Initial Quota Worksheets**

PQ Total: 44,584.226 kg

FDA Est.: 6.50%

Company:	(b)(4) [redacted]					
Request:	540.000	800.000	22,000.000	16,500.000	-	Initial
Current Year MQ:	32.000	800.000	22,000.000	12,443.000	300.000	
Prev. Year's Sales:	-	193.046	19,456.565	7,910.651	2.500	
Total Prev. Year's Sales:	27,639.507	27,639.507	27,639.507	27,639.507	27,639.507	
% of Prev. Year's Sales:	0%	1%	70%	29%	0%	
Share of Next Year's PQs:	-	311.395	31,384.637	12,760.367	4.033	
Prev. Yr. Year-end Inv.:	-	891.144	6,970.804	9.000	-	
Proj. Exports Current Year:	-	-	428.025	-	-	
Proj. Exports Next Year:	-	-	375.000	-	-	
Company's est. sales current yr	-	165.000	21,966.565	8,900.000	400.000	
Company's Proj. Inv. Current Yr.:	-	866.763	7,484.324	5,920.000	102.500	
DEA's Proj. Inv. Current Year:	32.000	1,526.144	6,576.214	3,552.000	(100.000)	
INITIAL MQs						
2/3 calculation	21.333	1,127.429	19,313.869	8,301.333	200.000	
Calc. Using Company's Inv.:	-	(399.670)	39,967.631	13,220.550	(96.451)	
Calc. Using DEA's Inv.:	(32.000)	(1,059.051)	40,875.741	15,588.550	106.049	
Calc. using CFR 50% inventory	(40.000)	(1,470.175)	35,874.670	13,488.121	130.666	
Further Calculation:	32.000	780.000	24,000.000	8,873.000	240.000	
MQ:	32.000	780.000	24,000.000	8,873.000	240.000	
Total Initial MQs:	33,925.000	+ others	1.101	=	33,926.101	

FURTHER CALCULATIONS Initial

Update numbers below

(b)(4) [redacted] batch 32 kg

MQs 2008	35,577.301
MQs 2009	40,086.110
Final 2008	36,300.000
Initial APQ	35,000.000

FDA est: APQ last year * est= 38659.5

morphine(sale) initial

Initial Aggregate Production Quotas for 2009

BASIC CLASS: 2009 Initial Quota Worksheets

Company:	(b)(4)																
Request:	150				12500			Initial	50000				17300				2475
Current Year MQ:	0				11000				63000				20949				3000
Prev. Yr. Year-end Inv.:	0				1,587.819				17,337.218				3,190.732				40.401
Company's Proj. Inv. Current Yr.:	0				1,318.419				8,856.493				8,800.000				264.69
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	sell to other companies
(based on request)	65	codeine	52.000	80%					20,454.545	codeine	18,000.000	88%	16,363.636	codeine	14,400.000	88%	
	313	codeine for	250.000	80%	10,500.000	codeine for	10,500.000	100%	46,428.571	codein for co	39,000.000	84%	-	codeine for	-	88%	
					681.818	hydromorpl	300.000	44%	2,629.630	hydromorphc	1,420.000	54%					
					952.381	morphine s	800.000	84%	2,947.368	dihydromorpl	2,800.000	95%					
									10.000	noroxymorph	3.500	35%					
									23,714.286	noroxy for co	8,300.000	35%					
									-	nalbuphine		26%					
total need	377.500				12,134.199				96,184.401				16,363.636				
INITIAL MQs																	
total x 50% inventory - prev. YEI	566.250				16,882.880				135,420.108				15,745.455				
MQ:	163.500				11.000.000				63,000.000				16,500.000				3,000.000
Total Initial MQs:	95,663.500	+ others		=	95,663.500						-						
FURTHER CALCULATIONS						MQs 2008			98,112.500								
						MQs 2009		Initial	82,669.000								
						Final 2008			100,000.000								
						Initial APQ			100,000.000								

Company:	(b)(4)															
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield
(based on granted)	65	codeine	52.000	80%	450.000	codeine	450.000	100%	20,454.545	codeine	18,000.000	88%	11,363.636	codeine	10,000.000	88%
	0	codeine for	-	80%	13,663.636	codeine for	6,012.000	44%	38,757.143	codeing for c	32,556.000	84%	-	codeine for	-	88%
					357.143	hydromorpl	300.000	84%	2,842.105	dihydromorpl	2,700.000	95%				
									10.000	noroxymorph	3.500	35%				
									25,714.286	noroxy for co	9,000.000	35%				
									-	nalbuphine		26%				
									2,174.074	hydromorphc	1,174.000	54%				
total need	65.000				14,470.779				89,952.153				11,363.636			
total x 50% inventory - prev. YEI	97.500				20,387.750				126,071.737				8,245.455			
MQ:																

###

Morph Mg for Conversion Unit

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2009 Initial Quota Worksheets**								
PQ Total:	101,096.615 kg						**FDA Est.:**	10.80%	
Company:	(b)(4)								
Request:	3,934.000	-	1,800.000	28,000.000	22,400.000	-	31,525.000	560.000	
Current Year MQ:	750.000	-	900.000	29,011.000	23,463.000	-	38,173.000	700.000	
Prev. Year's Sales:	-	-	303.287	22,780.491	14,818.000	21.400	23,429.268	29.049	
Total Prev. Year's Sales:	68,417.740	68,417.740	68,417.740	68,417.740	68,417.740	68,417.740	68,417.740	68,417.740	
% of Prev. Year's Sales:	0%	0%	0%	33%	22%	0%	34%	0%	
Share of Next Year's PQs:	-	-	448.148	33,661.307	21,895.632	31.621	34,619.964	42.924	
Prev. Yr. Year-end Inv.:	-	-	817.110	8,234.335	7,702.191	-	1,727.223	292.196	
Proj. Exports Current Year:	-	-	-	13.050	-	-	50.000	-	
estimated sales current year:	92.500	-	350.000	22,106.380	21,850.000	-	25,180.000	59.900	
Proj. Exports Next Year:	-	-	-	17.400	-	-	5,000.000	-	
Company's Proj. Inv. Current Yr.:	7.600	-	784.330	7,427.975	7,843.360	21.400	6,000.000	647.961	
DEA's Proj. Inv. Current Year:	657.500	-	1,367.110	15,125.905	9,315.191	-	14,670.223	932.296	-
INITIAL MQs									
2/3 calculation	500.000	-	1,144.740	24,830.223	20,776.794	-	26,600.149	661.464	74,513.370
Calc. Using Company's Inv.:	(7.600)	-	(201.737)	36,349.124	20,620.961	19.708	44,005.953	(592.160)	
Calc. Using DEA's Inv.:	(657.500)	-	(784.517)	28,651.194	19,149.130	41.108	35,335.730	(876.495)	
calc. using CFR 50% inventory	(821.875)	-	(1,072.880)	28,864.375	19,430.051	44.877	30,794.493	(1,104.453)	
Further Calculation:	750.000	-	883.000	24,000.000	27,700.000	-	21,109.000	450.000	
MQ:	750.000	-	883.000	24,000.000	27,700.000	-	21,109.000	450.000	
Total Initial MQs:	74,892.000	+ others	3.061	=	74,895.061				

FURTHER CALCULATIONS

Initial

Update numbers below

(b)(4) pliot 5@30; plant 3@200 kg

MQs 2008	92,999.061
MQs 2009	88,322.063
Final 2008	94,000.000
Initial APQ	94,000.000

FDA est: APQ last year * est= 104152

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2009 Initial Quota Worksheet**		9652					
PQ Total:	1,906.780 kg						**FDA Est.:**	-15.4%
Company:	(b)(4)							
Request:	0.001	0.060	75.000	376.000	2,000.000	3.000	-	Initial
Current Year MQ:	0.001	0.060	98.000	139.000	1,830.000	2.000	500.000	
Prev. Year's Sales:	-	0.003	-	93.940	946.973	-	-	
Total Prev. Year's Sales:	1,202.003	1,202.003	1,202.003	1,202.003	1,202.003	1,202.003	1,202.003	
% of Prev. Year's Sales:	0%	0%	0%	8%	79%	0%	0%	
Share of Next Year's PQs:	-	0.005	-	149.020	1,502.217	-	-	
Prev. Yr. Year-end Inv.:	-	0.206	-	25.731	216.224	2.113	-	
Proj. Exports Current Year:	-	-	-	-	0.083	-	-	
estimated current year sales:	0.001	0.004	-	100.000	1,236.667	1.300	-	
Proj. Exports Next Year:	-	-	-	-	0.083	-	-	
Company's Proj. Inv. Current Yr.:	0.001	0.202	-	11.437	447.853	0.300	-	
DEA's Proj. Inv. Current Year:	-	0.262	98.000	64.731	809.474	2.813	500.000	
INITIAL MQs								
2/3 calculation	0.001	0.177	65.333	109.821	1,364.149	2.742	333.333	
Calc. Using Company's Inv.:	(0.001)	(0.195)	-	212.094	1,805.555	(0.300)	-	
Calc. Using DEA's Inv.:	-	(0.255)	(98.000)	158.800	1,443.934	(2.813)	(500.000)	
Calc. using CFR 50% inventory	-	(0.321)	(122.500)	128.847	1,102.672	(3.516)	(625.000)	
Further Calculation:	0.001	0.060	98.000	300.000	1,560.000	2.000	500.000	
MQ:	0.001	0.060	98.000	300.000	1,560.000	2.000	500.000	
Total Initial MQs:	2,362.000	+ others		=	2,362.000			

FURTHER CALCULATIONS Initial

Update numbers below

(b)(4) lab runs 20@0.25; pliot 2 @31

(b)(4) demonstration and validation batches 4@ 125 = 500

MQs 2008	2,569.061
MQs 2009	3,014.063
Final 2008	2,570.000
Initial APQ	2,570.000

PQ * 1.5 - YEI = 1,384.89

FDA est: APQ last year * est = 2174.22

Oxymorphone Initial

Initial Aggregate Production Quotas for 2009

BASIC CLASS: 2009 Initial Quota Worksheets 9333

Company:	(b)(4)																							
Request:	15,208.000				30.000			Initial	43,000.000				14,600.000				19,750.000				3.000			
Current Year MQ:	3,500.000				10.000				50,305.000				21,000.000				7,000.000				-			
Prev. Yr. Year-end Inv.:	103.650				48.080				8,482.033				7,832.600				3,439.900				1,187.530			
Company's Proj. Inv. Current Yr.:	329.884				48.080				8,498.120				4,100.000				3,098.686				388.607			
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield
(based on request)	5672	oxycodone	3,934.0	67%	2,556.818	oxycodone	1,800.0	70%	35,000.000	oxycodone	28,000.0	80%	28,000.000	oxycodone	22,400.0	80%	0	oxycodone	-	88%	1714	hydromorphone	1,500.0	88%
	313	codeine for	250.0	80%																				
total need	6,184.142				2,556.818				35,000.000				28,000.000				-				1,714.266			
INITIAL MQs																								
total x 50% inventory - prev. YEI	8,946.329				3,787.147				44,003.880				37,900.000				(3,098.686)				2,204.822			
MQ:	3,411.000				6,814.000				35,000.000				25,000.000				20,000.000							
Total Initial MQs:	90,225.000	+ others	0.030	=	90,225.030												(supplies (b)(4)							

FURTHER CALCULATIONS

Update numbers below

		MQs 2008	100,815.032
		MQs 2009	117,381.030
		Final 2008	126,000.000
applyig FDA est of Oxy to thebaine:	139608	Initial APQ Initial	126,000.000

oxycodone APQ = 88000

using (b)(4) rough approximation of thebaine needed = APQ/0.69 127,536.232

keep same (oxycodone not changed)

###

Initial Aggregate Production Quotas for 2009

Opiates	2009 Initial Quota Worksheets				
Company (requests)	(b)(4)				
morphine for sale	540.000	800.000	22,000.000	16,500.000	-
morphine for conversion	150.000	12,500.000	50,000.000	17,300.000	2,475.000
total morphine	690.000	13,300.000	72,000.000	33,800.000	2,475.000
PQ opium for morphine	-	-	1,050.000	-	-
PQ CPS (AMA) for morphine	612.000	9,500.000	43,000.000	37,625.000	3,300.000
total morphine PQ	612.000	9,500.000	44,050.000	37,625.000	3,300.000
difference	78.000	3,800.000	27,950.000	(3,825.000)	(825.000)
thebaine	15,208.000	30.000	43,000.000	14,600.000	19,750.000
PQ CPS (ATA) for thebaine	15,462.000	5,000.000	40,000.000	108,000.000	18,000.000
difference	(254.000)	(4,970.000)	3,000.000	(93,400.000)	1,750.000
Company (grant)	(b)(4)				
morphine for sale	32.000	600.000	19,000.000	11,000.000	-
morphine for conversion	-	9,100.000	50,000.000	15,100.000	2,475.000
total morphine	32.000	9,700.000	69,000.000	26,100.000	2,475.000
PQ opium for morphine	-	-	1,050.000	-	-
PQ CPS (AMA) for morphine (need)	32.000	9,700.000	67,950.000	26,100.000	2,475.000
Grant					
thebaine (grant)	-	30.000	43,000.000	14,600.000	4,100.000
PQ CPS (ATA) for thebaine (need)					

2010 Proposed Initial Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- The attached Federal Register notice, prepared for your signature, proposes initial year 2010 aggregate production quotas (APQ) for schedules I and II controlled substances for which the United States has medical, scientific, industrial, export and reserve stock requirements. Also attached is a list of the 2007, 2008 and 2009 APQs for these substances for comparison.

- The initial 2010 APQ values are recommended at the corresponding 2009 aggregate levels. The following points provide brief explanations of the proposed APQs for selected substances:

Schedule I substances

- The small quantities listed for schedule I substances are manufactured mainly for use in analytical reference standards.

- Gamma hydroxybutyric acid (GHB) is used to manufacture Xyrem, a schedule III product used to treat narcolepsy. Xyrem is marketed by (b)(4)

- Marihuana plant material is being grown by the National Center for the Development of Natural Products, associated with the University of Mississippi, for purposes of extracting tetrahydrocannabinol (THC).

- Tetrahydrocannabinols (THC) is used to make the schedule III product Marinol and is also being used for the development of new products. The APQ for THC represents individual manufacturing quotas for synthetic THC, however one registrant, (b)(4) is utilizing naturally derived THC (obtained from marihuana cultivated at the University of Mississippi) for their product development of generic Marinol.

Schedule II substances

- Morphine (for conversion) is used to manufacture codeine, dihydromorphine, hydromorphone and noroxymorphone.

- Noroxymorphone (for conversion) is used to manufacture various "nal" (narcotic antagonist) drugs, specifically naloxone and naltrexone.

- Oxymorphone (for conversion) is used to manufacture noroxymorphone (for conversion).

- Tapentadol is in the process of becoming a schedule II controlled substance. On February 17, 2009, a Federal Register (74 FR 7386) was published proposing to place tapentadol in schedule II of the CSA.

Attachment

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-318P]

Controlled Substances:
Proposed Aggregate Production Quotas for 2010

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed year 2010 aggregate production quotas.

SUMMARY: This notice proposes initial year 2010 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Comments or objections must be received on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-318P" on all written and electronic correspondence. Written comments should be sent to the DEA Headquarters, Attn: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. § 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR § 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR § 0.104.

The proposed year 2010 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2010 to provide adequate supplies of each substance for: the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the year 2010 aggregate production quotas, the Deputy Administrator considered the following factors: total actual 2008 and estimated 2009 and 2010 net disposals of each substance by all manufacturers; estimates of 2009 year-end inventories of each substance and of any substance manufactured from it and trends in accumulation of such inventories; product development requirements of both bulk and finished dosage form manufacturers; projected demand as indicated by procurement quota applications filed pursuant to 21 CFR § 1303.12; and other pertinent information.

Pursuant to 21 CFR § 1303, the Deputy Administrator of the DEA will adjust the 2010 aggregate production quotas and individual manufacturing quotas allocated for the year based

upon 2009 year-end inventory and actual 2009 disposition data supplied by quota recipients for each basic class of schedule I or II controlled substance.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA of 1970 (21 U.S.C. § 826), and delegated to the Administrator of the DEA by 28 CFR § 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR § 0.104, the Deputy Administrator hereby proposes that the year 2010 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Established 2010 Quotas
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	25 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10 g
3,4-Methylenedioxymethamphetamine (MDMA)	20 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	27 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	5 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Aminorex	2 g
Benzylmorphine	2 g

Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	3 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	3,000 g
Dihydromorphine	2,549,000 g
Dimethyltryptamine	3 g
Gamma-hydroxybutyric acid	24,200,000 g
Heroin	20 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	1 g
Lysergic acid diethylamide (LSD)	10 g
Marihuana	4,500,000 g
Mescaline	7g
Methaqualone	5 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	7 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	16 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Psilocybin	7 g
Psilocyn	7 g
Tetrahydrocannabinols	312,500 g
Thiofentanyl	2 g
Trimeperidine	2 g

Basic Class – Schedule II	Established 2010 Quotas
1-Phenylcyclohexylamine	2 g
1-piperdinocyclohexanecarbonitrile	2 g
Alfentanil	8,000 g
Alphaprodine	2 g
Amobarbital	3 g
Amphetamine (for sale)	17,000,000 g
Amphetamine (for conversion)	5,000,000 g
Cocaine	247,000 g
Codeine (for sale)	39,605,000 g
Codeine (for conversion)	65,000,000 g
Dextropropoxyphene	106,000,000 g
Dihydrocodeine	1,200,000 g
Diphenoxylate	947,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	55,000,000 g
Hydromorphone	3,300,000 g
Isomethadone	2 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	10,000 g
Lisdexamfetamine	6,200,000 g
Meperidine	8,600,000 g
Meperidine Intermediate-A	3 g
Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	1 g
Methadone (for sale)	25,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
[680,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,405,000 grams for methamphetamine mostly for conversion to a schedule III product; and 45,000 grams for methamphetamine (for sale)]	
Methylphenidate	50,000,000 g
Morphine (for sale)	35,000,000 g
Morphine (for conversion)	100,000,000 g
Nabilone	9,002 g

Noroxymorphone (for sale)	10,000 g
Noroxymorphone (for conversion)	9,000,000 g
Opium (powder)	230,000 g
Opium (tincture)	1,050,000 g
Oripavine	15,000,000 g
Oxycodone (for sale)	77,560,000 g
Oxycodone (for conversion)	3,400,000 g
Oxymorphone (for sale)	2,000,000 g
Oxymorphone (for conversion)	12,000,000 g
Pentobarbital	28,000,000 g
Phenazocine	1 g
Phencyclidine	20 g
Phenmetrazine	2 g
Phenylacetone	1 g
Racemethorphan	2 g
Remifentanil	500 g
Secobarbital	67,000 g
Sufentanil	10,300 g
Tapentadol	519,000 g
Thebaine	126,000,000 g

The Deputy Administrator further proposes that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR §§ 1308.11 and 1308.12 be established at zero.

All interested persons are invited to submit their comments in writing or electronically regarding this proposal following the procedures in the "addresses" section of this document. A person may object to or comment on the proposal relating to any of the above-mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief.

In the event that comments or objections to this proposal raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public

hearing by notice in the Federal Register, summarizing the issues to be heard and setting the time for the hearing.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. § 601 et seq. The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary

under the provisions of the Unfunded Mandates Reform Act of 1995.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated:

Michele M. Leonhart
Deputy Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
CC:_____
CCR:_____
ODE:_____
ODE/D:(b)(6) _____
ODEQ:(b)(6) _____
ODEQ:(b)(6) 03-19-09
S:\ODE\Fed Reg\2010 Proposed Aggregate Production Quota
Webcims # ODE-09-022

Changes in the 2010 Initial Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Initial	Final Revised	Initial	Final Revised	Proposed Initial	Initial
Schedule I:	**2008**	**2008**	**2009**	**2009**	**2010**	**2010**
4-Methoxyamphetamine	77	77	27	27	27	77
Alpha-methyltryptamine (AMT)	5	5	0	0	0	2
Dihydromorphine	2,549,000	2,549,000	2,549,000	3,132,000	2,549,000	3,300,000
Lysergic Acid Diethylamide	61	61	10	10	10	15
Methaqualone	10	10	5	5	5	7
Schedule II:	**2008**	**2008**	**2009**	**2009**	**2010**	**2010**
Amphetamine (for conversion)	5,000,000	5,000,000	5,000,000	7,500,000	5,000,000	6,500,000
Isomethadone	2	2	2	2	2	11
Lisdexamfetamine	6,200,000	6,200,000	6,200,000	8,200,000	6,200,000	9,000,000
Methamphetamine	3,130,000	3,130,000	3,130,000	3,130,000	3,130,000	3,130,000
levo-desoxyephedrine	680,000	680,000	680,000	680,000	680,000	750,000
methamphetamine (for conversion)	2,405,000	2,405,000	2,405,000	2,405,000	2,405,000	2,331,000
methamphetamine (for sale)	45,000	45,000	45,000	45,000	45,000	49,000
Oxycodone (for sale)	70,000,000	70,000,000	77,560,000	94,000,000	77,560,000	86,000,000
Oxycodone (for conversion)	4,820,000	4,820,000	3,400,000	4,500,000	3,400,000	4,000,000
Oxymorphone (for sale)	2,400,000	2,000,000	2,000,000	2,570,000	2,000,000	2,570,000
Tapentadol	0	0	0	0	519,000	0

2010 Initial APQ Comments

Drug	Company	Comment	Response	Proposed	Established	Change
3,4-methylenedioxyamphetamine	(b)(4)	increase APQ	adequate APQ - no increase	0.025	0.025	-
3,4-methylenedioxyethylamphetamine		increase APQ	adequate APQ - no increase	0.010	0.010	-
3,4-methylenedioxymethamphetamine		increase APQ	adequate APQ - no increase	0.020	0.020	-
Alfentanil		increase APQ	adequate APQ - no increase	8.000	8.000	-
Amphetamine		increase APQ	adequate APQ - no increase	17,000.000	17,000.000	-
Codeine (for sale)		increase APQ	adequate APQ - no increase	39,605.000	39,605.000	-
Codeine (for conversion)		increase APQ increase APQ	adequate APQ - no increase	65,000.000	65,000.000	-
Dihydromorphine		increase APQ	increase APQ	2,549.000	3,300.000	751.000
Fentanyl		increase APQ	adequate APQ - no increase	1,428.000	1,428.000	-
gamma hydroxybutyric acid		increase APQ increase APQ	adequate APQ - no increase	24,200.000	24,200.000	-
Hydrocodone (for sale)		increase APQ	adequate APQ - no increase	55,000.000	55,000.000	-
Hydromorphone		increase APQ	adequate APQ - no increase	3,300.000	3,300.000	-
Isomethadone		increase APQ	increase APQ	0.002	0.011	0.009
Levo-desoxyephedrine		increase APQ	increase APQ	680.000	750.000	70.000
Levorphanol		increase APQ	adequate APQ - no increase	10.000	10.000	-
Lisdexamfetamine		increase APQ	increase APQ	6,200.000	9,000.000	2,800.000
Methamphetamine (for sale)		increase APQ	increase APQ	45.000	49.000	4.000
Morphine (for conversion)		increase APQ	adequate APQ - no increase	100,000.000	100,000.000	-
Nabilone		increase APQ increase APQ	adequate APQ - no increase	9.002	9.002	-
Opium (tincture)		increase APQ	adequate APQ - no increase	1,050.000	1,050.000	-
Oxycodone (for sale)		increase APQ increase APQ	increase APQ (2009 revised increased)	77,560.000	88,000.000	##########
Oxycodone (for conversion)		increase APQ	increase APQ	3,400.000	4,000.000	600.000
Oxymorphone (for sale)		increase APQ	increase APQ (2009 revised increased)	2,000.000	2,570.000	570.000
Remifentanil		increase APQ	adequate APQ - no increase	0.500	0.500	-
Sufentanil		increase APQ increase APQ	adequate APQ - no increase	10.300	10.300	-
Tapentadol		increase APQ increase APQ	decrease - no domestic manufacturing	519.000	-	(519.000)
Tetrahydrocannabinols		increase APQ increase APQ	adequate APQ - no increase	312.500	312.500	-
Thebaine		increase APQ increase APQ	adequate APQ - no increase	126,000.000	126,000.000	-

Number of Companies commenting: **12** (one non-registrant)
Number of drugs commented on: **28**

Additional Changes:

Drug	Response	Proposed	Established	Change
Alpha-Methyltryptamine (AMT)	new applications; increase	-	0.002	0.002
Amphetamine (for conversion)	increase in lisdexamfetamine APQ	5,000.000	6,500.000	1,500.000
4-methoxyamphetamine	new applications; increase	0.027	0.077	0.050
Lysergic Acid Diethylamide	new applications; increase	0.010	0.015	0.005
Methamphetamine (for conversion)	decreased to keep overall methamphetamine APQ the same	2,405.000	2,331.000	(74.000)
Methaqualone	new applications; increase	0.005	0.007	0.002
Phenylacetone	new applications; increase	0.001		

	Justification
3,4-methylenedioxyamphetamine	adequate, APQ >= requested MQ
3,4-methylenedioxyethylamphetamine	adequate, APQ >= requested MQ
3,4-methylenedioxymethamphetamine	adequate (b)(4) requested YEI more than authorized
Alfentanil	adequate, APQ > requested MQ
Amphetamine	adequate APQ
Codeine (for sale)	adequate, APQ > requested MQ
Codeine (for conversion)	adequate, APQ > requested MQ
Dihydromorphine	increase APQ (ensure precursor for hydromorphone available)
Fentanyl	adequate, APQ 76% of requested MQ ((b)(4) estimate is out of skew (b)(4) only 15% sourced by them)
gamma hydroxybutyric acid	adequate, APQ, no justification for increase
Hydrocodone (for sale)	adequate
Hydromorphone	adequate, APQ 93% of requested MQ
Isomethadone	increase APQ - new requirement BI
Levo-desoxyephedrine	
Levorphanol	adequate, APQ > Requested MQ
Lisdexamfetamine	increase APQ
Methamphetamine (for sale)	increase APQ - new manufacturer (b)(4)
Morphine (for conversion)	adequate, APQ > requested MQ
Nabilone	adequate, APQ > requested MQ
Opium (tincture)	adequate, APQ > requested MQ
Oxycodone (for sale)	adequate
Oxycodone (for conversion)	increase APQ
Oxymorphone (for sale)	adequate (b)(4)
Remifentanil	adequate ((b)(4) requesting too much YEI/MQ)
Sufentanil	adequate, APQ > requested MQ
Tapentadol	decrease to zero - no domestic manufacturing
Tetrahydrocannabinols	adequate, APQ > requested MQ
Thebaine	adequate, APQ > requested MQ

(b)(6)

From: (b)(4),(b)(6)
Sent: 22 June, 2009 15:06
To: DeaDiversionPolicy
Subject: Docket No. DEA-318P

(b)(4) Docket No. DEA-318P.pdf (5...

Attached are (b)(4) comments on the 2010 proposed aggregate production quotas. We are submitting new DEA Form's 189 and 250, as appropriate.

Regards

(b)(6)
(b)(4)

If the reader of this email is not the intended recipient(s), please be advised that any dissemination, distribution or copying of this information is strictly prohibited. (b)(4) has its main place of business at

(b)(4)

While (b)(4) aims to keep its network free from viruses you should note that we are unable to scan certain emails, particularly if any part is encrypted or password-protected, and accordingly you are strongly advised to check this email and any attachments for viruses. The company shall NOT ACCEPT any liability with regard to computer viruses transferred by way of email.

Please note that your communication may be monitored in accordance with (b)(4) internal policy documentation.

(b)(4)

CONFIDENTIAL

SENT VIA E-MAIL

June 22, 2009

DEA Headquarters
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Docket No. DEA-318P

Dear Sirs:

(b)(4) manufacturing registration (b)(4),(b)(7)(E) would like to comment on the Proposed 2010 Aggregate Production Quota for various products as published in the May 21, 2009 Federal Register.

We reviewed the DEA Form 189's and DEA Form 250's that were submitted to the DEA in April of this calendar year. We feel the proposed quantities for the material mentioned below is not sufficient to provide for adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements, and that the quotas should be increased to cover our requests. The forms are for the basic class of items are attached:

Codeine (for Sale), a revised 189 dated 06/19/09
Codeine (for Conversion), a revised 189 dated 06/19/09
Morphine (for Conversion), a revised 189 dated 06/19/09
Oxycodone (for Sale), a revised 189 dated 06/19/09
Remifentanil, a revised 189 dated 06/19/09
Sufentanil, a revised 189 dated 06/19/09
Tetrahydrocannabinol, a revised 189 dated 06/19/09
Thebaine, a revised 189 dated 06/19/09
Concentrate of Poppy Straw (AMA), a revised 250 dated 06/19/09
Concentrate of Poppy Straw (ATA), a revised 250 dated 06/19/09

Thank you for your consideration in this matter. Should you have any questions, please contact me at (b)(6)

The information in this letter and on the attached forms is considered confidential and proprietary and should not be released under the Freedom of Information Act per 5 USC Sec 552(b)(4).

Very truly yours,

(b)(6)

DEA Materials Control Manager

(b)(4)

U.S. Department of Justice
Drug Enforcement Administration

CONFIDENTIAL APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No individual manufacturing quota may be issued unless a completed application form has been received, 21 CFR 1303.22	*OMB Approval No. 1117-0006*

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA-189)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Codeine (for Sale)	II	9150

4. NAME AND ADDRESS OF REGISTRANT *(Include No., Street, City, State and ZIP Code)*	5. YEAR FOR WHICH QUOTA IS REQUESTED
(b)(4)	2010
	6. DEA REGISTRATION NUMBER (b)(4);(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. *(Include extension)*	9. FAX NO.	10. E-MAIL ADDRESS
(b)(6)			(b)(4);(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2007)	1st PRECEDING YEAR (2008)	CURRENT YEAR (2009)	(2010)
	450,000 grams	450,000 grams	450,000 grams	750,000 grams

12. PRODUCTION DATA	2ND PRECEDING YEAR	1ST PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	215,160	182,186	228,052	260,375
b. In-process material	0	0	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a + b + c)	215,160	182,186	228,052	260,375
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	17,381	403	370,000	740,000
b. Exports	0	0	0	0
TOTAL (a + b)	17,381	97,.995	370,000	740,000
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	33	65,021	415,866	772,323
b. Importation	0	0	0	0
TOTAL (a + b)	33	65,021	415,866	772,323

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	AUTHORITY TO MARKET THIS PRODUCT	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
			2ND PRECEDING YEAR	1ST PRECEDING YEAR	CURRENT YEAR	

14. REMARKS

SIGNATURE OF APPLICANT	PRINT OR TYPE NAME AND TITLE OF SIGNER	DATE
(b)(6)	(b)(6) DEA MATERIALS CONTROL MANAGER	JUNE 19, 2009

U.S. Department of Justice
Drug Enforcement Administration

CONFIDENTIAL APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No individual manufacturing quota may be issued unless a completed application form has been received, 21 CFR 1303.22	OMB Approval No. 1117-0006

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA-189)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Codeine (for Conversion)	II	9050

4. NAME AND ADDRESS OF REGISTRANT (Include No., Street, City, State and ZIP Code)	5. YEAR FOR WHICH QUOTA IS REQUESTED	6. DEA REGISTRATION NUMBER
(b)(4)	2010	(b)(4);(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. (Include extension)	9. FAX NO.	10. E-MAIL ADDRESS
(b)(6)			(b)(4);(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2007)	1st PRECEDING YEAR (2008)	CURRENT YEAR (2009)	(2010)
	4,400,000 grams	6,870,000 grams	7,500,000 grams	13,000,000 grams

12. PRODUCTION DATA	2ND PRECEDING YEAR	1ST PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	1,991,980	2,216,815	4,170,034	4,306,242
b. In-process material	441,998	0	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a + b + c)	2,433,978	2,216,815	4,170,034	4,306,242
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	403	217,164	9,046,781	12,863,792
b. Exports	0	0	0	0
TOTAL (a + b)	403	217,164	9,046,781	12,863,792
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	458,858	0	11,000,000	13,000,000
b. Importation	0	0	0	0
TOTAL (a + b)	458,858	0	11,000,000	13,000,000

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	AUTHORITY TO MARKET THIS PRODUCT	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
			2ND PRECEDING YEAR	1ST PRECEDING YEAR	CURRENT YEAR	
Hydrocodone		9193	2,759,368	0	4,935,823	53%
Codeine (for sale)		9050	142,171	65,600	460,600	91%
Oxycodone		9143	0	0	3,650,358	TBD

14. REMARKS

SIGNATURE OF APPLICANT	PRINT OR TYPE NAME AND TITLE OF SIGNER	DATE
(b)(6)	(b)(6) DEA MATERIALS CONTROL MANAGER	JUNE 19, 2009

DEA FORM 189 (May 2007) ALL PREVIOUS EDITIONS ARE OBSOLETE.

U.S. Department of Justice
Drug Enforcement Administration

CONFIDENTIAL APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No individual manufacturing quota may be issued unless a completed application form has been received, 21 CFR 1303.22	OMB Approval No. 1117-0006

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA-189)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Morphine (for Conversion)	II	9300

4. NAME AND ADDRESS OF REGISTRANT (Include No., Street, City, State and ZIP Code)	5. YEAR FOR WHICH QUOTA IS REQUESTED
(b)(4)	2010
	6. DEA REGISTRATION NUMBER: (b)(4);(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. (Include extension)	9. FAX NO.	10. E-MAIL ADDRESS
(b)(6)			(b)(4);(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2007)	1st PRECEDING YEAR (2008)	CURRENT YEAR (2009)	(2010)
	7,192,000 grams	5,000,000 grams	11,000,000 grams	14,500,000 grams

12. PRODUCTION DATA	2ND PRECEDING YEAR	1ST PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	470,233	1,280,170	2,658,351	3,324,840
b. In-process material	0	308,329	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a + b + c)	470,233	1,588,499	2,658,351	3,324,840
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	659,114	966,712	9,930,148	13,833,511
b. Exports	0	0	0	0
TOTAL (a + b)	659,114	966,712	9,930,148	13,833,511
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	1,113,755	2,084,970	11,000,000	14,500,000
b. Importation	0	0	0	0
TOTAL (a + b)	1,113,755	2,084,970	11,000,000	14,500,000

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	AUTHORITY TO MARKET THIS PRODUCT	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
			2ND PRECEDING YEAR	1ST PRECEDING YEAR	CURRENT YEAR	
Codeine (for conv)		9050	458,705	0	9,046,781	100%
Morphine (for sale)		9300	0	867,009	484,860	84%
Hydromorphone		9150	199,339	99,640	398,507	44%

14. REMARKS

SIGNATURE OF APPLICANT	PRINT OR TYPE NAME AND TITLE OF SIGNER	DATE
(b)(6)	(b)(6) DEA MATERIALS CONTROL MANAGER	JUNE 19, 2009

U.S. Department of Justice
Drug Enforcement Administration

CONFIDENTIAL

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No individual manufacturing quota may be issued unless a completed application form has been received, 21 CFR 1303.22	*OMB Approval No. 1117-0006*

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA-189)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Oxycodone (for Sale)	II	9143

4. NAME AND ADDRESS OF REGISTRANT *(Include No., Street, City, State and ZIP Code)*	5. YEAR FOR WHICH QUOTA IS REQUESTED
(b)(4)	2010
	6. DEA REGISTRATION NUMBER (b)(4);(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. *(Include extension)*	9. FAX NO.	10. E-MAIL ADDRESS
(b)(6)			(b)(4);(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2007)	1st PRECEDING YEAR (2008)	CURRENT YEAR (2009)	(2010)
	790,000 grams	892,000 grams	800,000 grams	2,800,000 grams

12. PRODUCTION DATA	2nd PRECEDING YEAR	1st PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	434,330	14,740	670,294	712,222
b. In-process material	0	805,554	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a + b + c)	434,330	820,294	670,294	712,222
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	211,026	448,289	1,350,000	2,700,000
b. Exports	0	0	0	0
TOTAL (a + b)	211,026	448,289	1,350,000	2,700,000
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	96,206	834,259	1,200,000	2,741,928
b. Importation	0	0	0	0
TOTAL (a + b)	96,206	834,259	1,200,000	2,741,928

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	AUTHORITY TO MARKET THIS PRODUCT	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
			2nd PRECEDING YEAR	1st PRECEDING YEAR	CURRENT YEAR	

14. REMARKS

SIGNATURE OF APPLICANT	PRINT OR TYPE NAME AND TITLE OF SIGNER	DATE
(b)(6)	(b)(6) DEA MATERIALS CONTROL MANAGER	JUNE 19, 2009

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APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No individual manufacturing quota may be issued unless a completed application form has been received, 21 CFR 1303.22	*OMB Approval No. 1117-0006*

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA–189)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Remifentanil	II	9739

4. NAME AND ADDRESS OF REGISTRANT *(Include No., Street, City, State and ZIP Code)*	5. YEAR FOR WHICH QUOTA IS REQUESTED
(b)(4)	2010
	6. DEA REGISTRATION NUMBER (b)(4);(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. *(Include extension)*	9. FAX NO.	10. E-MAIL ADDRESS
(b)(6)			(b)(4);(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2007)	1st PRECEDING YEAR (2008)	CURRENT YEAR (2009)	(2010)
	0 grams	0 grams	0 grams	1,200 grams

12. PRODUCTION DATA	2ND PRECEDING YEAR	1ST PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	0	0	100	300
b. In-process material	0	0	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a + b + c)	0	0	100	300
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	0	0	200	1,000
b. Exports	0	0	0	0
TOTAL (a + b)	0	0	200	1,000
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	0	0	300	1,200
b. Importation	0	0	0	0
TOTAL (a + b)	0	0	300	1,200

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	AUTHORITY TO MARKET THIS PRODUCT	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
			2ND PRECEDING YEAR	1ST PRECEDING YEAR	CURRENT YEAR	

14. REMARKS

SIGNATURE OF APPLICANT	PRINT OR TYPE NAME AND TITLE OF SIGNER	DATE
(b)(6)	(b)(6) DEA MATERIALS CONTROL MANAGER	JUNE 19, 2009

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APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No individual manufacturing quota may be issued unless a completed application form has been received, 21 CFR 1303.22	*OMB Approval No. 1117-0006*

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA-189)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Sufentanil	II	9740

4. NAME AND ADDRESS OF REGISTRANT *(Include No., Street, City, State and ZIP Code)*	5. YEAR FOR WHICH QUOTA IS REQUESTED
(b)(4)	2010
	6. DEA REGISTRATION NUMBER: (b)(4);(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. *(Include extension)*	9. FAX NO.	10. E-MAIL ADDRESS
(b)(6)			(b)(4);(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2007)	1st PRECEDING YEAR (2008)	CURRENT YEAR (2009)	(2010)
	900 grams	800 grams	600 grams	600 grams

12. PRODUCTION DATA	2ND PRECEDING YEAR	1ST PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	442	419	457	457
b. In-process material	230	536	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a + b + c)	672	955	457	457
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	374	253	498	600
b. Exports	0	0	0	0
TOTAL (a + b)	374	253	498	600
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	230	536	0	600
b. Importation	0	0	0	0
TOTAL (a + b)	230	536	0	600

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	AUTHORITY TO MARKET THIS PRODUCT	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
			2ND PRECEDING YEAR	1ST PRECEDING YEAR	CURRENT YEAR	

14. REMARKS

SIGNATURE OF APPLICANT	PRINT OR TYPE NAME AND TITLE OF SIGNER	DATE
(b)(6)	(b)(6) DEA MATERIALS CONTROL MANAGER	JUNE 19, 2009

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APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No individual manufacturing quota may be issued unless a completed application form has been received, 21 CFR 1303.22	*OMB Approval No. 1117-0006*

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA-189)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Thebaine	II	9333

4. NAME AND ADDRESS OF REGISTRANT *(Include No., Street, City, State and ZIP Code)*	5. YEAR FOR WHICH QUOTA IS REQUESTED
(b)(4)	2010
	6. DEA REGISTRATION NUMBER: (b)(4);(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. *(Include extension)*	9. FAX NO.	10. E-MAIL ADDRESS
(b)(6)			(b)(4);(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2007)	1st PRECEDING YEAR (2008)	CURRENT YEAR (2009)	(2010)
	0 grams	0 grams	0 grams	2,500,000 grams

12. PRODUCTION DATA	2ND PRECEDING YEAR	1ST PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	48,080	48,080	0	360,000
b. In-process material	0	0	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a + b + c)	48,080	48,080	0	360,000
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	0	0	58,080	2,140,000
b. Exports	0	0	0	0
TOTAL (a + b)	0	0	58,080	2,140,000
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	0	0	10,000	2,500,000
b. Importation	0	0	0	0
TOTAL (a + b)	0	0	10,000	2,500,000

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	AUTHORITY TO MARKET THIS PRODUCT	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
			2ND PRECEDING YEAR	1ST PRECEDING YEAR	CURRENT YEAR	
Oxycodone		9143	0	0	48,080	TBD
Buprenorphine		9064	0	0	10,000	TBD

14. REMARKS

SIGNATURE OF APPLICANT	PRINT OR TYPE NAME AND TITLE OF SIGNER	DATE
(b)(6)	(b)(6) DEA MATERIALS CONTROL MANAGER	JUNE 19, 2009

U.S. Department of Justice
Drug Enforcement Administration

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APPLICATION FOR PROCUREMENT QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No procurement quota may be issued unless a completed application form has been received, 21 CFR 1303.12(b)	*OMB Approval No. 1117-0008*

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA-250)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Concentrate of Poppy Straw (AMA)	II	9670

4. NAME AND ADDRESS OF REGISTRANT (Include No., Street, City, State and ZIP Code)	5. YEAR FOR WHICH QUOTA IS REQUESTED
(b)(4)	2010
	6. DEA MANUFACTURING REGISTRATION NUMBER (b)(4);(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. (Include extension)	9. FAX No.	10. E-MAIL ADDRESS
(b)(6)			(b)(4);(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2007)	1st PRECEDING YEAR (2008)	CURRENT YEAR (2009)	(2010)
	10,000,000 grams	15,000,000 grams	11,800,000 grams	9,500,000 grams

12. PRODUCTION DATA	2ND PRECEDING YEAR	1ST PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	169,692	2,048,777	2,956,575	2,754,928
b. In-process material	0	0	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a + b + c)	169,692	2,048,777	2,956,575	2,754,928
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	1,322,049	2,120,915	8,592,202	9,701,647
b. Exports	0	2,120,915	0	0
TOTAL (a + b)	1,322,049	0	8,592,202	9,701,647
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	0	0	0	0
b. Importation	0	4,000,000	9,500,000	9,500,000
TOTAL (a + b)	0	4,000,000	9,500,000	9,500,000

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
		2ND PRECEDING YEAR	1ST PRECEDING YEAR	CURRENT YEAR	
Morphine (for Conversion)	9300	626,525	2,120,836	1,072,470	80%
Codeine (for Conversion)	9050	695,520	0	7,403,998	80%
Dihydromorphine	9145	0	0	115,734	91%

14. IF THE PURPOSE IS TO MANUFACTURE THE BASIC CLASS OR LIST I CHEMCIAL INTO DOSAGE FORMS, FURNISH THE FOLOWING INFORMATION:

NAME OF DOSAGE FORM (Include product form, i.e., tablets, patches, etc. and strengths)	AUTHORITY TO MARKET THIS PRODUCT	SCHEDULE / LIST	AMOUNT USED FOR THIS PURPOSE		ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR QUOTA IS REQUESTED
			2ND PRECEDING YEAR	1ST PRECEDING YEAR		

SIGNATURE OF APPLICANT	PRINT or TYPE NAME and TITLE of SIGNER	DATE
(b)(6)	(b)(6) DEA MATERIALS CONTROL MANAGER	JUNE 19 , 2009

DEA FORM 250 (May 2007) ALL PREVIOUS EDITIONS ARE OBSOLETE.

U.S. Department of Justice
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APPLICATION FOR PROCUREMENT QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No procurement quota may be issued unless a completed application form has been received, 21 CFR 1303.12(b)	*OMB Approval No. 1117-0008*

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA-250)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Concentrate of Poppy Straw (ATA)	II	9670

4. NAME AND ADDRESS OF REGISTRANT *(Include No., Street, City, State and ZIP Code)*	5. YEAR FOR WHICH QUOTA IS REQUESTED	6. DEA MANUFACTURING REGISTRATION NUMBER
(b)(4)	2010	(b)(4);(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. *(Include extension)*	9. FAX No.	10. E-MAIL ADDRESS
(b)(6)			(b)(4);(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2007)	1st PRECEDING YEAR (2008)	CURRENT YEAR (2009)	(2010)
	440,000 grams	1,800,000 grams	7,000,000 grams	9,500,000 grams

12. PRODUCTION DATA	2ND PRECEDING YEAR	1ST PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	603,306	796,770	1,680,209	1,969,654
b. In-process material	0	0	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a + b + c)	603,306	796,770	1,680,209	1,969,654
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	0	1,601,308	3,116,561	9,210,555
b. Exports	0	0	0	0
TOTAL (a + b)	0	1,601,308	3,116,561	9,210,555
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	49	97	0	0
b. Importation	0	1,794,175	4,000,000	9,500,000
TOTAL (a + b)	49	1,794,272	4,000,000	9,500,000

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
		2ND PRECEDING YEAR	1ST PRECEDING YEAR	CURRENT YEAR	
Oxycodone	9143	0	1,601,162	0	47%
Codeine (for conversion)	9050	0	0	3,096,509	125%
Thebaine	9333	0	0	20,052	TBD

14. IF THE PURPOSE IS TO MANUFACTURE THE BASIC CLASS OR LIST I CHEMCIAL INTO DOSAGE FORMS, FURNISH THE FOLOWING INFORMATION:

NAME OF DOSAGE FORM (Include product form, i.e., tablets, patches, etc. and strengths)	AUTHORITY TO MARKET THIS PRODUCT	SCHEDULE / LIST	AMOUNT USED FOR THIS PURPOSE		ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR QUOTA IS REQUESTED
			2ND PRECEDING YEAR	1ST PRECEDING YEAR		

SIGNATURE OF APPLICANT	PRINT or TYPE NAME and TITLE of SIGNER	DATE
(b)(6)	(b)(6) DEA MATERIALS CONTROL MANAGER	JUNE 19, 2009

DEA FORM 250 (May 2007) ALL PREVIOUS EDITIONS ARE OBSOLETE.

(b)(4)

(b)(4)

June 22, 2009

Acting Deputy Administrator
Drug Enforcement Administration
Washington, D.C. 20537

Attn: DEA Federal Register Representative [Docket No. DEA-318P]

This letter constitutes (b)(4) comments on the Proposed Initial Aggregate Production Quotas for 2010, as published in Federal Register on May 21, 2009, FR Vol 74, No. 97, pages 23881-23884.

In light of the fact that (b)(4) has no knowledge of either the amounts of any available aggregate quotas or the planned allocation of any aggregate, (b)(4) requests that DEA make any adjustments to the aggregate quotas sufficient to satisfy our requests for increased manufacturing quotas, which are outlined below. Because this comment contains proprietary information on our manufacturing quota needs, we also request that DEA treat this entire document as confidential.

All requests below are stated in grams anhydrous base ("AA").

1100 Amphetamine

(b)(4) requests that the initial aggregate be sufficient to include our request for 2,900,000 grams AA of Amphetamine manufacturing quota for 2010.

9050 Codeine (for Conversion)

(b)(4) requests that the initial aggregate be sufficient to include our request for 39,000,000 grams AA of Codeine (for Conversion) manufacturing quota for 2010.

9145 Dihydromorphine

(b)(4) requests that the initial aggregate be sufficient to include our request for 2,800,000 grams AA of Dihydromorphine manufacturing quota for 2010.

9801 Fentanyl

(b)(4) requests that the initial aggregate be sufficient to include our request for 840,000 grams AA of Fentanyl manufacturing quota for 2010.

9193 Hydrocodone (for Sale)

(b)(4) requests that the initial aggregate be sufficient to include our request for 30,000,000 grams AA of Hydrocodone manufacturing quota for 2010.

9150 Hydromorphone

(b)(4) requests that the initial aggregate be sufficient to include our request for 1,420,000 grams AA of Hydromorphone manufacturing quota for 2010.

9220 Levorphanol

(b)(4) requests that the initial aggregate be sufficient to include our request for 8,300 grams AA of Levorphanol manufacturing quota for 2010.

9630 Opium Tincture

(b)(4) requests that the initial aggregate be sufficient to include our request for 930,000 grams AA of Opium Tincture manufacturing quota for 2010.

9143 Oxycodone (For Sale)

(b)(4) requests that the initial aggregate be sufficient to include our request for 28,000,000 grams AA of Oxycodone (For Sale) manufacturing quota for 2010.

9143 Oxycodone (For Conversion)

(b)(4) requests that the initial aggregate be sufficient to include our request for 4,400,000 grams AA of Oxycodone (For Conversion) manufacturing quota for 2010.

9652 Oxymorphone (For Sale)

(b)(4) requests that the initial aggregate be sufficient to include our request for 2,000,000 grams AA of Oxymorphone (For Sale) manufacturing quota for 2010.

All other quota requests remain unchanged from (b)(4) original request.

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

(b)(6)

(b)(4);(b)(6)

(b)(4)

(b)(4)

09 JUN 17 PM 2:50

(b)(4)

June 15, 2009

Drug Enforcement Administration
Office of Diversion Control
8701 Morrisette Drive
Springfield, VA 22152

Subject: FR Doc E9-11929[Federal Register: May 21, 2009 (Volume 74, Number 97)] [Notices] [Page 23881-23884]

Dear Dr. Sannerud:

(b)(4) wishes to comment on the proposed 2010 Tapentadol aggregate quota. The proposed amount for this class is 519,000 grams. On May 5, 2009 (b)(6) submitted a correspondence to DEA on behalf of (b)(4) asking for a ruling on whether manufacturing quota for Tapentadol synthesized from the ether is necessary. We have not received word at this time. Should quota be required to convert the ether to the Tapentadol base, (b)(4) is concerned that the proposed APQ will not provide the necessary level of quota to allow manufacture of Tapentadol to adequately supply the needs of our customers.

(b)(4) proposes the 2010 aggregate Tapentadol for Sale quota should be sufficiently increased to allow for adequate production to support 2010 and 2011 first quarter needs. The 2010 plan can be found in the following table. (b)(4) would require at a minimum 20,821 kilogram equiv. Tapentadol base of procurement quota to import the T003028 (methyl ether of Tapentadol) to support 2010 sales and support the 1Q2011 forecast. Should manufacturing quota be required to convert the ether to the base, for 2010 (b)(4) would require 16,996 kilogram base manufacturing quota to support 2010 sales and 1Q2011 forecast. The amounts above include manufacturing yield losses for the steps manufactured at (b)(4)

Controlled Substance	Molecular Weight	2010 Volume		1Q2011 Volume		2010 APQ	
		kg	eq. kg base	kg	eq. kg base	kg	eq. kg base
Tapentadol methyl ether, HBr salt (T003028)	316.28	18,716	13,098	11,037	7,724	29,752	20,821
Tapentadol Base (T002655)	221.34	NA	10,691	NA	6,304	NA	16,996
Tapentadol Hydrochloride (R331333)	258.80	11,206	9,621	6,608	5,673	17,814	15,294

*(b)(4) intends to import 7,000 kg T003028 (4,899 kg equiv. Tapentadol base) from (b)(4) in 4Q2009; the remaining volume (22,752 kg T003038, 15,922 kg equiv. Tapentadol base) will be imported in 2010.

(b)(4)
2010 Proposed Aggregate
Tapentadol

Tapentadol sales information will be presented in the (b)(4) (b)(4);(b)(7)(E) (b)(4) correspondence submitted with this (b)(4);(b)(7)(letter. If you have questions regarding this request, please do not hesitate to contact me at (b)(6)

Best regards,

(b)(6)

Director, Supply Chain Systems, DEA Compliance and Security

(b)(4)

Confidential

09 JUN 17 PM 2:50

15 June 2009

Dr. Christine Sannerud
Drug Enforcement Administration
Quota Unit - ODEQ
8701 Morrissette Drive
Springfield, VA 22152

Re: 2010 Proposed Tapentadol Aggregate Production Quota (APQ)
(b)(4) Registration (b)(4);(b)(7)(E) (b)(4)

Dear Dr. Sannerud:

(b)(4) **proposes that the 2010 Aggregate Production Quota for Tapentadol be set at 21,000 kg base drug.** This would be sufficient to allow for planned procurement of Tapentadol HCl by (b)(4) as well as adequate inventory allowance at (b)(4) for early 2011 shipments. Per the enclosed letter from (b)(4) importation of Tapentadol Methyl Ether in the amount of 20,821 kg base drug is necessary to support (b)(4) procurement requirements for 2010 and Q1 2011.

In my letter of May 5th, I raised the question of the applicability of Manufacturing Quota for the Tapentadol HCl manufacturing process at (b)(4) which involves Tapentadol Methyl Ether as a starting material. If Tapentadol Manufacturing Quota is indeed required, please take the following estimated 2010 (b)(4) plant requirements for Procurement Quota into account when creating the APQ:

(b)(4) **2010 Requirements:**
9,134 + 1,913 + 4,567 - 5,992 = 9,621 kg base
Sales + Mfg Loss + Allowance – Inventory = Quota Request

Forecast Sales consist of (b)(4) which will be launched after finalization of scheduling, and (b)(4) which will be submitted for NDA approval later this year. Of the 9,134 kg base forecast for 2010 Sales, the great majority, 8,127 kg base, is for the already approved (b)(4)

(b)(4)

(b)(4) are owned by (b)(4) (b)(4). If you have any questions or require further information, please call me at (b)(6)

Sincerely,

(b)(6)

Director, DEA Compliance

(b)(4)

2010 Establish Initial Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- The attached Federal Register notice, prepared for your signature, established initial year 2009 aggregate production quotas (APQ) for schedules I and II controlled substances for which the United States has medical, scientific, industrial, export and reserve stock requirements. Also attached is a list of the 2008 and proposed 2009 APQs for these substances for comparison.

- Expeditious publication of this notice is necessary to ensure that quota is available at the beginning of 2010 for manufacturing. The following points provide brief explanations of the changes from the proposed APQ values:

Schedule I substances

- The APQ for **4-methoxyamphetamine, alpha-methyltryptamine (AMT), lysergic acid diethylamide,** and **methaqualone,** were increased due to additional applications received. Most of these substances are used in diagnostic kits and or reference standards.

- The APQ for **dihydromorphine** was increased to support the manufacturing of hydromorphone.

Schedule II substances

- The APQ for **amphetamine (for conversion)** was increased. Amphetamine (for conversion) is used to manufacture lisdexamfetamine. Since the APQ for lisdexamfetamine is increasing, amphetamine (for conversion) subsequently needs to be increased.

- The APQ for **isomethadone** was increased due to additional applications received.

- The APQ for **lisdexamfetamine** increased due to increasing sales. The final 2009 revised APQ for lisdexamfetamine was also increased.

- The APQ for **methamphetamine** stayed the same but the individual allocations between **methamphetamine (for sale), methamphetamine (for conversion)** and **levo-desoxyephedrine** were adjusted slightly.

- The APQ for **oxycodone (for sale)** was increased for the following reasons:

    - Low ABUK oxycodone API. ABUK or alpha beta unsaturated ketones are impurities FDA has identified concerns with and subsequently requested manufacturers to alter their manufacturing processes to decrease the levels of ABUK in their API. Manufacturing low ABUK material incurs larger manufacturing losses.

    - Increased sales of dosage form manufacturers. The FDA estimated a 21.3% increased demand for oxycodone in 2009 and another 9.9% increase in 2010. The initial APQ is less than the final 2009 revised APQ.

- The APQ for **oxycodone (for conversion)** was increased. Oxycodone (for conversion) is used to manufacture oxymorphone. Since the APQ for oxymorphone is increasing, oxycodone (for conversion) subsequently needs to be increased.

- The APQ for **oxymorphone (for sale)** was increased due to increased sales, and is established at the final 2009 APQ value.

- The APQ for **phenylacetone** was increased due to additional applications received and to support new manufacturing efforts. Phenylacetone is used to manufacture amphetamine. Historically (b)(4) imported phenylacetone to support their amphetamine manufacturing efforts. They intend to manufacture a portion of their phenylacetone requirements as well as provide material to customers.

Initial Aggregate Production Quotas for 2009

BASIC CLASS: 2010 Initial Quota Worksheets

Company:	(b)(4)																			
Request:	#REF!				#REF!				#REF!				#REF!				#REF!		#REF!	
Current Year MQ:	-				9,100.000				50,000.000				12,500.000				4,511.000		244.000	
Prev. Yr. Year-end Inv.:	#REF!				#REF!				#REF!				#REF!				#REF!		#REF!	
Company's Proj. Inv. Current Yr.:	0				2,658.351				14,000.000				4,501.000				120		6.000	
					6.000															
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	sell to other companies		amt. need	
base on initial grant	#REF!	hydromorph	#REF!	%					#REF!	codein for sa	#REF!	88%	#REF!	codeine	#REF!	88%			#REF!	
	#REF!	oxycodone	#REF!	%	#REF!	codeine for	#REF!	100%	#REF!	codein for co	#REF!	88%	-	codeine for con		88%			#REF!	
					#REF!	hydromorpl	#REF!	44%	#REF!	dihydromorpl	#REF!	95%								
					#REF!	morphine	#REF!	84%	#REF!	hydromrophc	#REF!	54%								
									-	nalbuphine		26%								
total need	#REF!				#REF!				#REF!				#REF!						#REF!	
INITIAL MQs																				
utilized prev year (est)	-				9,530.148				37,097.320				21,418.840						25	
allowed YEt	#REF!				#REF!				#REF!				#REF!						#REF!	
calcualtion	#REF!				#REF!				#REF!				#REF!				(120.000)		#REF!	
MQ:	-				9,100.000				50,000.000				15,100.000				2,475.000		244.000	
Total Initial MQs:	76,675.000	+ others		=	76,675.000															

FURTHER CALCULATIONS

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Initial Aggregate Production Quotas for 2009

(b)(4)

substance	
codeine	
hydromorphone	

Initial Aggregate Production Quotas for 2009

BASIC CLASS: **2010 Initial Quota Worksheets**

PQ Total: #REF! kg est as 2010 request less 2009 packaging

Company:	(b)(4)						
Request:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Current Year MQ:	0	408.000	4,003.400	*29,011.000*	*23,463.000*	*38,173.000*	-
Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Total Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
% of Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Share of Next Year's PQs:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Prev. Yr. Year-end Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Proj. Exports Current Year:	0	-	-	17.409	-	2,000.000	-
estimated sales current year:	0	450.000	1,350.000	30,976.117	26,547.000	25,635.000	78.300
Proj. Exports Next Year:	0	-	-	17.400	-	3,000.000	-
Company's Proj. Inv. Current Yr.:	0	50.000	670.294	7,041.404	6,957.000	7,500.000	795.532
DEA's Proj. Inv. Current Year:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
INITIAL MQs							
2/3 calculation	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Calc. Using Company's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Calc. Using DEA's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
calc. using CFR 50% inventory	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Further Calculation:							
MQ:	-	-	475.000	28,000.000	22,400.000	31,525.000	-

Total Initial MQs: 82,400.000 + others #REF! = #REF!

FURTHER CALCULATIONS

Update numbers below

(b)(4) states sun is customer but they have not submitted quota applications for oxycodone

(b)(4) quotas were adjusted to what they should be after the revised APQ is published

(b)(4) sales are higher than the 2008 market share; est. 733 kg for 2009

FDA est: APQ last year * est= 0

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2010 Initial Quota Worksheet**		9652						
PQ Total:	#REF! kg								
Company:	(b)(4)								
Request:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Current Year MQ:	0.001	0.060	75.000	0	187.000	2,165.000	3,000	226.000	85
Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Total Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
% of Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Share of Next Year's PQs:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Prev. Yr. Year-end Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Proj. Exports Current Year:	-	-	-	0	-	66.400	-	-	-
estimated current year sales:	0.001	0.010	66.000	0	137.950	1,410.476	3.500	18.000	2.550
Proj. Exports Next Year:	-	-	-	0	-	66.400	-	-	-
Company's Proj. Inv. Current Yr.:	0.001	0.196	9.000	0	82.219	239.348	0.600	10.000	19.022
DEA's Proj. Inv. Current Year:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
INITIAL MQs									
2/3 calculation	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Calc. Using Company's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Calc. Using DEA's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Calc. using CFR 50% inventory	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Further Calculation:									
MQ:	0.001	0.060	-	0.002	187.000	2,000.000	3.000	300.000	-
Total Initial MQs:	2,490.063	+ others		=	2,490.063				

FURTHER CALCULATIONS Initial

Update numbers below

FDA est: APQ last year * est = 0

Initial Aggregate Production Quotas for 2009

BASIC CLASS: 2010 Initial Quota Worksheets 9333

Company:	(b)(4)																													
Request:	#REF!				#REF!				#REF!				#REF!				#REF!								#REF!					
Current Year MQ:	-				418,000				-				43,000,000				23,500,000								8,048,000					
Prev. Yr. Year-end Inv.:	#REF!				#REF!				#REF!				#REF!				#REF!								#REF!					
Company's Proj. Inv. Current Yr.:	-				1,202,000				-				7,536,379				282,000								3,156,000					
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance								
	#REF!	oxycodone	#REF!		#REF!	oxycodone	#REF!	80%	#REF!	oxycodone	#REF!	80%	#REF!	oxycodone	#REF!	60%	#REF!	oxycodone	#REF!	75%	#REF!	oxycodone								
	#REF!	hydromrph	#REF!		#REF!	hydrocodo	#REF!	61%		buprenorphine				buprenorphine																
total need	#REF!				#REF!				#REF!				#REF!				#REF!								#REF!					
INITIAL MQs																														
Utilizaztn previous year	-				2,402,402				56,080				42,900,134				22,822,000								4,100,193					
allowable YEI	#REF!				#REF!				#REF!				#REF!				#REF!								#REF!					
calculation	#REF!				#REF!				#REF!				#REF!				#REF!													
MQ:	-				-				757,000				43,000,000				14,600,000								4,100,000					
Total Initial MQs:	62,457,000	+ others	0.030	=	62,457,030																									

FURTHER CALCULATIONS

(b)(4) supplies (b)(4) thebaine:

2,445,652	hydrocodone	46%	1,125,000
-	oxycodone	70%	0
2,445,652	est 2010 need		
4755	est 2009 need		
1,800.16	allowable YEI 2010		
155.27	2009 est YEI		
4,090.55	kg PQ		

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Thebaine/OIP conversion [1-(2]

Initial Aggregate Production Quotas for 2009

MQ	yield
#REF!	66%

Initial Aggregate Production Quotas for 2009

BASIC CLASS: **2010 Initial Quota Worksheets**

PQ Total: #REF! kg est as 2010 request less 2009 packaging

Company:	(b)(4)					
Request:	#REF!	#REF!	#REF!	#REF!	#REF!	Initial
Current Year MQ:	32.000	600.000	19,000.000	16,724.000	-	
Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	
Total Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	
% of Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	
Share of Next Year's PQs:	#REF!	#REF!	#REF!	#REF!	#REF!	
Prev. Yr. Year-end Inv.:	#REF!	#REF!	#REF!	4,822.140	-	
Proj. Exports Current Year:	-	-	300.000	-	-	
Proj. Exports Next Year:	-	-	300.000	-	-	
Company's est. sales current yr	-	656.344	18,545.645	12,150.000		
Company's Proj. Inv. Current Yr.:	-	622.300	9,064.554	5,000.000		
DEA's Proj. Inv. Current Year:	#REF!	#REF!	#REF!	9,396.140	-	
INITIAL MQs						
2/3 calculation	#REF!	#REF!	#REF!	14,364.093	-	
Calc. Using Company's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	
Calc. Using DEA's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	
Calc. using CFR 50% Inventory	#REF!	#REF!	#REF!	#REF!	#REF!	
Further Calculation:						
MQ:	32.000	600.000	22,000.000	16,500.000	-	
Total Initial MQs:	39,132.000	+ others	#REF!	=	#REF!	

FURTHER CALCULATIONS

Update numbers below

(b)(4) efforts moved to 2010, recommend granting same quota in 2010

(b)(4) market share has increased compared to 2008; recommend granting 600.000 kg

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	2010 Initial Quota Worksheet		9230			
PQ Total:	#REF! kg		est as 2010 request less 2009 packaging			
Company:	(b)(4)					
Request:	0.001	#REF!	#REF!	46.000	#REF!	Initial
Current Year MQ:	0.001	3,908.000	0.002	46.000	950.000	
Prev. Year's Sales:	-	#REF!	#REF!	-	#REF!	
Total Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	
% of Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	
Share of Next Year's PQs:	#REF!	#REF!	#REF!	#REF!	#REF!	
Prev. Yr. Year-end Inv.:	#REF!	#REF!	#REF!	-	#REF!	
Proj. Exports Current Year:	-	-	-	-	74.255	
Company est. sales current yr.	0.001	3,850.000	0.002	-	1,343.246	
Proj. Exports Next Year:	-	-	-	-	43.500	
Company's Proj. Inv. Current Yr.:	0.001	1,147.000	0.001	-	686.000	
DEA's Proj. Inv. Current Year:	#REF!	#REF!	#REF!	46.000	#REF!	
INITIAL MQs						
2/3 calculation	#REF!	#REF!	#REF!	30.667	#REF!	
Calc. Using Company's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	
Calc. Using DEA's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	
calc. using CFR 50% inventory	#REF!	#REF!	#REF!	#REF!	#REF!	
Further Calculation:						
MQ:	0.001	2,200.000	0.002	46.000	#REF!	
Total Initial MQs:	#REF!	+ others		=	#REF!	

FURTHER CALCULATIONS

Update numbers below

(b)(4) plant runs 4 @ 11 kg; 10 lab @ 0.2kg

Mepetigine initial (2)

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2010 Initial Quota Worksheets**			9250		
PQ Total:	#REF!	kg				
Company:	(b)(4)					
Request:	#REF!		#REF!	#REF!	#REF!	
Current Year MQ:	3,056.500		80.000	12,000.000	2,900.000	
Prev. Year's Sales:	#REF!		#REF!	#REF!	#REF!	
Total Prev. Year's Sales:	#REF!		#REF!	#REF!	#REF!	
% of Prev. Year's Sales:	#REF!		#REF!	#REF!	#REF!	
Share of Next Year's PQs:	#REF!		#REF!	#REF!	#REF!	
Prev. Yr. Year-end Inv.:	#REF!		#REF!	#REF!	#REF!	
Proj. Exports Current Year:	-		-	-	-	
company est. sales current year	3,004.000		-	12,442.182	2,381.640	
Proj. Exports Next Year:	-		-	-	-	
Company's Proj. Inv. Current Yr.:	1,743.419		-	4,066.243	847.560	
DEA's Proj. Inv. Current Year:	#REF!		#REF!	#REF!	#REF!	
INITIAL MQs						
2/3 calculation	#REF!	-	#REF!	#REF!	#REF!	
Calc. Using Company's Inv.:	#REF!	-	#REF!	#REF!	#REF!	
Calc. Using DEA's Inv.:	#REF!	-	#REF!	#REF!	#REF!	
calc. using CFR 50% inventory	#REF!	-	#REF!	#REF!	#REF!	
Further Calculation:						
MQ:	2,352.000		62.000	12,000.000	2,900.000	
Total Initial MQs:	17,314.000		+ others	#REF!	=	#REF!

FURTHER CALCULATIONS

Update numbers below

Initial Aggregate Production Quotas for 2009

BASIC CLASS: **2010 Initial Quota Worksheets**
3000

Company:					(b)(4)						
Request:					#REF!				#REF!		
Current Year MQ:					-				12,000.000		
Prev. Yr. Year-end Inv.:					#REF!				#REF!		
Company's Proj. Inv. Current Yr.:					-				4,400.000		
Calculations				amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield
				#REF!	methadone	#REF!	50%	#REF!	methadone	#REF!	97%
total need				#REF!				#REF!			
utilization previous year				-				13,773.915			
allowable year-end inventory				#REF!				#REF!			
calculated MQ required				#REF!				#REF!			
MQ				3,500.000				12,800.000			
MQ total:	20,400.000	+ other	#REF!								

Company:					(b)(4)						
Request:					#REF!				#REF!		
Current Year MQ:					-				12,000.000		
Prev. Yr. Year-end Inv.:					#REF!				#REF!		
Company's Proj. Inv. Current Yr.:					-				4,400.000		
Calculations				amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield
				#REF!	methadone	#REF!	50%	#REF!	methadone	#REF!	97%
total need				#REF!				#REF!			
utilization previous year				-				13,773.915			
allowable year-end inventory				#REF!				#REF!			
calculated MQ required				#REF!				#REF!			
MQ				3,500.000				12,800.000			
MQ total:	20,400.000	+ other	#REF!								

FURTHER CALCULATIONS

Update numbers below

(b)(4) purchased methadon intermediate from (b)(4) and now is going to manufacture a portion of their requirements

PQ request	3,000.000
MQ request	3,500.000
	6,500.000

Initial Aggregate Production Quotas for 2009

yield
92%

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2010 Initial Quota Worksheets**		9273			
PQ Total:	#REF! kg					
Company:				(b)(4)		
Request:				#REF!	#REF!	Initial
Current Year MQ:				19,000.000	43,037.000	
Prev. Year's Sales:				#REF!	#REF!	
Total Prev. Year's Sales:				#REF!	#REF!	
% of Prev. Year's Sales:				#REF!	#REF!	
Share of Next Year's PQs:				#REF!	#REF!	2010 est. sales
Prev. Yr. Year-end Inv.:				#REF!	#REF!	
Proj. Exports Current Year:				414.000	1,440.000	
Proj. Exports Next Year:				414.000	1,440.000	
company est. sales current year				37,675.827	58,779.300	2009 est. sales
Company's Proj. Inv. Current Yr.:				10,847.752	19,100.000	
DEA's Proj. Inv. Current Year:				#REF!	#REF!	
INITIAL MQs						
2/3 calculation				#REF!	#REF!	
Calc. Using Company's Inv.:				#REF!	#REF!	
Calc. Using DEA's Inv.:				#REF!	#REF!	
Calc. w/ CFR 50% inventory				#REF!	#REF!	
Further Calculation:						
MQ:				38,000.000	36,737.000	
Total Initial MQs:	74,737.000	+ others	#REF!	=	#REF!	

FURTHER CALCULATIONS

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	**2010 Initial Quota Worksheets**						
PQ Total:	#REF! kg		est as 2010 request less 2009 packaging			**FDA Est.:**	3.80%
Company:	(b)(4)						
Request:	#REF!		#REF!	#REF!	#REF!		Initial
Current Year MQ:	72.000		22.500	500.000	620.000		
Prev. Year's Sales:	#REF!		#REF!	#REF!	#REF!		
Total Prev. Year's Sales:	#REF!		1,410.179	#REF!	#REF!		
% of Prev. Year's Sales:	#REF!		#REF!	#REF!	#REF!		
Share of Next Year's PQs:	#REF!		#REF!	#REF!	#REF!		
Prev. Yr. Year-end Inv.:	#REF!		#REF!	#REF!	#REF!		
Proj. Exports Current Year:	3.000		-	-	71.059		
estimated sales current year:	103.000		13.000	874.956	614.313		
Proj. Exports Next Year:	5.000		-	-	104.480		
Company's Proj. Inv. Current Yr.:	5.525		5.608	407.612	170.672	589.417	
DEA's Proj. Inv. Current Year:	#REF!		#REF!	#REF!	#REF!		
INITIAL MQs							
2/3 calculation	#REF!		#REF!	#REF!	#REF!	#REF!	
Calc. Using Company's Inv.:	#REF!		#REF!	#REF!	#REF!		
Calc. Using DEA's Inv.:	#REF!		#REF!	#REF!	#REF!		
calc. w/ CFR 50% inventory	#REF!		#REF!	#REF!	#REF!		
Further Calculation:							
MQ:	82.000		6.000	711.000	840.000		
Total Initial MQs:	1,639.000	+ others	0.003	=	1,639.003	too high > APQ	

FURTHER CALCULATIONS

Redacted Initial (b)(4)

Initial Aggregate Production Quotas for 2009

BASIC CLASS: **2010 Initial Quota Worksheets** 9193

PQ Total: #REF! kg est as request less (b)(4) transfer request

Company:	(b)(4)					
Request:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Current Year MQ:	281.000	4,135.000	22,000.000	25,306.000	-	2,697.000
Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Total Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
% of Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Share of Next Year's PQs:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Prev. Yr. Year-end Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Proj. Exports Current Year:	-	-	6.100	-	-	-
estimated sales current year:	250.000	3,662.425	23,550.487	24,545.000	200.000	3,050.000
Proj. Exports Next Year:	-	-	6.100	-	-	-
Company's Proj. Inv. Current Yr.:	150.000	1,667.927	8,600.000	5.013	1,000.000	2,649.242
DEA's Proj. Inv. Current Year:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
INITIAL MQs						
2/3 calculation	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Calc. Using Company's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Calc. Using DEA's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Calc. using CFR 50% inventory (based on market shar	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!
Further Calculation:						
MQ:	-	3,096.000	20,578.000	24,211.000	500.000	1,125.000

Total Initial MQs: 49,510.000 + others 0.021 = 49,510.021

FURTHER CALCULATIONS

Update numbers below

(b)(4) has no justification for their request - recommend zero

(b)(4) grant one batch 400 kg (based on 2009 sales, 2010 est sales, allowable YEI in 2010 and estimated 2009 YEI)

(b)(4) sales are estimating to triple next year! Arcos shows 8 kg sold through June, stick to est. based on market share

(b)(4) situation is very complicated: they keep switching material back and forth between facilities for various salt manufacturing and next year they are switching rates

Initial Aggregate Production Quotas for 2009

BASIC CLASS: 2010 Initial Quota Worksheets

PQ Total: #REF! est. as request less 2009 packaging

Company:	(b)(4)							
Request:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
Current Year MQ:	-	156.000	400.000	300.000	1,174.000	898.000	40.000	
Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
Total Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
% of Prev. Year's Sales:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
Share of Next Year's PQs:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
Prev. Yr. Year-end Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
Proj. Exports Current Year:	-	-	-	-	50.000	-	-	
company's est. current year sales	-	153.000	252.000	218.050	1,128.588	808.000	-	
Proj. Exports Next Year:	-	-	-	-	13.350	-	-	
Company's Proj. Inv. Current Yr.:	-	3.000	-	95.193	467.759	639.000	12.923	
DEA's Proj. Inv. Current Year:	#REF!	#REF!	125.000	#REF!	#REF!	#REF!	#REF!	
INITIAL MQs								
2/3 calculation	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
Calc. Using Company's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
Calc. Using DEA's Inv.:	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
Calc. using CFR 50% inventory	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	#REF!	
Further Calculation:								
MQ:	-	156.000	336.000	300.000	1,420.000	1,369.000	-	too high >> APQ
Total Initial MQs:	3,581.000	+ others	#REF!	=	#REF!			

FURTHER CALCULATIONS

Update numbers below

(b)(4) but no justification; requesing same as last year - grant

(b)(4) no justification

Initial Aggregate Production Quotas for 2009

BASIC CLASS:	2010 Initial Quota Worksheet	9050					
PQ Total:	#REF! kg						
Company:		(b)(4)					
Request:		#REF!	#REF!	#REF!	#REF!	#REF!	requested
Current Year MQ:		450.000	18,000.000	10,013.000	3,750.000		
Prev. Year's Sales:		#REF!	#REF!	#REF!	#REF!		
Total Prev. Year's Sales:		#REF!	#REF!	#REF!	#REF!		
% of Prev. Year's Sales:		#REF!	#REF!	#REF!	#REF!		
Share of Next Year's PQs:		#REF!	#REF!	#REF!	#REF!		
Prev. Yr. Year-end Inv.:		#REF!	#REF!	#REF!	#REF!		
Proj. Exports Current Year:		-	740.000	-	-		
Company est. current year sales		370.000	14,768.000	11,866.000	925.000		
Proj. Exports Next Year:		-	740.000	-	-		
Company's Proj. Inv. Current Yr.:		228.052	7,474.029	5,600.000	600.000		
DEA's Proj. Inv. Current Year:		#REF!	#REF!	#REF!	#REF!		
INITIAL MQs							
2/3 calculation		#REF!	#REF!	#REF!	#REF!		
Calc. Using Company's Inv.:		#REF!	#REF!	#REF!	#REF!		
Calc. Using DEA's Inv.:		#REF!	#REF!	#REF!	#REF!		
Calc. w/ CFR 50% inventory		#REF!	#REF!	#REF!	#REF!		
Further Calculation:							
MQ:		450.000	10,320.000	3,305.000	800.000		
Total Initial MQs:	14,875.000	+ others	#REF!	=	#REF!		

FURTHER CALCULATIONS

Update numbers below

2010 MQ request	#REF!
2010 APQ	#REF!

Initial Aggregate Production Quotas for 2009

BASIC CLASS: 2010 Initial Quota Worksheets 9050

Company:	(b)(4)															
Request:	#REF!				#REF!				#REF!				#REF!			
Current Year MQ:	0				14000				32556				280			
Prev. Yr. Year-end Inv.:	#REF!				#REF!				#REF!				#REF!			
Company's Proj. Inv. Current Yr.:	0				4,170,034				2,446.999				430.000			
Calculations	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield	amt. needed	substance	MQ	yield
(based on initial MQ)	0	hydrocodon	-	85%	#REF!	hydrocodor	#REF!	53%	#REF!	hydrocodone	#REF!	92%	#REF!	hydrocodor	#REF!	85%
						oxycodone	#REF!		#REF!	dihydrocodei	#REF!	82%				
					#REF!	codeine (sa	#REF!	91%								
total need	0				#REF!				#REF!				#REF!			
INITIAL MQs																
Utilized previous year	0				9,046.781				28,938.690				850.000			
Authorized YE!	0				#REF!				#REF!							
calculation	-				#REF!				#REF!				#REF!			
MQ:	0				6012				32,556.000				0			
Total Initial MQs:	38568	+ others		=	38,568.000											

FURTHER CALCULATIONS

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Codeine (for convers.on) to (2)

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA # 318E]

Controlled Substances:
Established Initial Aggregate Production Quotas for 2010

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of aggregate production quotas for 2010.

SUMMARY: This notice establishes initial 2010 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

EFFECTIVE DATE: (insert date of publication).

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug & Chemical Evaluation Section, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. § 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR § 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR § 0.104.

The 2010 aggregate production quotas represent those quantities of controlled substances that may be produced in the United States in 2010 to provide adequate supplies of each substance for: the estimated medical, scientific, research and industrial needs of the United States; lawful

export requirements; and the establishment and maintenance of reserve stocks (21 U.S.C. § 826(a) and 21 CFR § 1303.11). These quotas do not include imports of controlled substances for use in industrial processes.

On May 21, 2009, a notice of the proposed initial 2010 aggregate production quotas for certain controlled substances in schedules I and II was published in the Federal Register (74 FR 23881). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before June 22, 2009.

Twelve responses (eleven from DEA registered manufacturers, and one from a non-DEA registrant) were received within the published comment period, offering comments on a total of 28 schedule I and II controlled substances. One additional comment was received after the comment period ended and therefore was not considered. The commenters stated that the proposed aggregate production quotas for 3,4-methylenedioxyamphetmaine, 3,4-methylenedioxyethylamphetamine, 3,4-methylenedioxymethamphetamine, alfentanil, amphetamine (for sale), codeine (for sale), codeine (for conversion), dihydromorphine, fentanyl, gamma hydroxybutyric acid, hydrocodone, hydromorphone, isomethadone, levo-desoxyephedrine, levorphanol, lisdexamfetamine, methamphetamine (for sale), morphine (for conversion), nabilone, opium (tincture), oxycodone (for sale), oxycodone (for conversion), oxymorphone (for sale), remifentanil, sufentanil, tapentadol, tetrahydrocannabinols, and thebaine were insufficient to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

In arriving at the aggregate production quotas, DEA has taken into consideration the above comments along with the factors set forth at 21 CFR § 1303.11(b) and other relevant 2009 factors, including 2009 manufacturing quotas, current 2009 sales and inventories, 2010 export requirements, additional applications received, and research and product development requirements. Based on this information, DEA has adjusted the initial aggregate production quotas for 4-methoxyamphetamine, alpha-methyltryptamine, amphetamine (for conversion), dihydromorphine, isomethadone, levo-desoxyephedrine, lisdexamfetamine, lysergic acid diethylamide, methamphetamine (for sale), methamphetamine (for conversion), methaqualone, oxycodone (for sale), oxycodone (for conversion), oxymorphone (for sale) and phenylacetone to meet the legitimate needs of the United States.

DEA proposed the aggregate production quota for tapentadol at 519,000 g in the 2010 proposed initial aggregate production quota notice published on May 21, 2009 in the Federal Register (74 FR 23881). Tapentadol is no longer listed because the material will be imported into the United States and not manufactured domestically.

Regarding 3,4-methylenedioxyamphetmaine, 3,4-methylenedioxyethylamphetamine, 3,4-methylenedioxymethamphetamine, alfentanil, amphetamine (for sale), codeine (for sale), codeine (for conversion), fentanyl, gamma hydroxybutyric acid, hydrocodone, hydromorphone, levorphanol, morphine (for conversion), nabilone, opium (tincture), remifentanil, sufentanil, tetrahydrocannabinols, and thebaine DEA has determined that the proposed initial 2010 aggregate production quotas are sufficient to meet the current 2010 estimated medical, scientific, research and industrial needs of the United States.

Pursuant to 21 CFR § 1303, the Deputy Administrator of DEA will, in 2010, adjust

aggregate production quotas and individual manufacturing quotas allocated for the year based upon 2009 year-end inventory and actual 2009 disposition data supplied by quota recipients for each basic class of schedule I or II controlled substance.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. § 826), and delegated to the Administrator of DEA by 28 CFR § 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR § 0.104, the Deputy Administrator hereby orders that the 2010 initial aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Established 2010 Quotas
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	25 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10 g
3,4-Methylenedioxymethamphetamine (MDMA)	20 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	5 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g

Alpha-methyltryptamine	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	3 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	3,000 g
Dihydromorphine	3,300,000 g
Dimethyltryptamine	3 g
Gamma-hydroxybutyric acid	24,200,000 g
Heroin	20 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	1 g
Lysergic acid diethylamide (LSD)	15 g
Marihuana	4,500,000 g
Mescaline	7 g
Methaqualone	7 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	7 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	16 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Psilocybin	7 g
Psilocyn	7 g
Tetrahydrocannabinols	312,500 g

Thiofentanyl	2 g
Trimeperidine	2 g

Basic Class – Schedule II	Established 2010 Quotas
1-Phenylcyclohexylamine	2 g
1-piperdinocyclohexanecarbonitrile	2 g
Alfentanil	8,000 g
Alphaprodine	2 g
Amobarbital	3 g
Amphetamine (for sale)	17,000,000 g
Amphetamine (for conversion)	6,500,000 g
Cocaine	247,000 g
Codeine (for sale)	39,605,000 g
Codeine (for conversion)	65,000,000 g
Dextropropoxyphené	106,000,000 g
Dihydrocodeine	1,200,000 g
Diphenoxylate	947,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	55,000,000 g
Hydromorphone	3,300,000 g
Isomethadone	11 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	10,000 g
Lisdexamfetamine	9,000,000 g
Meperidine	8,600,000 g
Meperidine Intermediate-A	3 g
Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	1 g
Methadone (for sale)	25,000,000 g
Methadone Intermediate	26,000,000 g

Methamphetamine	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]	
Methylphenidate	50,000,000 g
Morphine (for sale)	35,000,000 g
Morphine (for conversion)	100,000,000 g
Nabilone	9,002 g
Noroxymorphone (for sale)	10,000 g
Noroxymorphone (for conversion)	9,000,000 g
Opium (powder)	230,000 g
Opium (tincture)	1,050,000 g
Oripavine	15,000,000 g
Oxycodone (for sale)	88,000,000 g
Oxycodone (for conversion)	4,000,000 g
Oxymorphone (for sale)	2,570,000 g
Oxymorphone (for conversion)	12,000,000 g
Pentobarbital	28,000,000 g
Phenazocine	1 g
Phencyclidine	20 g
Phenmetrazine	2 g
Phenylacetone	12,500,001 g
Racemethorphan	2 g
Remifentanil	500 g
Secobarbital	67,000 g
Sufentanil	10,300 g
Thebaine	126,000,000 g

The Deputy Administrator further orders that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR §§ 1308.11 and 1308.12 be established at zero.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce

its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. § 601 et seq. The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export

markets.

Dated:

Michele M. Leonhart
Deputy Administrator

2010 Proposed Revised Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- The attached Federal Register notice, prepared for your signature, Proposed Revised Aggregate Production Quotas (APQ) for 2010 for schedules I and II controlled substances for which the United States has medical, scientific, industrial, export and reserve stock requirements. Also attached is a list of the 2008 and 2009 APQs for these substances for comparison.

- To ensure compliance with CFR deadlines, the proposed APQ revision is being published earlier than in the past. As such, some of the values may change between the proposed revised and the final revised values due to the fact less data (actual sales from manufacturers of controlled substances) is available.

- An expedited review and publication is requested to ensure an uninterruptable supply of schedule I and II controlled substances for medical, scientific, industrial, and export requirements of the U.S.

- The following points provide brief explanations of the changes from the proposed APQ values:

Schedule I substances

- The APQ for, 3,4-methylenedioxyamphetamine (MDA), 5-methoxy-N-N-diisopropyltyrptamine, N,N-dimethylamphetamine, mescaline, psilocybin, and psilocyn were decreased. Most of these substances are used in diagnostic kits, or as reference standards.

- The APQ for dihydromorphine was increased due to the increase in hydromorphone APQ. Dihydromorphine is used to manufacture hydromorphone.

- The APQ for marihuana and tetrahydrocannabinols (THC) were decreased because (b)(4) has abandoned their generic Marinol product utilizing natural THC vs. synthetic.

Schedule II substances

- The APQ for 1-piperidinocyclohexanecarbonitrile, alfentanil, dextropropoxyphene, dihydrocodeine, diphenoxylate, meperidine, methadone, morphine (for conversion), noroxymorphone (for sale), phencyclidine (PCP), and sufentanil were decreased.

- The APQ for hydromorphone was increased due to increased sales.

- The APQ for remifentanil was increased due to new validation efforts of (b)(4) Historically, remifentanil has been imported.

Aggregate Production Quotas Changes

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Final Revised	Proposed Initial	Initial	Proposed Revised
Schedule I:	**2008**	**2009**	**2010**	**2010**	**2010**
3,4-Methylenedioxyamphetamine (MDA)	20	25	25	25	20
5-Methoxy-N,N-diisopropyltryptamine	5	5	5	5	0
Dihydromorphine	2,549,000	3,132,000	2,549,000	3,300,000	3,500,000
Marihuana	4,500,000	4,500,000	4,500,000	4,500,000	11,000
Mescaline	2	7	7	7	5
N,N-Dimethylamphetamine	7	7	7	7	2
Psilocybin	7	7	7	7	2
Psilocyn	7	7	7	7	2
Tetrahydrocannabinols	312,500	312,500	312,500	312,500	216,000
Schedule II:					
1-piperdinocyclohexanecarbonitrile	0	2	2	2	0
Alfentanil	8,000	8,000	8,000	8,000	6,300
Dextropropoxyphene	106,000,000	106,000,000	106,000,000	106,000,000	92,000,000
Dihydrocodeine	1,200,000	1,200,000	1,200,000	1,200,000	800,000
Diphenoxylate	761,000	947,000	947,000	947,000	627,000
Hydromorphone	3,300,000	3,340,000	3,300,000	3,300,000	3,455,000
Meperidine	8,600,000	8,600,000	8,600,000	8,600,000	6,600,000
Methadone (for sale)	25,000,000	25,000,000	25,000,000	25,000,000	20,000,000
Morphine (for conversion)	100,000,000	100,000,000	100,000,000	100,000,000	83,000,000
Noroxymorphone (for sale)	10,000	10,000	10,000	10,000	5,000
Phencyclidine	2,021	20	20	20	14
Remifentanil	410	500	500	500	2,500
Sufentanil	10,300	10,300	10,300	10,300	7,000

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-318R]

Controlled Substances:
Proposed Revised Aggregate Production Quotas for 2010

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed revised 2010 aggregate production quotas.

SUMMARY: This notice proposes revised 2010 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-318R" on all written and electronic correspondence. Written comments should be sent to the DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov. An electronic copy of this document is also available at the http://www.regulations.gov website. However, persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. § 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR § 0.100. The Administrator in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR § 0.104.

On May 21, 2009, a notice of proposed 2010 aggregate production quotas for certain controlled substances in schedules I and II was published in the Federal Register (74 FR 23881). This notice stipulated that the DEA would adjust the quotas in 2010 as provided for in 21 CFR part 1303. The 2010 established aggregate production quotas were published in the Federal Register (74 FR 54080) on October 21, 2010.

The proposed revised 2010 aggregate production quotas represent those quantities of controlled substances in schedules I and II that may be produced in the United States in 2010 to provide adequate supplies of each substance for: the estimated medical, scientific, research and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

The proposed revisions are based on a review of 2009 year-end inventories, 2009 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information available to the DEA.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. § 826), and delegated to the Administrator of the DEA by 28 CFR § 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR § 0.104, the Deputy Administrator hereby proposes the following revised 2010 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base:

Basic Class – Schedule I	Previously Established Initial 2010 Quotas	Proposed Revised 2010 Quotas
2,5-Dimethoxyamphetamine	2 g	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g	2 g
3-Methylfentanyl	2 g	2 g
3-Methylthiofentanyl	2 g	2 g
3,4-Methylenedioxyamphetamine (MDA)	25 g	20 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10 g	10 g
3,4-Methylenedioxymethamphetamine (MDMA)	20 g	20 g
3,4,5-Trimethoxyamphetamine	2 g	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g	2 g
4-Methoxyamphetamine	77 g	77 g
4-Methylaminorex	2 g	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g	2 g
5-Methoxy-N,N-diisopropyltryptamine	5 g	0 g
Acetyl-alpha-methylfentanyl	2 g	2 g
Acetyldihydrocodeine	2 g	2 g
Acetylmethadol	2 g	2 g
Allylprodine	2 g	2 g
Alphacetylmethadol	2 g	2 g
Alpha-ethyltryptamine	2 g	2 g
Alphameprodine	2 g	2 g
Alphamethadol	2 g	2 g
Alpha-methylfentanyl	2 g	2 g
Alpha-methylthiofentanyl	2 g	2 g
Alpha-methyltryptamine (AMT)	2 g	2 g
Aminorex	2 g	2 g
Benzylmorphine	2 g	2 g

Betacetylmethadol	2 g	2 g
Beta-hydroxy-3-methylfentanyl	2 g	2 g
Beta-hydroxyfentanyl	2 g	2 g
Betameprodine	2 g	2 g
Betamethadol	2 g	2 g
Betaprodine	2 g	2 g
Bufotenine	3 g	3 g
Cathinone	3 g	3 g
Codeine-N-oxide	602 g	602 g
Diethyltryptamine	2 g	2 g
Difenoxin	3,000 g	3,000 g
Dihydromorphine	3,300,000 g	3,500,000 g
Dimethyltryptamine	3 g	3 g
Gamma-hydroxybutyric acid	24,200,000 g	52,156,000 g
Heroin	20 g	20 g
Hydromorphinol	2 g	2 g
Hydroxypethidine	2 g	2 g
Ibogaine	1 g	1 g
Lysergic acid diethylamide (LSD)	15 g	15 g
Marihuana	4,500,000 g	11,000 g
Mescaline	7 g	5 g
Methaqualone	7 g	7 g
Methcathinone	4 g	4 g
Methyldihydromorphine	2 g	2 g
Morphine-N-oxide	605 g	605 g
N-Benzylpiperazine	2 g	2 g
N,N-Dimethylamphetamine	7 g	2 g
N-Ethylamphetamine	2 g	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g	2 g
Noracymethadol	2 g	2 g
Norlevorphanol	52 g	52 g
Normethadone	2 g	2 g
Normorphine	16 g	16 g
Para-fluorofentanyl	2 g	2 g
Phenomorphan	2 g	2 g
Pholcodine	2 g	2 g
Psilocybin	7 g	2 g
Psilocyn	7 g	2 g
Tetrahydrocannabinols	312,500 g	216,000 g
Thiofentanyl	2 g	2 g
Trimeperidine	2 g	2 g

Basic Class – Schedule II	Previously Established Initial 2010 Quotas	Proposed Revised 2010 Quotas
1-Phenylcyclohexylamine	2 g	2 g
1-Piperdinocyclohexanecarbonitrile	2 g	0 g
Alfentanil	8,000 g	6,300 g
Alphaprodine	2 g	2 g
Amobarbital	3 g	3 g
Amphetamine (for sale)	17,000,000 g	17,000,000 g
Amphetamine (for conversion)	6,500,000 g	6,500,000 g
Cocaine	247,000 g	247,000 g
Codeine (for sale)	39,605,000 g	39,605,000 g
Codeine (for conversion)	65,000,000 g	65,000,000 g
Dextropropoxyphene	106,000,000 g	92,000,000 g
Dihydrocodeine	1,200,000 g	800,000 g
Diphenoxylate	947,000 g	627,000 g
Ecgonine	83,000 g	83,000 g
Ethylmorphine	2 g	2 g
Fentanyl	1,428,000 g	1,428,000 g
Glutethimide	2 g	2 g
Hydrocodone (for sale)	55,000,000 g	55,000,000 g
Hydromorphone	3,300,000 g	3,455,000 g
Isomethadone	11 g	11 g
Levo-alphacetylmethadol (LAAM)	3 g	3 g
Levomethorphan	5 g	5 g
Levorphanol	10,000 g	10,000 g
Lisdexamfetamine	9,000,000 g	9,000,000 g
Meperidine	8,600,000 g	6,600,000 g
Meperidine Intermediate-A	3 g	3 g
Meperidine Intermediate-B	7 g	7 g
Meperidine Intermediate-C	3 g	3 g
Metazocine	1 g	1 g
Methadone (for sale)	25,000,000 g	20,000,000 g
Methadone Intermediate	26,000,000 g	26,000,000 g
Methamphetamine	3,130,000 g	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]		
Methylphenidate	50,000,000 g	50,000,000 g
Morphine (for sale)	35,000,000 g	35,000,000 g

Morphine (for conversion)	100,000,000 g	83,000,000 g
Nabilone	9,002 g	9,002 g
Noroxymorphone (for sale)	10,000 g	5,000 g
Noroxymorphone (for conversion)	9,000,000 g	9,000,000 g
Opium (powder)	230,000 g	230,000 g
Opium (tincture)	1,050,000 g	1,050,000 g
Oripavine	15,000,000 g	15,000,000 g
Oxycodone (for sale)	88,000,000 g	88,000,000 g
Oxycodone (for conversion)	4,000,000 g	4,000,000 g
Oxymorphone	2,570,000 g	2,570,000 g
Oxymorphone (for conversion)	12,000,000 g	12,000,000 g
Pentobarbital	28,000,000 g	28,000,000 g
Phenazocine	1 g	1 g
Phencyclidine	20 g	14 g
Phenmetrazine	2 g	2 g
Phenylacetone	12,500,001 g	12,500,001 g
Racemethorphan	2 g	2 g
Remifentanil	500 g	2,500 g
Secobarbital	67,000 g	67,000 g
Sufentanil	10,300 g	7,000 g
Thebaine	126,000,000 g	126,000,000 g

The Deputy Administrator further proposes that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR §§ 1308.11 and 1308.12 remain at zero.

All interested persons are invited to submit their comments in writing or electronically regarding this proposal following the procedures in the "Addresses" section of this document. A person may object to or comment on the proposal relating to any of the above-mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief. Persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. In the event that comments or objections to this proposal raise one or more issues which the

Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public hearing by notice in the Federal Register, summarizing the issues to be heard and setting the time for the hearing as per 21 CFR § 1303.13(c).

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this action will not have a significant economic impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. §§ 601-612. The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

Executive Order 12866

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

Executive Order 13132

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the

application of Executive Order 13132.

Executive Order 12988

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Unfunded Mandates Reform Act of 1995

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $126,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This action will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated:

Michele M. Leonhart
Deputy Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
CC:_____
CCR:_____
ODE:_____
ODE/D:(b)(6) _____
ODEQ:(b)(6) _____
ODEQ:(b)(6) 03-31-10, retyped 04-12-10
S:\ODE\Fed Reg\Revised Aggregate Production Quota for 2010
Webcims # ODE-10-012
(DFN#: 680-03 Drug control files - Manufacturing and Procurement quotas)

BASIC CLASS:	**2009 Revised Quota Worksheets**		**9050 Codeine**				
PQ Total:	31,092.714 kg					**FDA Est.:**	0.90%
						IMS:	
Company:	(b)(4)						
Request:	52.000	450.000	18,000.000	14,238.000	1,600.000	128	Initial
Current Year MQ:	52.000	450.000	18,000.000	10,013.000	3,750.000	0	
Prev. Year's Sales:	-	214.156	13,126.060	10,900.660	1,122.365	-	
Total Prev. Year's Sales:	25,363.279	25,363.279	25,363.279	25,363.279	25,363.279	25,363.279	
% of Prev. Year's Sales:	0%	1%	52%	43%	4%	-	
Share of current Year's PQs:	-	262.533	16,091.170	13,363.063	1,375.902	-	
Prev. Yr. Year-end Inv.:	-	419.485	6,148.841	7,405.802	248.534	-	
Proj. Exports Current Year:	-	-	740.000	-	-		
Revised MQs share PQ x 1.5 - YEI + exports							
Typcial calculation	-	(25.686)	18,727.914	12,638.793	1,815.318	-	
Calucations w/ CFR 50%	-	(37.780)	17,986.636	12,023.192	1,751.934	-	
Further Calculation:							
Final MQ:	52.000	450.000	18,000.000	10,013.000	3,750.000	92.000	
Total revised MQs:	32,357.000	+ others	3.101	=	32,360.101		

FURTHER CALCULATIONS

(b)(4) commented requesting 14,097 kg (4084 kg short) available in APQ

						Initial
current PQ	31,092.714				**Initial APQ**	39,605.000
Current MQ	32,306.101				**Proposed revised APQ**	39,605.000
inventory	14,223.537				**Final Revised APQ**	39,605.000
MQ need = PQx1.5-MQ-inventory	109.433		CFR 50% rule	(1,322.926)		
last years APQ	39,605.000					
FDA est = APQ x est	39,961.445					
IMS est = APQ x est						

BASIC CLASS:	2009 Revised Quota Worksheets			9050 Codeine (for conversion)											
Company:	(b)(4)														
Request:	250.000			6,453.000			10,500.000			39,000.000			1,125.000		
Current Year MQ:	-			280.000			14,000.000			32,556.000			1,125.000		
Year end inventory	-			-			1,966.7030			6,850.6820			-		
Calculations	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	subtance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild
hydrocodone	0	-	0.850	331	281.000	0.850	7,801.887	4,135.000	0.530	23,913.043	22,000.000	0.920	31,241.975	25,306.000	0.810
dihydrocodeine										475.610	390.000	0.820			
codeine for sale							494.505	450.000	0.910						
hydromorphone			TBD												
oxycodone			TBD						TBD						
TOTAL NEED:	0			331			8,296.392			24,388.653			31,241.975		
Revised MQ															
total x 50% Inventory - YEI	0.000			495.882			10,475.885			29,732.298			46,862.963		
previous year MQ	0.000			1100.000			7,500.000			43,000.000			7,900.000		
CFR 50% calculation	-			408.235			(3,723.213)			1,829.135			39,802.469		
Final MQ	-			280.000			10,276.787			32,556.000			1,125.000		
Total revised MQs:	44238	+ others	96.000				=	44,333.787							

FURTHER CALCULATIONS

(b)(4) commented to APQ: requesting 1125 kg - already granted

Initial APQ	65,000.000
Proposed Final APQ	65,000.000
Final Revised APQ	65,000.000

Confidential Treatment Requested

BASIC CLASS:	**2010 Revised Quota Worksheet**			**9273 Dextropropoxyphene**				
PQ Total:	**63,523.462 kg**						**FDA Est.:**	**-6.80%**
							IMS:	
Company:	(b)(4)							
Request:	0.001	-	-	0.002	-	38,000.000	53,000.000	
Current Year MQ:	0.001	-	-	0.002	-	19,000.000	43,037.000	
Prev. Year's Sales:	-	-	-	-	-	37,609.260	47,593.847	
Total Prev. Year's Sales:	85,203.107	85,203.107	85,203.107	85,203.107	85,203.107	85,203.107	85,203.107	85,203.107
% of Prev. Year's Sales:	0%	0%	0%	0%	0%	44%	56%	0%
Share of current Year's PQs:	-	-	-	-	-	28,039.710	35,483.752	-
Prev. Yr. Year-end Inv.:	-	-	-	-	-	9,577.021	20,995.939	
Proj. Exports Current Year:	-	-	-	-	-	414.000	1,440.000	
Revised MQs share PQ x 1.5 - YEI + exports								
Typcial calculation	-	-	-	-	-	32,896.544	33,669.689	
Calcualtion with CFR 50%	-	-	-	-	-	35,288.931	36,697.213	
Further Calculation:								
Final MQ:	0.001	-	-	0.002	-	38,000.000	43,037.000	
Total revised MQs:	81,037.003	+ others	-	=	81,037.003			

FURTHER CALCULATIONS

					Initial
current PQ	63,523.462			**Initial APQ**	106,000.000
Current MQ	62,037.003			proposed revised	92,000.000
Inventory	30,572.960			**Final Revised APQ**	92,000.000
MQ need = PQx1.5-MQ-inventory	2,675.230	CFR 50%	8,095.141		
APQ last year	106,000.000				
FDA est = APQ x est	98,792.000				
IMS est = APQ x est					

BASIC CLASS:	2009 Revised Quota Worksheets		9801 Fentanyl					
PQ Total:	1,052.326						FDA Est.:	1.80%
							IMS est:	
Company:	(b)(4)							
Request:	0.001	3	516	85	0.002	50	925	840
Current Year MQ:	0.001	1.1	72	85	0.002	22.5	500	620
Prev. Year's Sales:	0	0	40.221	17.426	-	2.550	439.236	630.519
Total Prov. Year's Sales:	1130	1130	1,129.952	1,129.952	1,129.952	1,129.952	1,129.952	1,129.952
% of Prev. Year's Sales:	0%	0%	4%	2%	0%	0%	39%	56%
Share of current Year's PQs:	0	0	37.458	16.229	-	2.375	409.061	587.203
Prev. Yr. Year-end Inv.:	0	0	58.120	11.285	-	-	531.749	248.064
Proj. Exports Current Year:	0		5.000	52.500	-	-		104.480
Revised MQs share PQ x 1.3 - YEI + exports								
Typcial calculation	0.000	0.000	-4.425	62.313	0.000	3.087	0.030	619.780
calculation with 50% CFR	0.000	0.000	3.758	65.858	0.000	3.606	89.386	748.050
Further Calculation:								
Final MQ:	0.001	1.100	72.000	85.000	0.002	22.500	500.000	620.000
Total revised MQs:	1301 + others		-	=	1,300.603			

FURTHER CALCULATIONS

					Initial
current PQ	1,052.326			Initial APQ	1,428.000
Current MQ	1,300.603			proposed revised APQ	1,428.000
inventory	849.218			Final Revised APQ	1,428.000
MQ need = PQx1.3-MQ-inventory	(781.797)	CFR 50%	(551.926)		
last year APQ	1,428.000				
FDA est = APQ x est	1,453.704				
IMS est = APQ x est					

BASIC CLASS:	**2010 Revised Quota Worksheet**		**9193 Hydrocodone**				
PQ Total:	42,445.183					**FDA est:**	7.70%
						IMS est:	
Company:	(b)(4)				#REF!	(b)(4)	
Request:	4,802.000	4,000.000	30,000.000	41,378.000	#REF!	2,000.000	10,000.000
Current Year MQ:	281.000	4,135.000	22,000.000	25,306.000	#REF!	-	2,697.000
Prev. Year's Sales:	-	2,565.110	28,154.154	35,279.997	#REF!	16.434	64.615
Total Prev. Year's Sales:	52,131.180	52,131.180	52,131.180	52,131.180	#REF!	52,131.180	52,131.180
% of Prev. Year's Sales:	0%	5%	54%	68%	#REF!	0%	0%
Share of current Year's PQs:	-	2,088.511	22,923.099	28,724.957	#REF!	13.381	52.610
Prev. Yr. Year-end Inv.:	-	3,105.981	7,532.469	7,803.663	#REF!	1,132.834	2,761.049
Proj. Exports Current Year:	-		6.100	-	-		
Revised MQs share PQ x 1.5 - YEI + exports							
Typcial calculation	-	26.786	26,858.280	35,283.773	#REF!	(1,112.763)	(2,682.135)
calcualtion with 50% CRF	-	145.936	28,166.044	36,922.533	#REF!	(1,112.000)	(2,679.133)
Further Calculation:							
Final MQ:	281.000	4,135.000	22,000.000	20,631.000		500.000	2,697.000
Total revised MQs:	50,244.000	+ others	0.021	=	50,244.021		

FURTHER CALCULATIONS

(b)(4) commented to APQ requesting	23878	kg	current MQ	20,631.000	3,247.000	440.000	kg

difference in APQ - DENIED temp 10437 have adequate quota

current PQ	42,445.183			**Initial APQ**	55,000.000
Current MQ	54,419.021			proposed APQ	55,000.000
inventory	18,183.338			**Final Revised APQ**	55,000.000
MQ need = PQx1.5-MQ-inventory	(8,934.584)	CFR 50%	(6,513.085)		
APQ 2008	55,500.000				
FDA est = APQ x est	59,773.500				
IMS est = APQ x est					

BASIC CLASS:	2010 Revised Quota Worksheets			9150						
PQ Total:	3,493,162 kg							FDA Est.:	11.20%	
								IMS est:		
Company:	(b)(4)									
Request:	-	100.000	156.000	330.000	336.255	300.000	1,420.000	1,500.000	-	60.000
Current Year MQ:	-	-	156.000	192.000	400	300.000	1,174.000	898.000	-	40.000
Prev. Year's Sales:	134.338	-	-	15.757	183.335	209.514	1,168.740	662.459	-	7.129
Total Prev. Year's Sales:	2,381.272	2,381.272	2,381.272	2,381.272	2,381.272	2,381.272	2,381.272	2,381.272	2,381.272	2,381.272
% of Prev. Year's Sales:	6%	0%	0%	1%	8%	9%	49%	28%	0%	0%
Share of current Year's PQs:	197.065	-	-	23.114	183.335	307.343	1,714.461	971.782	-	10.458
Prev. Yr. Year-end Inv.:	-	-	-	2.630	46.55	116.076	562.181	654.287	-	3.798
Proj. Exports Current Year:		-		-		-	13.350	-	-	
Revised MQs share PQ x 1.5 - YEI + exports										
Typcial calculation	295.597	-	-	32.042	228.453	344.938	2,002.861	803.386	-	11.889
50% CFR Inventory	279.915	-	-	30.202	228.453	320.481	1,866.430	726.055	-	11.056
Final MQ:	-	-	156.000	192.000	462.000	300.000	1,174.000	989.000	-	40.000
Total revised MQs:	3,313.000	+ others		0.021	=	3,313.021				

FURTHER CALCULATIONS

(b)(4) commented: temp 10436 justified in increase 70 kg with batch size increase 72 kg

commented: temp 10026; justified in 62 kg but increaes 66.3

current PQ	*3,493,162*			Initial APQ	3,300.000	
Current MQ	3,160.021			Proposed Final APQ	3,455.000	
inventory	*1,405.562*			Final revised APQ	3,455.000	
MQ need = PQx1.5-MQ-inventory	674.160	CFR 50%	330.783			
APQ last year	3,340.000					
FDA est = APQ x est	3,714.080					
IMS est = APQ x est						

BASIC CLASS:	2010 Revised Quota Worksh	9230					
PQ Total:	4,339.836 kg					**FDA Est.:**	-19.60%
						IMS:	
Company:	(b)(4)						
Request:	0.001	3908	0.002	46.000	-	2,400.000	
Current Year MQ:	0.001	2917	0.002	46.000	-	950.000	
Prev. Year's Sales:	-	2604.998	-	-	#REF!	1,182.210	
Total Prev. Year's Sales:	3,787.208	3,787.208	3,787.208	3,787.208	3,787.208	3,787.208	
% of Prev. Year's Sales:	0%	69%	0%	0%	#REF!	31%	
Share of current Year's PQs:	-	2,985.12	-	-	#REF!	1,354.718	
Prev. Yr. Year-end Inv.:	-	1837.052	0.002	-	#REF!	845.855	
Proj. Exports Current Year:	-		-	20.000	-	43.500	
Revised MQs share PQ x 1.5 - YEI + exports							
Typcial calculation	-	2,640.626	(0.002)	20.000	#REF!	1,229.721	-
calculation with CFR 50%	-	2,545.595	(0.002)	20.000	#REF!	1,186.595	
Further Calculation:							
Final MQ:	0.001	2,917.000	0.002	46.000	-	950.000	
Total revised MQs:	3,913.003	+ others	-	=	3,913.003		

FURTHER CALCULATIONS

(b)(4) commented requesting : 950 kg - granted

current PQ	4,339.836				Initial APQ	6,600.000
Current MQ	3,913.003				proposed APQ	6,600.000
Inventory	2,682.909				Final Revised APQ	6,600.000
MQ need = PQx1.5-MQ-inventory+export	(22.658)		CFR 50%	(224.315)		
last year APQ	8,600.000					
FDA est = APQ x est	6,914.400					
IMS est = APQ x est						

BASIC CLASS:	2010 Revised Quota Worksheets		9250 Methadone			
PQ Total:	15,390.469 kg.				FDA Est.:	0.05%
					IMS:	
Company:	(b)(4)					
Request:	3,196.000	665.000	12,000.000	2,900.000		
Current Year MQ:	3,056.500	80.000	12,000.000	2,900.000		
Prev. Year's Sales:	3,047.554	-	11,323.016	2,224.618		
Total Prev. Year's Sales:	16,595.190	16,595.190	16,595.190	16,595.190		
% of Prev. Year's Sales:	18%	0%	68%	13%		
Share of current Year's PQs:	2,826.318	-	10,501.026	2,063.123		
Prev. Yr. Year-end Inv.:	1,691.711	-	4,988.682	665.346		
Proj. Exports Current Year:	-	150.000		-		
Revised MQs share PQ x 1.3 - YEI + exports						
Typcial calculation	1,982.502	150.000	8,662.652	2,016.714		
calculation with CFR 50%	2,603.075	150.000	10,968.355	2,469.712		
Further Calculation:						
Final MQ:	3,056.500	80.000	12,000.000	2,900.000		
Total revised MQs:	18,036.500	+ others	0.006 =		18,036.506	

FURTHER CALCULATIONS

Update numbers below

(b)(4) commented to APQ: requested 2038 kg increase (available in APQ)

justified 704 kg 1334 kg still available

current PQ	15,390.469		
Current MQ	18,036.504		
inventory	7,345.744		
MQ need = PQx1.3-MQ-inventory+export	(5,224.638)	CFR 50%	(1,995.364)
APQ last year	25,000.000		
FDA est = APQ x est	25,012.500		
IMS est = APQ x est			

	Initial
Initial APQ	20,000.000
Proposed APQ	20,000.000
Final Revised APQ	20,000.000

BASIC CLASS:	2010 Revised Quota Workshee		9300 Morphine				
PQ Total:	32,840.757 kg						FDA Est.: 8.20%
Company:	(b)(4)						IMS:
Request:	540.000	235	800.000	22,000.000	16,500.000	-	
Current Year MQ:	32.000	96	600.000	19,000.000	16,724.000	-	
Prev. Year's Sales:	-	0	700.599	17,008.165	12,859.872	#REF!	
Total Prev. Year's Sales:	30,568.647	30,568.647	30,568.647	30,568.647	30,568.647	30,568.647	
% of Prev. Year's Sales:	0%	0%	2%	56%	42%	#REF!	
Share of current Year's PQs:	-	-	752.673	18,272.350	13,815.722	#REF!	
Prev. Yr. Year-end Inv.:	-	0	813.818	7,703.440	4,437.083	#REF!	
Proj. Exports Current Year:	-			300.000	-	-	
Revised MQs share PQ x 1.5 - YEI + exports							
Typcial calculation	-	-	315.192	20,005.085	16,286.500	#REF!	
Calculation with CFR 50%	-	-	302.173	19,689.039	16,047.538	#REF!	
Further Calculation:							
Final MQ:	32.000	96.000	600.000	19,000.000	18,355.683		
Total revised MQs:	38,083.683	+ others	11.110	=	38,094.793		

FURTHER CALCULATIONS

(b)(4) did not comment - assume their quota is suff.cient

(b)(4) commented; requesting 20626 kg quota;

justified in 2784 kg; granted 1272 kg short 1512

					Initial
current PQ	32,840.757			Initial APQ	39,000.000
Current MQ	36,502.108			Proposed APQ	35,000.000
inventory	12,955.513			Final Revised APQ	
MQ need = PQx1,5-MQ-inventory	(196.486)	CFR 50%	(764.513)		
last year APQ	36,300.000				
FDA est = APQ x est	39,276.600				
IMS est = APQ x est					

BASIC CLASS:	2010 Revised Quota Worksheets	#REF!	9300														
Company:	(b)(4)																
Request:	150		244			12500			50000			17300			2475		
Current Year MQ:	0		244			9100			50000	Initial		12500			4511		
Year end inventory	0		0			562			12865			5581			37,984		
Calculations	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild	amt needed	substance MQ	yeild
codeine for sale		-		76.471	52.000	0.680				20,454.545	18,000.000	0.880	11,425.000	10,054.000	0.880	-	-	0.910
codeine for conversion		-					14,000.000	14,000.000	1.000	36,995.455	32,556.000	0.880	1,278.409	1,125.000	0.880	-	-	0.910
hdyromorphone			TBD	205.263	156.000	0.760	681.818	300.000	0.440	2,174.074	1,174.000	0.540						
dihydromorphine										2,814.737	2,674.000	0.950						
noroxymorphone (for sale)																		
nalbuphine																		
morphine (for sale)							714.286	600.000	0.840									
oxycodone			TBD															
total need	0			281.734			14,681.818			62,438.811			12,703.409			-		
Revised MQ																		
total x 50% inventory - YEI	0.000			422.601			21,461.136			80,793.375			13,494.556			(37.984)		
previous MQ	0.000			32.000			800.000			22,000.000			12,443.000			300.000		
50% CRD calc.	-			116.167			8,890.682			20,683.673			929.453			(4,473.984)		
Final MQ	0.000			224.000			9,100.000			50,000.000			14,876.000			4,511.000		
Total revised MQs:	78487	+ others			1.110	=		78,487.000										

FURTHER CALCULATIONS

	Initial
Initial APQ	100,000.000
Proposed Final APQ	83,000.000
Final Revised APQ	100,000.000

BASIC CLASS:	2010 Revised Quota Worksheets			9143 Oxycodone						
PQ Total:	74,557.142	kg						FDA Est.:	12.20%	
								IMS:		
Company:	(b)(4)									total
Request:	100.000	3,934.000	-	1,800.000	28,000.000	22,400.000	-	31,525.000	560.000	88,319.000
Current Year MQ:	-	408.000	-	4,003.400	28,000.000	34,714.000	-	37,221.000	-	#########
Prev. Year's Sales:	-	132.931	-	1,094.884	24,292.917	21,652.557	-	24,572.476	175.534	
Total Prev. Year's Sales:	76,960.047	76,960.047	76,960.047	76,960.047	76,960.047	76,960.047	76,960.047	76,960.047	76,960.047	
% of Prev. Year's Sales:	0%	0%	0%	1%	32%	28%	0%	32%	0%	
Share of current Year's PQs:	-	128.781	-	1,060.699	23,534.425	20,976.504	-	23,805.256	170.053	
Prev. Yr. Year-end Inv.:	-	-	-	629.362	11,970.122	8,581.363	-	7,465.353	681.368	
Proj. Exports Current Year:	-		-	-	17.400	-	-	3,391.000		
								(from temp 9056)		
Revised MQs share PQ x 1.3 - YEI + exports										
Typcial calculation	-	167.415	-	749.546	18,642.031	18,688.093	-	26,872.479	(460.299)	
calculation with 50% CRF	-	194.208	-	970.232	23,538.539	23,052.407	-	31,825.335	(424.918)	
Further Calculation:		317.000				10,337.000		3,226.000		
Final MQ:	100.000	725.000	-	4,003.400	28,000.000	45,051.000	-	40,447.000	-	
Total revised MQs:	118,326.400		+ others	3.063	=	118,329.463				

FURTHER CALCULATIONS

(b)(4)	commented to APQ	want	9700	justified in	3,226.000	*kg increase*
(b)(4)	commented to APQ	want	49627 kg	justified in	10,337.000	*kg increase*
(b)(4)	(temp 10297)			justified in	317.000	*kg increase*

					Initial
current PQ	74,557.142			Initial APQ	#########
Current MQ	104,349.461			proposed revised	88,000.000
inventory	30,268.297			Final Revised APQ	#########
MQ need = PQx1.3-MQ-inventory	(37,693.473)	CFR 50%	(22,181.319)		
last year APQ	94,000.000				
FDA est = APQ x est	105,468.000				
IMS est = APQ x est					

BASIC CLASS:	**2010 Revised Quota Worl**			9333 Thebaine												
Company:	(b)(4)															
Request:	15,208.000			30.000			43,000.000			14,603.000			19,750.000			22,500.000
Current Year MQ:	416.000			30.000			43,000.000			23,500.000			8,048.000			29,500.000
Year end Inventory	101.882			47.620			9,040.544			2,143.026			1,225.813			8,412.849
Calculations	amt needed	MQ	yeild	amt needed	MQ	yeild	amt needed	MQ	yeild	amt needed	MQ	yeild	amt needed	MQ	yeild	amt needed
oxycodone	906.250	725.000	0.800	5,719.143	4,003.400	0.700	35,000.000	28,000.000	0.800	60,068.000	45,051.000	0.750	-	-	0.880	53,929.333
oxycodone for conversion							7,000.000	5,600.000	0.800							
hydrocodone via codeine for conv.	460.656	281.000	0.610											#REF!	1.000	-
total need	1,366.906			5,719.143			42,000.000			60,068.000			-			53,929.333
Revised MQ																
total x 50% inventory - YEI	1948			8,531.094			53,959.456			87,958.974			(1,225.813)			72,481.151
2009 MQ	3500			10.000			50,305.000			21,000.000			7,000.000			19,000.000
CFR 50% calc.	2,065.75			7,073.81			13,035.71			54,691.97			(7,523.81)			34,248.82
Final MQ	416.000			30.000			43,000.000			25,000.000			8,048.000			29,500.000
Total revised MQs:	105994	+ others	153.030	=		106,147.030										

FURTHER CALCULATIONS

(b)(4) commented to APQ - 10,500 kg; granted already

Initial APQ	Initial	126,000
Proposed Final APQ		126,000
Final APQ		126,000

rough calculation

oxycodone APQ	105500	0.690	152,898.551	thebaine needed

Thebaine (conversion) revised

2010 Revised APQ Comments

Drug	Company	Comment	Response	Proposed APQ	Revised APQ	Change
alfentanil	(b)(4)	increase APQ	increase APQ (back to orginal value)	6.300	8.000	1.700
amphetamine (for conversion)		increase APQ	increase APQ	6,500.000	7,500.000	1,000.000
amphetamine (for sale)		increase APQ	increase APQ	17,000.000	18,600.000	1,600.000
codeine (for sale)		increase APQ	APQ adequate, no change	39,605.000	39,605.000	-
codeine (for conversion)		increase APQ	APQ adequate, no change	65,000.000	65,000.000	-
dextropropoxyphene		increase APQ	APQ adequate, no change	92,000.000	92,000.000	-
dihydromorphine		increase APQ increase APQ	increase APQ	3,500.000	3,608.000	108.000
diphenoxylate		increase APQ	increase APQ (lower than established)	627.000	827.000	200.000
gamma hydroxybutryic acid		increase APQ increase APQ increase APQ increase APQ	APQ adequate, no change	52,156.000	52,156.000	-
hydrocodone		increase APQ	APQ adequate, no change	55,000.000	55,000.000	-
hydromorphone		increase APQ increase APQ increase APQ	APQ adequate, no change	3,455.000	3,455.000	-
lisdexamphetamine		increase APQ	APQ adequate, no change	9,000.000	9,000.000	-
meperidine		increase APQ	APQ adequate, no change	6,600.000	6,600.000	-
metahdone		increase APQ increase APQ	APQ adequate, no change	20,000.000	20,000.000	-
methylphenidate		increase APQ	APQ adequate, no change	50,000.000	50,000.000	-
morphine (for sale)		increase APQ	increase APQ	35,000.000	39,000.000	4,000.000
morphine (for conversion)		increase APQ increase APQ increase APQ	APQ adequate, no change	83,000.000	83,000.000	-
nabilone		increase APQ	APQ adequate, no change	9.002	9.002	-
opium (tincture)		increase APQ increase APQ	increase APQ	1,050.000	1,500.000	450.000
oxycodone (for conversion)		increase APQ	increase APQ	4,000.000	5,600.000	1,600.000
oxycodone (for sale)		increase APQ increase APQ	increase APQ	88,000.000	105,500.000	#########
oxymorphone (for sale)		increase APQ increase APQ increase APQ	increase APQ	2,570.000	3,070.000	500.000
remifentanil		increase APQ	APQ adequate, no change	2.500	2.500	-
sufentanil		increase APQ	APQ adequate, no change	7.000	7.000	-
tapentadol		increase APQ increase APQ	increase APQ/establish APQ	-	1,000.000	1,000.000
tetrahydrocannabinols		increase APQ	increase APQ (lower than established)	216.000	264.000	48.000
thebaine		increase APQ	APQ adequate, no change	126,000.000	126,000.000	-
tilidine		increase APQ	increase APQ/establish APQ	-	0.010	0.010

Number of Companies commenting: 14 (one non-registrant)
Number of drugs commented on: 28

Additional Changes:

Drug	Response	Proposed	Revised	Change
ANPP (4-anilino-N-phenethyl-4-	newly controlled (August 4, 2010) (75 FR 37295)	-	1,100.000	1,100.000
carfentanil	increase APQ - new applications	-	0.200	0.200
marihuana	increase APQ - new applications	11.000	21.000	10.000
noroxymorphone (for sale)	increase APQ - new applications	5.000	41.000	36.000
oxymorphone (for conversion)	increase APQ (additional export requirements)	12,000.000	12,800.000	800.000

Justification

alfentanil	(b)(4) export 0.880 kg to UK, export to Germany; requesting 1.8 kg increase; temp 10403 (b)(4) justified in 1.8 kg; keep at 8.0
amphetamine (for conversion)	asking for 33 kg increase;
amphetamine (for sale)	asking for 1,823.5 kg;
codeine (for sale)	(b)(4) asking for 14097 kg
codeine (for conversion)	asking for 1125 kg
dextropropoxyphene	asking for 10000 kg increase
dihydromorphone	(b)(4) requests APQ 3828
diphenoxylate	Asking for 820 kg; justified - available in established APQ
gamma hydroxybutryic acid	(b)(4) asking for 1,639 kg; (b)(4) asking for 4560 kg
hydrocodone	(b)(4) asking for 23878 kg
hydromorphone	(b)(4) wants 81 kg; (b)(4) sole supplier request APQ 3630; (b)(4) requesting 66.213 kg
lisdexamphetamine	(b)(4) asking for 33 kg increase;
meperidine	(b)(4) Asking 2,300 kg; available in APQ
methadone	(b)(4) asking for 2,038 kg increase; 2560 kg thru 7/23; estimated sales 4055 kg total (b)(4) APQ is sufficient for increase
methylphenidate	(b)(4) asking for 18000 kg
morphine (for sale)	asking for 20095 kg
morphine (for conversion)	(b)(4) requests APQ 100607.2; (b)(4) asking for 20626 kg
nabilone	(b)(4 requesting 4 kg - available in APQ
opium (tincture)	(b)(4) requesting an additional 250 kg - process/PD; (b)(4) justified in 252 kg; with (b)(4) increase 564 kg; increase to 1500 kg
oxycodone (for conversion)	(b)(4) asking 5600 kg
oxycodone (for sale)	(b)(4) asking for 49627 kg; (b)(4) asking for 9700 kg increase
oxymorphone (for sale)	(b)(4 asking for 113 kg - not justified now but may be later; (b)(4) asking 2700 kg (justified in 2050 kg); (b)(4) asking forkg. Recommend 400 k 85 kg PD; FDA estimated 15.7% increase or approximately 400
remifentanil	(b)(4) asking for 1.855 kg - proposed APQ has this quantity
sufentanil	asking for 0.190 kg - available in proposed APQ
tapentadol	(b)(4) requesting APQ 1,000 kg; stating 450 kg to support (b)(4) published 10/28/09; (b)(4) not pub.
	(b)(4) comment 0.010 kg
tetrahydrocannabinols	requesting 40 kg increase
thebaine	(b)(4) requesting 10500 kg increase
tilidine	comment 0.010 kg

(b)(4)

VIA FEDERAL EXPRESS

DEA Federal Register Representative/ODL
Drug Enforcement Administration Headquarters
8701 Morrissette Drive
Springfield, VA 22152

RE: Comments to Federal Register DOCKET No. DEA-318R
Proposed Revised 2010 Aggregate Production Quota for Methadone for sale (Code 9250)
(b)(4) **Bulk Manufacturing Registration No.:** (b)(4);(b)(7)(E)

July 21, 2010

ATTENTION: DEA FEDERAL REGISTER REPRESENTATIVE/ODL

Telephone (b)(4);(b)(6)
Telefax (b)(4);(b)(6)
E-Mail (b)(4);(b)(6)
(b)(4);(b)(6)
(b)(4)

The purpose of this correspondence is to formally submit comments to the Drug Enforcement Administration's ("DEA") Notice in the Federal Register published June 23, 2010 (Docket No.: DEA-318R) proposing to decrease the 2010 Methadone for sale (Code 9250) aggregate production quota from 25,000,000 grams to 20,000,000 grams.

(b)(4) is requesting that the Methadone for sale aggregate quota be adjusted, as necessary, to meet (b)(4) requirements for an additional **2,038 kg base (2,290 kg salt)** Methadone production quota.

Additional quota is required to supply the annual 2010 and First Quarter 2011 Methadone Active Pharmaceutical Ingredient ("API") requirements of (b)(4) (b)(4), our sister company and Methadone API customer. Year to date, (b)(4) has shipped 2,560 kg base (2,876 kg salt) to (b)(4) (b)(4) does not export Methadone.

(b)(4) Methadone Activity for 2010 is summarized in the following table:

(b)(4) **2010 Methadone Activity (Kg Base Equivalence)**				
Customer Name	Net Sales to Date[1.]	Open DEA Form 222 Order[2.]	Planned Orders to be Submitted[3.,4.]	Total Projected Sales[4.]
(b)(4) (DEA No.: (b)(4);(b)(7)(E)	2,560 (2,876 salt)	275 (309 salt)	1,220 (1,371 salt)	4,055 (4,556 salt)

1. As of 07/23/10
2. Scheduled to ship 08/03/10
3. (b)(4) estimated requirements; reference comments to Federal Register DOCKET No. DEA-318R submitted 07/21/10 by (b)(6) (b)(4) Senior Compliance Professional

(b)(4)

(b)(4) current 2010 Methadone manufacturing quota is 2,352 kg base (2,643 salt). Our additional quota requirement based on the following calculation is **2,038 kg base (2,290 salt)**:

	2560	kg	*(2876*	*salt)*	Net 2010 Year to Date Sales
+	275	kg	*(309*	*salt)*	Open 222 order (scheduled to ship 08/03/10))
+	1220	kg	*(1371*	*salt)*	Planned Orders, subject to (b)(4) procurement quota
+	2027	kg	*(2278*	*salt)*	2010 End of Year 50% Inventory Allowance
-	2352	kg	*(2643*	*salt)*	Current 2010 Quota Grant
-	1692	kg	*(1901*	*salt)*	2009 Year End Inventory
=	**2038**	**kg**	*(2290*	***Salt)***	***Additional Methadone 2010 Production Quota Required***

Methadone Demand:
Sales to (b)(4) year to date have been 2,560 kg base (2,876 salt) and a DEA 222 order/Certificate of Procurement Quota issued by (b)(4) for an additional 275 kg base (309 salt) has been received. As described in (b)(4) comments to DOCKET No. DEA-318R under separate letter to your attention, (b)(4) estimates they will require procurement from (b)(4) of an additional 1,220 kg base (1,371 salt) in 2010 to support their 2010 sales and year-end inventory. (b)(4) is in the process of finalizing their requirements and (b)(4) will submit a consistent increase to meet these requirements. Both of our quota increase requests will be submitted within the next few weeks.

Methadone Inventory:
Included in (b)(4) requirements for quota is an inventory allowance of 2,027 kg base (2,278 salt) needed to meet (b)(4) 2011 First Quarter supply needs and allow (b)(4) to maintain a critical safety stock inventory level. Since (b)(4) is their preferred supplier, (b)(4) has expressed to us the importance of timely delivery of Methadone active pharmaceutical ingredients ("APIs").

If (b)(4) is to satisfy (b)(4) requirements for the balance of 2010 and First Quarter 2011, it is essential that the 2010 Methadone aggregate be appropriately adjusted to provide for (b)(4) additional quota requirements equal to **2,038 kg base (2,290 salt).** The additional quota is needed to prevent disruption of the supply of methadone final product to (b)(4) customers/patients.

Please contact (b)(6) Regulatory Compliance Controlled Substance Analyst, by phone at (b)(6) or email (b)(4);(b)(6) if you have any questions or require additional information..

We appreciate your review and consideration of our comments and I want to thank you in advance for your kind assistance in this matter.

(b)(6)

Senior Division Counsel and Assistant Secretary

(b)(6)

From: (b)(4);(b)(6)
Sent: Friday, July 23, 2010 10:50 AM
To: DeaDiversionPolicy
Subject: Docket No. DEA-318R
Attachments: 4587_001.pdf

Attention: Federal Register Representative/ODL

Attached are (b)(4);(b)(7)(E) comments to FR Volume 75, Number 120.

Reference Docket No. DEA-318R

<<4587_001.pdf>>

(b)(4)

(b)(4)

July 23, 2010

Acting Deputy Administrator
Drug Enforcement Administration
Washington, D.C. 20537

Attn: DEA Federal Register Representative [Docket No. DEA-318R']

This letter constitutes (b)(4) comments on the Proposed Revised Aggregate Production Quotas for 2010, as published in Federal Register on June 23, 2010, FR Doc 2010-15159 pages Page 35838-35841. In light of the fact that (b)(4) has no knowledge of either the amounts of any available aggregate quotas or the planned allocation of any aggregate, (b)(4) requests that DEA make any adjustments to the aggregate quotas sufficient to satisfy our requests for increased manufacturing quotas, which are outlined below. Because this comment contains proprietary information on our manufacturing quota needs, we also request that DEA treat this entire document as confidential.

All requests below are stated in grams anhydrous base ("AA").

9230 Meperidine

(b)(4) requests that the revised aggregate be sufficient to include our request for 2,300,000 grams AA of Meperidine manufacturing quota for 2010.

9170 Diphenoxylate

(b)(4) requests that the revised aggregate be sufficient to include our request for 820,000 grams AA of Diphenoxylate manufacturing quota for 2010.

9630 Opium Tincture

(b)(4) requests that the revised aggregate be sufficient to include our request for 1,330,000 grams AA of Opium Tinctire manufacturing quota for 2010.

9652 Oxymorphone (For Sale)

(b)(4) requests that the revised aggregate be sufficient to include our request for 2,700,000 grams AA of Oxymorphone (For Sale) manufacturing quota for 2010.

9143 Oxycodone (for Conversion)

(b)(4) requests that the revised aggregate be sufficient to include our request for 5,600,000 grams AA of Oxycodone (for Conversion) manufacturing quota for 2010.

All other quota requests remain unchanged from (b)(4) original request.

Sincerely,

(b)(6)

Manager, Controlled Substance Compliance

(b)(6)

(b)(4);(b)(6)

CONFIDENTIAL

(b)(4)

SENT VIA UPS - NEXT DAY AIR

July 22, 2010

DEA Headquarters
Attn: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Comments on Proposed Revised 2010 Alfentanil Manufacturing Quota

Dear DEA Federal Register Representative:

(b)(4) manufacturing registration (b)(4),(b)(7)(E) would like to comment on the 2010 Proposed Revised Aggregate Production Quota for Alfentanil as published in the June 23, 2010 Federal Register.

We feel the proposed quantity of 6,300 grams as base of Alfentanil manufacturing quota is not sufficient to provide adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements. Our primary customer for the Alfentanil product line is the export volume to (b)(4) in Germany. To support their needs, along with an export request for 880 grams to the UK and our domestic volume, we need to request an increase in the aggregate production quota. Separate from this communication, we are also submitting an application request for an additional 1,800 grams of Alfentanil manufacturing quota. For the above reason, we feel the 6,300 grams of Alfentanil manufacturing quota is not sufficient and should be increased by at least 1,800 grams as base to a new total of 8,100 grams as base.

Thank you for your consideration in this matter. Should you have any questions, please contact me at (b)(6)

Very truly yours,

(b)(6)

DEA Materials Control Manager

(b)(4)

CONFIDENTIAL

SENT VIA UPS - NEXT DAY AIR

July 22, 2010

DEA Headquarters
Attn: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Comments on Proposed Revised 2010 Oxymorphone Manufacturing Quota

Dear DEA Federal Register Representative:

(b)(4) manufacturing registration (b)(4);(b)(7)(E) would like to comment on the 2010 Proposed Revised Aggregate Production Quota for Oxymorphone as published in the June 23, 2010 Federal Register.

We feel the proposed quantity of 2,570,000 grams as base of Oxymorphone manufacturing quota is not sufficient to provide adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements. We have four primary customers for Oxymorphone; (b)(4) (b)(4) These customers are in the process of receiving FDA approval for the generic form of Opana®, both for the IR and the ER formulations. Once they receive approval, we expect them to purchase approximately 71,200 grams each as base to support their launch. Separate from this communication, we are also submitting an application request for an additional 113,000 grams of Oxymorphone manufacturing quota. For this reason, we feel the 2,570,000 grams of Oxymorphone manufacturing quota is not sufficient and should be increased by at least 113,000 grams as base to a new total of 2,683,000 grams as base.

Thank you for your consideration in this matter. Should you have any questions, please contact me at (b)(6)

Very truly yours,

(b)(6)

DEA Materials Control Manager

CONFIDENTIAL

(b)(4)

SENT VIA UPS - NEXT DAY AIR

July 22, 2010

DEA Headquarters
Attn: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Comments on Proposed Revised 2010 Remifentanil Manufacturing Quota

Dear DEA Federal Register Representative:

(b)(4) manufacturing registration (b)(4);(b)(7)(E) would like to comment on the 2010 Proposed Revised Aggregate Production Quota for Remifentanil as published in the June 23, 2010 Federal Register.

We feel the proposed quantity of 2,500 grams as base of Remifentanil manufacturing quota is not sufficient to provide adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements. Our customer for the Remifentanil is (b)(4) through (b)(4) and they have identified a need for 1,600 grams of material this calendar year. (b)(4) is migrating from importing the Remifentanil to qualifying a domestic source. Separate from this communication, we are submitting an application request for an additional 1,855 grams of Remifentanil manufacturing quota.. For this reason, we feel the 2,500 grams of Remifentanil manufacturing quota is not sufficient and should be increased by at least 1,855 grams as base to a new total of 4,355 grams as base.

Thank you for your consideration in this matter. Should you have any questions, please contact me at (b)(6)

Very truly yours,

(b)(6)

DEA Materials Control Manager

CONFIDENTIAL

(b)(4)

SENT VIA UPS - NEXT DAY AIR

July 22, 2010

DEA Headquarters
Attn: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Comments on Proposed Revised 2010 Sufentanil Manufacturing Quota

Dear DEA Federal Register Representative:

(b)(4) manufacturing registration (b)(4);(b)(7)(E) would like to comment on the 2010 Proposed Revised Aggregate Production Quota for Sufentanil as published in the June 23, 2010 Federal Register.

We feel the proposed quantity of 7,000 grams as base of Sufentanil manufacturing quota is not sufficient to provide adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements. We have signed a commercial agreement with a new customer in Germany and will begin supplying them annually with 420 grams as base of material beginning in January 2011. Since our current inventory of Sufentanil will be low in the forth quarter of this year and we need to begin building inventory to meet their needs in the first quarter of 2011, we need to request additional quota for this year in order to have sufficient inventory to meet our needs. Separate from this communication, we are also submitting an application request for an additional 190 grams of Sufentanil manufacturing quota. For this reason, we feel the 7,000 grams of Sufentanil manufacturing quota is not sufficient and should be increased by at least 190 grams as base to a new total of 7,190 grams as base.

Thank you for your consideration in this matter. Should you have any questions, please contact me at (b)(6).

Very truly yours,

(b)(6)

DEA Materials Control Manager

(b)(4)

July 14, 2010

DEA Headquarters
8701 Morrissette Drive
Springfield, VA 22152

Attn: DEA Federal Register Representative/ODL)

Re: Comments on "Controlled Substances: Proposed Revised Aggregate Production Quotas for 2010, "75 Federal Register (June 23, 2010); Docket No. DEA-318R"

Dear Representative:

(b)(4) herewith comments on a portion of the above referenced Federal Register proposal, specifically, the 2010 Proposed Revised Aggregate Production Quota for Opium (drug code 9630). (b)(4) signed an agreement to transfer the manufacture of Opium Tincture to (b)(4) in 2010. On June10, 2010, (b)(4) received 303000 grams of procurement quota for Opium Tincture.

As noted in the attached letter, (b)(4) has requested that (b)(4) apply for an additional 250000 grams of Opium Tincture to support the transfer, validation, and clinical study for Opium Tincture.

(b)(4) is requesting an increase of 250000 grams to the Opium Tincture aggregate for 2010 to ensure that there is adequate supply for the transfer, validation, and clinical study along with an uninterrupted supply for patients using this medication.

Thank you for your time and consideration in this important matter.

Respectfully submitted,

(b)(6)

Manager DEA Compliance & Security

Attachments

(b)(4)

July 20th, 2010

(b)(6)
Manager DEA Compliance & Security
(b)(4)

Dear (b)(6)

Under the terms of the commercial manufacturing agreement between (b)(4) and (b)(4) effective January 2010 (b)(4) has agreed to manufacture Opium Tincture, USP (Deodorized) for (b)(4)

As a follow up to (b)(4) letter dated March 23rd 2010, (b)(4) would like (b)(4) to submit to DEA a request for additional procurement quota for Opium Tincture, DEA Code No. 9630. (b)(4) acknowledges the following:

1) (b)(4) is in the process of completing the necessary technology transfer and product development required to allow for future production of Opium Tincture, USP on behalf of (b)(4)

2) (b)(4) has received approval for 303 kg Opium (Tincture), DEA Code No. 9630 for registration runs in support of (b)(4) NDA. Due to the challenges posed in the manufacturing of Opium Tincture, USP and the fact that (b)(4) has not previously manufactured this product at their facility, (b)(4) will request an additional 250 kg of Opium (Tincture), DEA Code 9630:

   a. 200 kg will be allocated 1) to produce a full scale product development run prior to the start of the process validation runs, and this will provide material for clinical studies; 2) to allow for production of a fourth registration run to ensure that at least three runs are successfully completed in support of (b)(4) NDA filing.
   b. The additional 50 kg is required to have a 10% excess (of 303 kg already approved + additional 200 Kg) for sample analysis, stability sampling, and due to known assay variability in the Opium Tincture DEA Code No. 9630.

3) Commencing in 2011, all manufacturing of Opium Tincture, USP for the benefit of (b)(4) (b)(4) will be done by (b)(4) At the appropriate time, (b)(4) may request additional procurement quota based on product demand.

(b)(4) believes this additional quota is necessary to ensure the success of the technology transfer, and to ensure that the necessary data is generated in support of clinical trials and the filing of the NDA by (b)(4) with the United States FDA.

Furthermore, the additional drug product produced will guarantee the availability of Opium Tincture, USP for the patients that are dependent on this very important product.

Thank you very much for your attention to this matter. Please do not hesitate to contact me if you need clarification on any point.

Sincerely,

(b)(6)

President and CEO

(b)(4)

Cc: File

(b)(4)

(b)(4)

From: (b)(4);(b)(6)
Sent: Thursday, July 22, 2010 5:09 PM
To: DeaDiversionPolicy
Cc: (b)(6)
Subject: Comment to Proposed 2010 Revised Aggregate Production Quotas (Docket No. DEA-318R) [CONFIDENTIAL]
Attachments: (b)(4) fedreg comment 07132010.PDF

See attached.

(b)(6)
Vice President, Regulatory Affairs
(b)(4)
Direct Line: (b)(6)
Fax: (b)(6)
(b)(4);(b)(6)

CONFIDENTIALITY NOTICE

This email is the property of (b)(4) and/or its relevant affiliates and may contain confidential and privileged material for the sole use of the intended recipient(s). Any review, use, distribution or disclosure by or to others is strictly prohibited. If you are not the intended recipient (or authorized to receive for the recipient), please contact the sender at (b)(6) or reply to (b)(4) at (b)(4);(b)(6) and delete all copies of the message.

(b)(4)

CONFIDENTIAL

13 July 2010

Drug Enforcement Administration
Attn: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Comment on Proposed 2010 Revised Aggregate Production Quotas
Docket No. DEA-318R

Dear Sir or Madam:

(b)(4) is submitting this comment in reference to the Proposed 2010 Revised Aggregate Production Quotas published in the Federal Register under citation Vol. 75, No. 120, pages 35838-35841, dated 23 June 2010. This is Docket No. DEA-318R. This comment relates to two controlled substances.

(b)(4) is currently registered as a bulk manufacturer for Tapentadol (9780) and has applied to be registered as a bulk manufacturer for Tilidine (9750). It is uncertain whether DEA will complete the registration process for Tilidine in time for a manufacturing quota to be utilized in 2010. However, (b)(4) is submitting this comment for that substance in case that occurs. Currently, there is no aggregate production quota assigned for 2010 for either of these substances. Any material that (b)(4) bulk manufactures of these substances will be used to produce exempt chemical preparations for sale as analytical reference materials. Also, quotas for 2011 will be requested for these substances at the appropriate time.

(b)(4) requests that the 2010 aggregate production quota for the following two substances be revised to cover (b)(4) anticipated requirement in the amounts listed:

Tapentadol (9780)	10 g
Tilidine (9750)	10 g

Should you have any questions regarding this comment, please contact me at (b)(6) (b)(6)

Sincerely,

(b)(6)

Vice President
Regulatory Affairs

(b)(4)

(b)(6)

From: (b)(4);(b)(6)
Sent: Wednesday, July 21, 2010 2:54 PM
To: DeaDiversionPolicy
Cc: (b)(4);(b)(6)
Subject: (b)(4) Comments - Proposed Aggregate Production Quota Docket No. DEA-318R
Attachments: 2010 Comments on Proposed APQ 7-21-2010.pdf

Importance: High

Dear Deputy Administrator:

(b)(4) wishes to comment on the Schedule II compounds listed in the Proposed Revised Aggregate Production Quotas for 2010. Attached (in Adobe PDF format) please find our document for your review and consideration. Please do not hesitate to contact me with any questions.

Best regards,

(b)(6)
DEA Compliance/Security Manager
(b)(4)
(b)(6) office
fax
(b)(4);(b)(6)

Confidentiality Notice: This e-mail transmission may contain confidential or legally privileged information that is intended only for the individual or entity named in the e-mail address. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or reliance upon the contents of this e-mail is strictly prohibited. If you have received this e-mail transmission in error, please reply to the sender, so that (b)(4) can arrange for the proper delivery, and then please delete the message from your inbox. Thank you.

(b)(4)

(b)(4)

July 21, 2010

DEA Headquarters
Attention: DEA Federal Register Representative/CCD
8701 Morrissette Drive
Springfield, VA 22152

Subject: Docket No. DEA-318R

Dear Deputy Administrator:

(b)(4) wishes to comment on seven basic classes of Schedule II compounds listed in the subject document whereby we believe the Aggregate Production Quota (APQ) is not sufficient to support our projected customer needs for the remainder of 2010 and into the first Quarter of 2011. (b)(4) is concerned that of these, six are proposed to remain at the Established Initial 2010 Quota levels, and one is proposed to be reduced.

(b)(4) suggests that APQ should be increased in the following Basic Classes:

Basic Class	Previously Established Initial 2010 Quotas	Proposed Revised 2010 Quotas	2010 Quota issued	2010 Quota Required	Date of Quota Request
	grams	grams	grams	grams	
Codeine (sale)	39,605,000	39,605,000	9,392,000	14,097,000	6/29/2010
Codeine (conv)	65,000,000	65,000,000	0	1,125,000	7/19/2010
Hydrocodone (sale)	55,000,000	55,000,000	20,000,000	23,878,000	7/19 & 7/21/10
Methylphenidate	50,000,000	50,000,000	11,890,000	18,000,000	7/9/2010
Morphine (sale)	35,000,000	35,000,000	13,942,000	20,095,000	7/19/2010
Morphine (conv)	100,000,000	83,000,000	13,924,000	20,626,000	7/19/2010
Oxycodone (sale)	88,000,000	88,000,000	28,670,000	49,627,000	7/19/2010

(b)(4) **has submitted quota requests to Dr. Christine A. Sannerud, Ph.D., Chief, Drug & Chemical Evaluation Section, which include specific data to support our position for increasing APQ in the above tabled basic classes.**

Please consider this information in finalizing the 2010 aggregate quota. If you have questions regarding this request, please do not hesitate to contact me at (b)(4);(b)(6)

Best regards,

(b)(4);(b)(6)

DEA Compliance/Security Manager

(b)(6)

From: (b)(4);(b)(6)
Sent: Wednesday, July 21, 2010 1:21 PM
To: DeaDiversionPolicy
Subject: (b)(4) comments to DEA Docket No. DEA-318R - attached pdf
Attachments: (b)(4) -aggregate-comment-letter.pdf

Importance: High

<<(b)(4) -aggregate-comment-letter.pdf>>

(b)(4) comments are included in the attached pdf.

Thank you for your consideration in this matter.

Best regards,

(b)(6)
Senior Compliance Professional, Compliance Services
(b)(4);(b)(6)
(b)(4);(b)(6)

(b)(4)

July 21, 2010

Via Email

Dea.diversion.policy@usdoj.gov

(b)(4)

Re: Notice of Proposed Revised Aggregate Production Quotas – 2010
Methadone (for sale); Ref: Docket No. DEA-318R

Attention: DEA Federal Register Representative

Reference is made to the Federal Register Notice dated June 23, 2010 (Docket No. DEA-318R) in which the Administration published their proposal to decrease the Methadone (for sale) aggregate quota from 25,000,000 grams to 20,000,000 grams. This letter is being submitted to comment on this proposal.

(b)(4) - DEA Registration # (b)(4);(b)(7)(E) procures Methadone (for sale) active drug substance for the manufacture of finished dosage forms. We have reached a point in this quota year where we have evaluated our sales figures versus our 2010 authorized quota and anticipated inventory. (b)(4) has experienced an increase in 2010 sales for Methadone over and above the sales rate for 2009. Based upon this evaluation we are in the process of preparing a quota increase request for approximately 1220 Kgs of Methadone base. In discussions with (b)(4) our sister company and Methadone API supplier, they will also submit a consistent increase for their Methadone production quota to meet (b)(4) increase in sales. Both of our quota increase requests should be submitted within the next few weeks.

(b)(4)

(b)(4) will require respective Methadone procurement quota and production quota increases in order for (b)(4) to continue to provide the marketplace with our finished dosage forms in 2010 and early 2011. We are concerned that if the Methadone (for sale) aggregate production quota is lowered, additional active drug substance for the legitimate medical use in the United States will not be available. We therefore respectfully request that the Administration not reduce the initially published quota of 25,000,000 grams of Methadone (for sale).

Please contact me at (b)(6) if you have any questions or require additional information.

Sincerely,

(b)(6)

Senior Compliance Professional, Compliance Services
(b)(4)
☎ (b)(6)
✉ (b)(4);(b)(6)

(b)(6)

From: (b)(4);(b)(6)
Sent: Tuesday, July 20, 2010 10:14 AM
To: DeaDiversionPolicy
Cc: (b)(4);(b)(6)
Subject: DOCKET NO. DEA-318R - (b)(4) COMMENTS Proposed Revised Aggregate Production Quota for 2010 Tapentadol (9780)
Attachments: Docket No. DEA-318R, (b)(4) comments, 20 July 2010.pdf

To whom it may concern,

Attached you will find comments from (b)(4) on the Docket No. DEA-318R.

(See attached file: Docket No. DEA-318R, (b)(4) comments, 20 July 2010.pdf)

Please confirm receipt.

If you have any questions please let me know.

Best regards,
(b)(6)

Sr. Quality & Regulatory Affairs Specialist (b)(4)
(b)(4);(b)(6)

(b)(4)

(b)(4)

July 20, 2010

ATTN: Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Sent via email: dea.diversion.policy@usdoj.gov

RE: Docket No. DEA-318R
Proposed Revised Aggregate Production Quotas for 2010
Tapentadol (9780)

(b)(4) (b)(4);(b)(7)(E) submitted application for bulk manufacturing registration of Tapentadol on May 22, 2009. The Notice of Application was posted on the federal register on 28 Oct 2009. As of today, the (b)(4) Notice of Registration has not been posted.

DEA requested more customer information to support our application. (b)(4) provided two customer letters of intent (LOI) to purchase 445 kg Tapentadol from (b)(4) in 2010/2011. Additional customer interest is expected as generic pharmaceutical manufacturers are beginning drug formulation development for this product. (b)(4) will partner initially with (b)(4) (b)(4) to manufacturing bulk drug product to support their Abbreviated New Drug Application (ANDA).

(b)(4) requests that the DEA revise the 2010 aggregate production quota to establish at least 1000 kg of Tapentadol manufacturing quota. (b)(4) will apply for manufacturing quota once the anticipated (b)(4) Tapentadol manufacturing registration is published. This aggregate quota is essential to support the formulation development work per anticipated product development schedules.

Thank you for your consideration of this request.

Respectfully yours,

(b)(6)

Directory of Quality, EH&S

(b)(6)

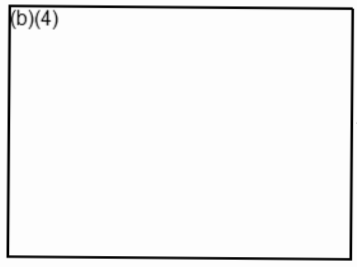
From: (b)(4);(b)(6)
Sent: Monday, June 22, 2009 6:40 PM
To: DeaDiversionPolicy
Cc: (b)(6)
Subject: Attn: DEA Federal Register Representative [Docket No. DEA-318P]

DEA Federal Register Representative:

Please see the attached comments to the Proposed 2010 Aggregate Production Quotas for (b)(4);(b)(6) (b)(4);(b)(6)

Sincerely,

(b)(6)
Supervisor, Controlled Substance Compliance
(b)(4)
Telephone (office) (b)(6)
(b)(4);(b)(6)



July 16, 2010

DEA Headquarters
8701 Morrissette Drive
Springfield, VA 22152
Attn: DEA Federal Register Representative/ODL

Re: Comments on "Controlled Substances: Proposed Revised Aggregate Production Quotas for 2010", 75 Federal Register (June 23, 2010); On behalf of the following manufacturing registrant:

(b)(4) - **Registration #** (b)(4),(b)(7)(E)

Re: Docket No. DEA-318R

CONFIDENTIAL

Dear Deputy Administrator:

(b)(4) herewith comments to a portion of the above referenced Federal Register proposal. Specifically, (b)(4) believes that the Proposed Revised Aggregate Production Quota for 2010 for the following controlled substances:

Oxycodone (Sale) (Drug Code 9143)
Tetrahydrocannibinols (Drug Code 7370)
Thebaine (Drug Code 9333)

may not be adequate for the medical, scientific, research and industrial needs of the United States.

The revised aggregate quota for 2010 for Oxycodone (sale) has been proposed at 88,000,000 grams which is the same level as the initial aggregate quota for 2010. At this time (b)(4) has a quota request pending with DEA for 9,700 kg. (b)(4) (b)(4) requests that its pending application be considered when finalizing the revision to the 2010 Aggregate Production Quota for Oxycodone (sale).

The revised aggregate quota for 2010 for Tetrahydrocannibinols has been proposed at 216,000 grams which is 96,000 grams less than the initial aggregate quota for 2010. At the present time (b)(4) has a quota request pending with DEA for 40,000 grams. (b)(4) requests that its pending application be considered when finalizing the revision to the 2010 Aggregate Production Quota for Tetrahydrocannibinols.

The revised aggregate quota for 2010 for Thebaine has been proposed at 126,000,000 grams which is the same level as the initial aggregate quota for 2010. At this time (b)(4) has a quota request pending with DEA for 10,500 kg. (b)(4) requests that its pending application be considered when finalizing the revision to the 2010 Aggregate Production Quota for Thebaine.

Any issues or correspondence pertaining to the above matter may be addressed to my attention.

Respectfully submitted,

(b)(6)

Director, Regulatory Affairs

July 13, 2010

DEA Headquarters
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA-318R

Dear Deputy Administrator:

(b)(4) submit the following comments regarding the Proposed Revised 2010 Aggregate Quota for controlled substances in schedules I and II of the Controlled Substances Act.

(b)(4) is a producer of Hydromorphone HCl API, and are the only FDA approved supplier of Hydromorphone HCl API to (b)(4) (b)(4)

We are seeing an increase of approximately 10% in the market demand for Hydromorphone HCl, supported by the attached drug shortage page from the American Society of Health –System Pharmacists.

Due to this demand increase, we propose that the 2010 Aggregate Quota be increased by 10% for Hydromorphone. (b)(4) synthetic pathway to produce Hydromorphone requires 1.6 to 1 kg of Dihydromorphine, so this quota should be increased by 16%. Morphine (for conversion) is the starting material for this synthesis and (b)(4) consumes 1.15 kg per kg of Dihydromorphine.

Therefore, our recommended 2010 Revised Aggregate Quota is as follows:

Hydromorphone	3,630,000 g
Dihydromorphine	3,828,000 g
Morphine (for conversion)	100,607,200 g

Sincerely,

(b)(6)

Executive Vice President
(b)(4)
(b)(6)

American Society of Health-System Pharmacists
TOGETHER WE MAKE A GREAT TEAM

Hydromorphone Hydrochloride Injection

01 July 2010

Products Affected - Description

Dilaudid-HP powder for injection, Purdue
250 mg vial (NDC 59011-0446-25)

Hydromorphone hydrochloride injection, Hospira
1 mg/mL, 1 mL Carpuject syringe (NDC 00409-1283-31)
2 mg/mL, 1 mL Carpuject syringe (NDC 00409-1312-30)
1 mg/mL, 1 mL ampul (NDC 00409-2552-01)
10 mg/mL, 1 mL ampul (NDC 00409-2172-01) - *discontinued*

Hydromorphone hydrochloride injection, Teva
10 mg/mL, 1 mL vial (NDC 00555-1117-05)
10 mg/mL, 5 mL vial (NDC 00555-1117-06)
10 mg/mL, 50 mL vial (NDC 00555-1117-07)

Reason for the Shortage

Hospira's Carpuject syringes have been in short supply due to increased demand for product.

Purdue Pharma, Teva, and Baxter could not provide a reason for the shortage.

Estimated Resupply Dates

Purdue Pharma has Dilaudid HP powder for injection on back order with an estimated release date of mid-July, 2010. Dilaudid is available in 1 mg/mL 1 mL 10 count (NDC 59011-0441-10), 2 mg/mL 1 mL 10 count (NDC 59011-0442-10) and 25 count (NDC 59011-0442-25), and 4 mg/mL 1 mL 10 count (NDC 59011-0444-10) ampules. Dilaudid HP is available in 10 mg/mL 1 mL (NDC 59011-0445-01) and 5 mL (NDC 59011-0445-05) ampules, and 10 mg/mL 50 mL (NDC 59011-0445-50) vials.

Hospira has available several presentations of hydromorphone injection in Carpuject syringes, vials, and ampules. Hydromorphone 4 mg/mL Carpuject syringes (NDC 00409-1304-31) are readily available. The 1 mg/mL and 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date in the 4th quarter of 2010. The 1 mg/mL 1 mL ampule is on back order and the company estimates a release date of mid-July, 2010. The 2 mg/mL 1 mL ampule (NDC 00409-3356-01) and vial (NDC 00409-3365-01), 10 mg/mL 1 mL (NDC 00409-2634-01), 5 mL (NDC 00409-2634-05), and 50 mL (NDC 00409-2634-50) vials, and 4 mg/mL 1 mL ampules (NDC 00409-2540-01) are readily available.

Baxter has available hydromorphone 2-mg/mL in 1 mL (NDC 00641-0121-025) and 20-mL (NDC 00641-2341-41) vials.

Teva (formerly Barr) has all hydromorphone presentations on back order with an estimated release date of late-September, 2010.

Related Shortages

Acetaminophen/dichloralphenazone/isometheptene— Resolved

Alfentanil Injection— Resolved

Butorphanol Injection— Resolved

Choline Magnesium Trisalicylate

Codeine Phosphate Injection— No Longer Available

Codeine Phosphate Oral Solution— No Longer Available

Diazepam Injection

Fentanyl Transdermal System Patch— Resolved

Hydrocodone Tablets— Resolved

Indomethacin Capsules— Resolved

Indomethacin Injection

Ketorolac Injection

Meperidine— Resolved

Meperidine / Promethazine— No Longer Available

Methadone Hydrochloride Injection— Resolved

Methadone Hydrochloride Tablets— Resolved

Methadone Injection— Resolved

Methadone Oral Tablets and Liquid— Resolved

Morphine PCA Syringes— Resolved

Morphine Sulfate— No Longer Available

Morphine Sulfate: Extended-Release Products— Resolved

Morphine Sulfate: Oral Concentrated Solution

Oxycodone Combinations Capsules and Tablets— Resolved

Oxycodone Extended-Release Tablets— Resolved

Oxycodone Tablets, Capsules, and Solutions— Resolved

Pentazocine / Naloxone Tablets— Resolved

Piroxicam Capsules

Remifentanil Hydrochloride— Resolved

Sufentanil Injection— Resolved

Updated

July 1, 2010; June 8, 2010; May 13, 2010; April 21, 2010; April 7, 2010; March 15, 2010; February 9, 2010; January 19, 2010; December 22, 2009; December 3, 2009; November 11, 2009; October 21, 2009; September 2, 2009; August 12, 2009; July 16, 2009; June 23, 2009; May 29, 2009; May 20, 2009; May 7, 2009; April 28, 2009; April 14, 2009; April 1, 2009; March 20, 2009; March 16, 2009; March 12, 2009. University of Utah, Drug Information Service. Copyright 2010, Drug Information Service, University of Utah, Salt Lake City, UT.

Back to Drug Shortage Product Bulletins

(b)(4)

DEA Headquarters
Attn: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

(b)(4)

(b)(4);(b)(6)

July 1, 2010

Subject: Docket No. DEA-318R - Oxymorphone

Dear Federal Register Representative,

(b)(4) is a registered manufacturer (b)(4);(b)(7)(C) of Oxymorphone. The 2010 Proposed Revised Aggregate Production Quota for Oxymorphone is not sufficient. On April 1, 2010 (b)(4) submitted a DEA Form 189 requesting 85 kg of Oxymorphone manufacturing quota, which was denied on May 13th due to constraints of the aggregate.

(b)(4) requested this quota to manufacture two technical and four validation batches of a new low impurity Oxymorphone process. (b)(4) has forecasted Oxymorphone HCl, low impurity sales of 31 kg (26.35 kg as base) for 2010.

(b)(4) respectfully requests that the 2010 aggregate production quota for Oxymorphone be established at least at 2,655,000 grams, which is the amount DEA is proposing plus 85 kg for (b)(4)

Once the increased aggregate has been finalized, (b)(4) will submit another DEA Form 189 to request the 85 kg of manufacturing quota. If you have any questions or require additional information, please feel free to contact me directly.

Sincerely,

(b)(4)

(b)(6)

DEA Compliance Manager

(b)(4)

DEA Headquarters
Attn: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

(b)(4)

(b)(4);(b)(6)

July 1, 2010

Subject: Docket No. DEA-318R - Dextropropoxyphene

Dear Federal Register Representative,

(b)(4) is a registered manufacturer (b)(4);(b)(7)(E) of Dextropropoxyphene. Under separate cover (b)(4) is submitting a DEA Form 189 for an increase of 10,000 kg in our Dextropropoxyphene manufacturing quota for 2010. (b)(4) wants to be sure that the reduction in the national aggregate from 106,000 kg to 92,000 kg will still allow sufficient quota in the aggregate for (b)(4) to be granted the requested 10,000 kg.

Briefly, (b)(4) beginning inventory of Dextropropoxyphene was 21,154 kg, our current manufacturing quota is 36,737 kg as base, our sales through 6/30/10 were 32,084 kg as base and are projected to be 16,500 kg as base for the balance of the year. Our current quota will not allow sufficient inventory to be carried into 2011 to meet our first quarter demand 15,000 kg as base.

(b)(4) respectfully requests that the 2010 aggregate production quota for Dextropropoxyphene be established at a level that will allow sufficient quota for (b)(4) to be granted an additional 10,000 kg of manufacturing quota in 2010. If you have any questions or require additional information, please feel free to contact me directly.

Sincereiy,

(b)(4)

(b)(4);(b)(6)

DEA Compliance Manager

(b)(4)

(b)(4)

July 6, 2010

DEA Headquarters
8701 Morrissette Drive
Springfield, VA 22152

Attn: DEA Federal Register Representative/ODL)

Re: Comments on "Controlled Substances: Proposed Revised Aggregate Production Quotas for 2010, "75 Federal Register (June 23, 2010); Docket No. DEA-318R"

Dear Representative:

(b)(4) herewith comments on a portion of the above referenced Federal Register proposal, specifically, the 2010 Proposed Revised Aggregate Production Quota for Hydromorphone (drug code 9150). During 2010 (b)(4) (b)(4) submitted a manufacturing allocation request dated April 19, 2010 and an updated request via email on May 11, 2010 , which DEA was unable to process due to insufficient quantity remaining in the aggregate.

(b)(4) received Hydromorphone quota for 336000 grams base for 2010. (b)(4) requires an additional 66213 grams base of Hydromorphone to satisfy the demands of our customers for 2010. Attached find the supporting documentation for the increase.

Based on (b)(4) customer and inventory reserve requirements, there is a demonstrated need to provide for a minimum increase of 67,000 grams (base), for a total of 403,000 grams base Hydromorphone to meet the requirements of (b)(4)

Thank you for your time and consideration in this important matter.

Respectfully submitted,

(b)(6)

Manager DEA Compliance & Security

Attachments

Hydromorphone

Customers	Sales 1/1/2010 thru 5/11/2010
	grams base
(b)(4);(b)(7)(E)	
Total	27110.47
(b)(4);(b)(7)(E)	-
Total	56835.04
(b)(4);(b)(7)(E)	-
Total	35207.6
(b)(4);(b)(7)(E)	-
Hydromorphone HCL	22250.00
TOTAL	141403.11

Hydromorphone Forecast Sales May thru Dec 2010

US Brand and Generic					grams base
May-Dec Total (b)(4) (b)(4) 2010					43980
May-Dec Total Hydromorphone - (b)(4) 2010					63650
May-Dec (b)(4) Domestic 2010					40000
Tech Transfer (b)(4) (b)(4)					22000
Exports					kg(base)
May-Dec Total (b)(4) (b)(4) 2010					3550
May-Dec Total (b)(4) (b)(4) 2010					87630

Total **260820**

Forecast + Sales
260820 + 141403 = 402223

(b)(4)

FED EX

April 19, 2010

Drug Enforcement Administration Headquarters
Attn.: Christine Sannerud, Ph D.,Chief
Drug and Chemical Evaluation Section (ODE)
8701 Morrissette Drive
Springfield, VA 22152

2010 Hydomorphone (9150) and Morphine (9300)Quota
Manufacturer DEA # (b)(4);(b)(7)(E)

Ladies and Gentlemen:

(b)(4) is requesting additional quota for 22 kgs of Hydromorphone base for the Tech Transfer of Hydromorphone IR tablets for (b)(4)

(b)(4) will also require 37.5 kgs of Morphine base to manufacture the 22 kgs of Hydromorphone base.

This request is supported by the attached quota letter provided by (b)(4) (b)(4)

If you have any additional questions, please contact me at (b)(6) or email (b)(4);(b)(6)

Sincerely,

(b)(6)

Manager DEA Compliance & Security

(b)(4)

(b)(4)

February 2, 2010

Christine A. Sannerud, PH.D., Chief
DEA Headquarters
8701 Morrissette Drive
Springfield, VA 22152

Re: 2010 Hydromorphone (9150) Product Development Allocation for (b)(4) (b)(4) **Registration** (b)(4);(b)(7)(E)

Authority is requested to procure 22.0 kgs(base), an increase of 22.0 kgs(base) over the current authorization of 0.0 kgs.(Attached is an updated DEA-250 to support this request.)

This material is requested to support the Tech Transfer of Hydromorphone IR Tablets (Dilaudid) from (b)(4) to (b)(4) as outlined in Attachment I. Due to unexpected uniformity results from the three *initial* validation batches additional quota is required to repeat the Characterization/Registration/Validation batches.

Note: DEA granted an increase on 11/17/09 to support this project, however, (b)(4) (b)(4) **was unable to supply the API by 12/31/09.**

Any issues or correspondence pertaining to the above subject should be addressed to:

(b)(4);(b)(6)

Respectfully submitted,

(b)(6)

Senior Executive Director-SCM

Attachment

(b)(4)

RECEIVED

(b)(4)

10 JUL 21 PM 3:06

10423

July 20, 2010

DEA Headquarters
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152
Dea.diversion.policy@usdoj.gov

RE: **Controlled Substances: Proposed Revised Aggregate Production Quotas for 2010 (Docket No. DEA-318R)**

Dear Deputy Administrator:

(b)(4) submits the following comments regarding the Proposed Revised 2010 Aggregate Quota for controlled substances in schedules I and II of the Controlled Substances Act (Federal Register/ Volume 75, No. 120 / June 23, 2010).

(b)(4) is a producer of Hydromorphone HCl finished product:

- Hydromorphone Hydrochloride Injection USP, 10 mg/mL – 10 mg / 1 mL ampules
- Hydromorphone Hydrochloride Injection USP, 10 mg/mL – 50 mg / 5 mL ampules
- Hydromorphone Hydrochloride Injection USP, 10 mg/mL – 500 mg / 50 mL vials

Our only FDA approved source of Hydromorphone HCl active pharmaceutical ingredient (API) is (b)(4).

We are seeing an increase of approximately 10% in the market demand for Hydromorphone HCl finished product, and we are unable to satisfy customer demand due to a shortage of API. This circumstance is confirmed by the July 2010 issue from American Society of Health – System Pharmacists (drug shortage page attached):

http://www.ashp.org/Import/PRACTICEANDPOLICY/PracticeResourceCenters/DrugShortages/GettingStarted/CurrentShortages/Bulletin.aspx?id=524

Due to this demand increase, we propose that the 2010 Aggregate Quota be increased by 10% for Hydromorphone.

API Status: (b)(4) synthetic pathway to produce Hydromorphone requires 1.6 to 1 kg of Dihydromorphine, so this quota should be increased by 16%. Morphine (for conversion) is the starting material for this synthesis and (b)(4) consumes 1.15 kg per kg of Dihydromorphine.

Therefore, the recommended 2010 Revised Aggregate Quota is as follows:

Hydromorphone	3,630,000 g
Dihydromorphine	3,828,000 g
Morphine (for conversion)	100,607,200 g

Finished Product Status:

Based on current sales forecasts and customer orders, (b)(4) most recently requested a quota increase from 23,300 grams (in 2009) to 81,000 grams in 2010. DEA granted an increase to 63,000 grams. On July 14th, (b)(4) once again requested a quota authorization increase for 2010 in the amount of 19,000 – so as to allow an increase from 63,000 grams to the previously requested total of 81,000 grams, for 2010. (See attached DEA Forms 250).

Your immediate attention to this matter is greatly appreciated.

(b)(6)

20 July 2010

Executive Vice-President - Operations,
Global Quality Assurance & Technical Services
Toll Free: (b)(4);(b)(6)
Direct:
Fax:
Email: (b)(4);(b)(6)

(b)(4) **Quality Policy:** It is (b)(4) policy to preserve and improve patient health by consistently delivering high quality, safe and effective specialty pharmaceutical products, that meet or exceed customer expectations.

Attachments:

- American Society of Health – System Pharmacists (drug shortage page)
- FDA product approval letters (b)(4)
- DEA Forms 250 (b)(4)

Dated: June 8, 2010.
Mark J. Musaus,
Acting Regional Director.
[FR Doc. 2010–15169 Filed 6–22–10; 8:45 am]
BILLING CODE 4310–55–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–318R]

Controlled Substances: Proposed Revised Aggregate Production Quotas for 2010

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed revised 2010 aggregate production quotas.

SUMMARY: This notice proposes revised 2010 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before July 23, 2010.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–318R" on all written and electronic correspondence. Written comments should be sent to the DEA Headquarters, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov*. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. However, persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, *Telephone:* (202) 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

On May 21, 2009, a notice of proposed 2010 aggregate production quotas for certain controlled substances in schedules I and II was published in the **Federal Register** (74 FR 23881). This notice stipulated that the DEA would adjust the quotas in 2010 as provided for in 21 CFR part 1303. The 2010 established aggregate production quotas were published in the **Federal Register** (74 FR 54080) on October 21, 2010.

The proposed revised 2010 aggregate production quotas represent those quantities of controlled substances in schedules I and II that may be produced in the United States in 2010 to provide adequate supplies of each substance for: The estimated medical, scientific, research and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

The proposed revisions are based on a review of 2009 year-end inventories, 2009 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information available to the DEA.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. 826), and delegated to the Administrator of the DEA by 28 CFR 0.100, and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby proposes the following revised 2010 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base:

Basic class	Previously established initial 2010 quotas	Proposed revised 2010 quotas
Schedule I		
2,5-Dimethoxyamphetamine	2 g	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g	2 g
3-Methylfentanyl	2 g	2 g
3-Methylthiofentanyl	2 g	2 g
3,4-Methylenedioxyamphetamine (MDA)	25 g	20 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10 g	10 g
3,4-Methylenedioxymethamphetamine (MDMA)	20 g	20 g
3,4,5-Trimethoxyamphetamine	2 g	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	2 g	2 g
4-Methoxyamphetamine	77 g	77 g
4-Methylaminorex	2 g	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g	2 g
5-Methoxy-N,N-diisopropyltryptamine	5 g	0 g
Acetyl-alpha-methylfentanyl	2 g	2 g
Acetyldihydrocodeine	2 g	2 g
Acetylmethadol	2 g	2 g
Allylprodine	2 g	2 g
Alphacetylmethadol	2 g	2 g
Alpha-ethyltryptamine	2 g	2 g
Alphameprodine	2 g	2 g
Alphamethadol	2 g	2 g
Alpha-methylfentanyl	2 g	2 g
Alpha-methylthiofentanyl	2 g	2 g

Basic class	Previously established initial 2010 quotas	Proposed revised 2010 quotas
Alpha-methyltryptamine (AMT)	2 g	2 g
Aminorex	2 g	2 g
Benzylmorphine	2 g	2 g
Betacetylmethadol	2 g	2 g
Beta-hydroxy-3-methylfentanyl	2 g	2 g
Beta-hydroxyfentanyl	2 g	2 g
Betameprodine	2 g	2 g
Betamethadol	2 g	2 g
Betaprodine	2 g	2 g
Bufotenine	3 g	3 g
Cathinone	3 g	3 g
Codeine-N-oxide	602 g	602 g
Diethyltryptamine	2 g	2 g
Difenoxin	3,000 g	3,000 g
Dihydromorphine	3,300,000 g	3,500,000 g
Dimethyltryptamine	3 g	3 g
Gamma-hydroxybutyric acid	24,200,000 g	52,156,000 g
Heroin	20 g	20 g
Hydromorphinol	2 g	2 g
Hydroxypethidine	2 g	2 g
Ibogaine	1 g	1 g
Lysergic acid diethylamide (LSD)	15 g	15 g
Marihuana	4,500,000 g	11,000 g
Mescaline	7 g	5 g
Methaqualone	7 g	7 g
Methcathinone	4 g	4 g
Methyldihydromorphine	2 g	2 g
Morphine-N-oxide	605 g	605 g
N-Benzylpiperazine	2 g	2 g
N,N-Dimethylamphetamine	7 g	2 g
N-Ethylamphetamine	2 g	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g	2 g
Noracymethadol	2 g	2 g
Norlevorphanol	52 g	52 g
Normethadone	2 g	2 g
Normorphine	16 g	16 g
Para-fluorofentanyl	2 g	2 g
Phenomorphan	2 g	2 g
Pholcodine	2 g	2 g
Psilocybin	7 g	2 g
Psilocyn	7 g	2 g
Tetrahydrocannabinols	312,500 g	216,000 g
Thiofentanyl	2 g	2 g
Trimeperidine	2 g	2 g
Schedule II		
1-Phenylcyclohexylamine	2 g	2 g
1-Piperidinocyclohexanecarbonitrile	2 g	0 g
Alfentanil	8,000 g	6,300 g
Alphaprodine	2 g	2 g
Amobarbital	3 g	3 g
Amphetamine (for sale)	17,000,000 g	17,000,000 g
Amphetamine (for conversion)	6,500,000 g	6,500,000 g
Cocaine	247,000 g	247,000 g
Codeine (for sale)	39,605,000 g	39,605,000 g
Codeine (for conversion)	65,000,000 g	65,000,000 g
Dextropropoxyphene	106,000,000 g	92,000,000 g
Dihydrocodeine	1,200,000 g	800,000 g
Diphenoxylate	947,000 g	627,000 g
Ecgonine	83,000 g	83,000 g
Ethylmorphine	2 g	2 g
Fentanyl	1,428,000 g	1,428,000 g
Glutethimide	2 g	2 g
Hydrocodone (for sale)	55,000,000 g	55,000,000 g
Hydromorphone	3,300,000 g	3,455,000 g
Isomethadone	11 g	11 g
Levo-alphacetylmethadol (LAAM)	3 g	3 g
Levomethorphan	5 g	5 g
Levorphanol	10,000 g	10,000 g
Lisdexamfetamine	9,000,000 g	9,000,000 g
Meperidine	8,600,000 g	6,600,000 g

Basic class	Previously established initial 2010 quotas	Proposed revised 2010 quotas
Meperidine Intermediate-A	3 g	3 g
Meperidine Intermediate-B	7 g	7 g
Meperidine Intermediate-C	3 g	3 g
Metazocine	1 g	1 g
Methadone (for sale)	25,000,000 g	20,000,000 g
Methadone Intermediate	26,000,000 g	26,000,000 g
Methamphetamine	3,130,000 g	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]		
Methylphenidate	50,000,000 g	50,000,000 g
Morphine (for sale)	35,000,000 g	35,000,000 g
Morphine (for conversion)	100,000,000 g	83,000,000 g
Nabilone	9,002 g	9,002 g
Noroxymorphone (for sale)	10,000 g	5,000 g
Noroxymorphone (for conversion)	9,000,000 g	9,000,000 g
Opium (powder)	230,000 g	230,000 g
Opium (tincture)	1,050,000 g	1,050,000 g
Oripavine	15,000,000 g	15,000,000 g
Oxycodone (for sale)	88,000,000 g	88,000,000 g
Oxycodone (for conversion)	4,000,000 g	4,000,000 g
Oxymorphone	2,570,000 g	2,570,000 g
Oxymorphone (for conversion)	12,000,000 g	12,000,000 g
Pentobarbital	28,000,000 g	28,000,000 g
Phenazocine	1 g	1 g
Phencyclidine	20 g	14 g
Phenmetrazine	2 g	2 g
Phenylacetone	12,500,001 g	12,500,001 g
Racemethorphan	2 g	2 g
Remifentanil	500 g	2,500 g
Secobarbital	67,000 g	67,000 g
Sufentanil	10,300 g	7,000 g
Thebaine	126,000,000 g	126,000,000 g

The Deputy Administrator further proposes that aggregate production quotas for all other schedules I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

All interested persons are invited to submit their comments in writing or electronically regarding this proposal following the procedures in the ADDRESSES section of this document. A person may object to or comment on the proposal relating to any of the above-mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief. Persons wishing to request a hearing should note that such requests must be written and manually signed; requests for a hearing will not be accepted via electronic means. In the event that comments or objections to this proposal raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing as per 21 CFR 1303.13(c).

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this action will not have a significant economic impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601–612. The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for lawful export requirements, and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

Executive Order 12866

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

Executive Order 13132

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

Executive Order 12988

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Unfunded Mandates Reform Act of 1995

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $126,000,000 or more (adjusted for inflation) in any one year,

and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This action will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated: June 17, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–15159 Filed 6–22–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Proposed Extension of Information Collection Request Submitted for Public Comment; Prohibited Transaction Class Exemption 91–55—Transactions Between Individual Retirement Accounts and Authorized Purchasers of American Eagle Coins

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (the Department), in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the reporting burden on the public and helps the public understand the Department's information collection requirements and provide the requested data in the desired format. Currently, the Employee Benefits Security Administration is soliciting comments on the proposed extension of the information collection provisions of Prohibited Transaction Class Exemption 91–55. A copy of the information collection request (ICR) may be obtained by contacting the office listed in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office shown in the Addresses section on or before August 23, 2010.

ADDRESSES: G. Christopher Cosby, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210, (202) 693–8410, FAX (202) 693–4745 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION:

I. Background

Prohibited Transaction Exemption 91–55 permits purchases and sales by certain "individual retirement accounts," as defined in Internal Revenue Code section 408 (IRAs) of American Eagle bullion coins ("Coins") in principal transactions from or to broker-dealers in Coins that are "authorized purchasers" of Coins in bulk quantities from the United States Mint and which are also "disqualified persons," within the meaning of Code section 4975(e)(2), with respect to IRAs. The exemption also describes the circumstances under which an interest-free extension of credit in connection with such sales and purchases is permitted. In the absence of an exemption, such purchases and sales and extensions of credit would be impermissible under the Employee Retirement Income Security Act of 1974 (ERISA).

Among other conditions, the exemption requires certain information related to covered transactions in Coins must be disclosed by the authorized purchaser to persons who direct the transaction for the IRA. Currently, it is standard industry practice that most of this information is provided to persons directing investments in an IRA when transactions in Coins occur. The exemption also requires that the disqualified person maintain for a period of at least six years such records as are necessary to allow accredited persons, as defined in the exemption, to determine whether the conditions of the transaction have been met. Finally, an authorized purchaser must provide a confirmation statement with respect to each covered transaction to the person who directs the transaction for the IRA. The requirements constitute information collections within the meaning of the PRA, for which the Department has obtained approval from the Office of Management and Budget (OMB) under OMB Control No. 1210–0079. The OMB approval is currently scheduled to expire on August 31, 2010.

The recordkeeping requirement facilitates the Department's ability to make findings under section 408 of ERISA and section 4975(c) of the Code. The confirmation and disclosure requirements protect a participant or beneficiary who invests in IRAs and transacts in Coins with authorized purchasers by providing the investor or the person directing his or her investments with timely information about the market in Coins and about the individual's account in particular.

II. Current Actions

This notice requests public comment pertaining to the Department's request for extension of OMB approval of the information collection contained in PTE 91–55. After considering comments received in response to this notice, the Department intends to submit an ICR to OMB for continuing approval. No change to the existing ICR is proposed or made at this time. An agency may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a valid OMB control number. A summary of the ICR and the current burden estimates follows:

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Prohibited Transaction Class Exemption 91–55.

Type of Review: Extension of a currently approved collection of information.

OMB Number: 1210–0079.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions.

Respondents: 3.

Responses: 663,431.

Frequency: On occasion.

Estimated Total Burden Hours: 11,063.

Estimated Total Burden Cost: $152,589.

III. Focus of Comments

The Department of Labor (Department) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the

American Society of Health-System Pharmacists®
TOGETHER WE MAKE A GREAT TEAM

Hydromorphone Hydrochloride Injection

01 July 2010

Products Affected - Description

Dilaudid-HP powder for injection, Purdue
250 mg vial (NDC 59011-0446-25)

Hydromorphone hydrochloride injection, Hospira
1 mg/mL, 1 mL Carpuject syringe (NDC 00409-1283-31)
2 mg/mL, 1 mL Carpuject syringe (NDC 00409-1312-30)
1 mg/mL, 1 mL ampul (NDC 00409-2552-01)
10 mg/mL, 1 mL ampul (NDC 00409-2172-01) - *discontinued*

Hydromorphone hydrochloride injection, Teva
10 mg/mL, 1 mL vial (NDC 00555-1117-05)
10 mg/mL, 5 mL vial (NDC 00555-1117-06)
10 mg/mL, 50 mL vial (NDC 00555-1117-07)

Reason for the Shortage

Hospira's Carpuject syringes have been in short supply due to increased demand for product.

Purdue Pharma, Teva, and Baxter could not provide a reason for the shortage.

Estimated Resupply Dates

Purdue Pharma has Dilaudid HP powder for injection on back order with an estimated release date of mid-July, 2010. Dilaudid is available in 1 mg/mL 1 mL 10 count (NDC 59011-0441-10), 2 mg/mL 1 mL 10 count (NDC 59011-0442-10) and 25 count (NDC 59011-0442-25), and 4 mg/mL 1 mL 10 count (NDC 59011-0444-10) ampules. Dilaudid HP is available in 10 mg/mL 1 mL (NDC 59011-0445-01) and 5 mL (NDC 59011-0445-05) ampules, and 10 mg/mL 50 mL (NDC 59011-0445-50) vials.

Hospira has available several presentations of hydromorphone injection in Carpuject syringes, vials, and ampules. Hydromorphone 4 mg/mL Carpuject syringes (NDC 00409-1304-31) are readily available. The 1 mg/mL and 2 mg/mL 1 mL Carpuject syringes are on back order and the company estimates a release date in the 4th quarter of 2010. The 1 mg/mL 1 mL ampule is on back order and the company estimates a release date of mid-July, 2010. The 2 mg/mL 1 mL ampule (NDC 00409-3356-01) and vial (NDC 00409-3365-01), 10 mg/mL 1 mL (NDC 00409-2634-01), 5 mL (NDC 00409-2634-05), and 50 mL (NDC 00409-2634-50) vials, and 4 mg/mL 1 mL ampules (NDC 00409-2540-01) are readily available.

Baxter has available hydromorphone 2-mg/mL in 1 mL (NDC 00641-0121-025) and 20 mL (NDC 00641-2341-41) vials.

Teva (formerly Barr) has all hydromorphone presentations on back order with an estimated release date of late-September, 2010.

Related Shortages

Acetaminophen/dichloralphenazone/isometheptene— Resolved

Alfentanil Injection— Resolved

Butorphanol Injection— Resolved

Choline Magnesium Trisalicylate

Codeine Phosphate Injection— No Longer Available

Codeine Phosphate Oral Solution— No Longer Available

Diazepam Injection

Fentanyl Transdermal System Patch— Resolved

Hydrocodone Tablets— Resolved

Indomethacin Capsules— Resolved

Indomethacin Injection

Ketorolac Injection

Meperidine— Resolved

Meperidine / Promethazine— No Longer Available

Methadone Hydrochloride Injection— Resolved

Methadone Hydrochloride Tablets— Resolved

Methadone Injection— Resolved

Methadone Oral Tablets and Liquid— Resolved

Morphine PCA Syringes— Resolved

Morphine Sulfate— No Longer Available

Morphine Sulfate: Extended-Release Products— Resolved

Morphine Sulfate: Oral Concentrated Solution

Oxycodone Combinations Capsules and Tablets— Resolved

Oxycodone Extended-Release Tablets— Resolved

Oxycodone Tablets, Capsules, and Solutions— Resolved

Pentazocine / Naloxone Tablets— Resolved

Piroxicam Capsules

Remifentanil Hydrochloride— Resolved

Sufentanil Injection— Resolved

Updated

July 1, 2010; June 8, 2010; May 13, 2010; April 21, 2010; April 7, 2010; March 15, 2010; February 9, 2010; January 19, 2010; December 22, 2009; December 3, 2009; November 11, 2009; October 21, 2009; September 2, 2009; August 12, 2009; July 16, 2009; June 23, 2009; May 29, 2009; May 20, 2009; May 7, 2009; April 28, 2009; April 14, 2009; April 1, 2009; March 20, 2009; March 16, 2009; March 12, 2009, University of Utah, Drug Information Service. Copyright 2010, Drug Information Service, University of Utah, Salt Lake City, UT.

Back to Drug Shortage Product Bulletins

U.S. Department of Justice
Drug Enforcement Administration

APPLICATION FOR PROCUREMENT QUOTA

SEE INSTRUCTIONS ON SEPARATE PAGE	No procurement quota may be issued unless a completed application form has been received, 21 CFR 1303.12(b)	OMB Approval No. 1117-0008

1. NAME OF BASIC CLASS OR LIST I CHEMICAL (Only one per DEA-250)	2. SCHEDULE / LIST NUMBER	3. DEA DRUG / CHEMICAL CODE NUMBER
Hydromorphone	II	9150

4. NAME AND ADDRESS OF REGISTRANT (Include No., Street, City, State and ZIP Code)	5. YEAR FOR WHICH QUOTA IS REQUESTED	6. DEA MANUFACTURING REGISTRATION NUMBER
(b)(4)	2010	(b)(7)(E)

7. NAME OF CONTACT PERSON	8. TELEPHONE No. (Include extension)	9. FAX No.	10. E-MAIL ADDRESS
(b)(6)			(b)(4),(b)(6)

NOTE: All quantities are to be expressed in grams of anhydrous acid, base, or alkaloid (not as salts).

11. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR (2008)	1st PRECEDING YEAR (2009)	CURRENT YEAR (2010)	(2010)
	35,000 grams	23,300 grams	63,000 grams	19,000 grams

12. PRODUCTION DATA	2ND PRECEDING YEAR	1ST PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk Controlled Substance or List I Chemical	4,000	16,879	0	0
b. In-process material	0	0	0	0
c. Contained in FINISHED Dosage Forms	0	0	0	0
TOTAL (a+b+c)	4,000	16,879	0	0
II. DISPOSITION (SALE) / UTILIZATION				
a. Domestic	0	1,308	63,000	82,000
b. Exports	0	0	0	
TOTAL (a+b)	0	1,308	63,000	82,000
III. ACQUISITION / PRODUCTION				
a. Domestic Sources	0	14,240	63,000	82,000
b. Importation	0	0	0	
TOTAL (a+b)	0	14,240	63,000	82,000

13. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE(S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	DEA CHEMICAL CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
		2ND PRECEDING YEAR	1ST PRECEDING YEAR	CURRENT YEAR	

14. IF THE PURPOSE IS TO MANUFACTURE THE BASIC CLASS OR LIST I CHEMCIAL INTO DOSAGE FORMS, FURNISH THE FOLOWING INFORMATION:

NAME OF DOSAGE FORM (Include product form, i.e., tablets, patches, etc. and strengths)	AUTHORITY TO MARKET THIS PRODUCT	SCHEDULE / LIST	AMOUNT USED FOR THIS PURPOSE		ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR QUOTA IS REQUESTED
			2ND PRECEDING YEAR	1ST PRECEDING YEAR		
Injection Sample quantities not shown 1mL @ 10mg/mL 5mL @ 10mg/mL 50mL @ 10mg/mL	FDA	II	0	1,962 grams (used for R&D exhibit batches and stability samples	37,00 grams will be used up in testing, the rest will be destroyed	82,000 grams Please see attached.

SIGNATURE OF APPLICANT	PRINT or TYPE NAME and TITLE of SIGNER	DATE
(b)(6)	(b)(6) Compliance Specialist	07/14/2010

DEA FORM 250 (May 2007) ALL PREVIOUS EDITIONS ARE OBSOLETE.

(b)(6)

From: (b)(6)

Sent: Thursday, April 08, 2010 11:16 AM

To: (b)(6)

Cc:

Subject: Hydromorphone Demands - API

(b)(6)

We have the following annual projection for Hydromorphone.

have estimated the API needs. Please verify API needs for the projected units and begin necessary equests to increase DEA allocation.

	Form	mg	Projected Units	Total mg Need	kg Need
50mL	Vial	500	108,522	54,261,000	54.3
5mL	Amp	50	537,820	26,891,000	26.9
1mL	Amp	10	46,848	468,480	0.5
			693,190	81,620,480	81.6

(b)(6)

VP. Sales and Marketing

(b)(4)

hone: (b)(6)

mail: (b)(4);(b)(6)

2010 Final Revised Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).

- The regulations require that DEA revise the aggregate production quota (APQ) annually after review of pertinent information provided from various sources including DEA-registered manufactures and the Food and Drug Administration (FDA).

- The attached Federal Register seeks to establish the final revised APQ for 2010. A table summarizing the APQ and the changes made to the initial established value are attached for reference.

- OD is recommending an increase (from zero) in the APQ for **4-anilino-N-phenethyl-4-piperidine (ANPP).** ANPP is used to manufacture fentanyl and will become a schedule II controlled substance August 30, 2010 (75 FR 37295).

- OD is recommending an increase in the APQ for **alfentanil**. While the revised value is higher than the proposed revised 2010 APQ, it is the same value as the initial established 2010 APQ for alfentanil.

- OD is recommending an increase in APQ for **amphetamine (for conversion)**. Amphetamine (for conversion) is used to manufacture lisdexamfetamine, a schedule II controlled substance.

- OD is recommending an increase in the APQ for **amphetamine (for sale)**. The increase is due to increased sales and is consistent with the FDA's estimated 9.4% increased demand for amphetamine in 2010.

- OD is recommending an increase (from zero) in the APQ for **carfentanil**. Carfentanil is used solely for veterinarian uses and is manufactured once every 3-5 years depending on consumption.

- OD is recommending an increase in APQ for **dihydromorphine**. Dihydromorphine is used to manufacture hydromorphone.

- OD is recommending an increase in the APQ for **diphenoxylate**. While the revised value is higher than the proposed revised 2010 APQ, it is still lower than the initial established 2010 APQ for diphenoxylate.

- OD is recommending an increase in the APQ for **marihuana**. While the revised value is higher than the proposed revised 2010 APQ, it is the lower than the initial established 2010 APQ for marihuana. This material will be used to supply the NIDA research program, and the manufacturing of cannabinoids such as cannabidiol, cannabinol, cannabigerol, etc.

- OD is recommending an increase in the APQ for **morphine (for sale)**. The increase is due to increased sales and is consistent with the FDA's estimated 8.2% increased demand for morphine in 2010.

- OD is recommending an increase in the APQ for **noroxymorphone (for sale)**. The increase is to support the validation efforts of a new manufacturer (b)(4) for NKRT-118, also known as mPEG-Naloxol. NKRT-118 falls under the noroxymorphone basic drug class.

- OD is recommending an increase in the APQ for **opium (tincture)** to support increased sales and validation efforts of a new dosage form manufacturer (b)(4)

- OD is recommending an increase in the APQ for **oxycodone (for conversion).** Oxycodone (for conversion) is used to manufacture oxymorphone. Since the APQ for oxymorphone is increasing, oxycodone (for conversion) subsequently needs to be increased.

- OD is recommending an increase in the APQ for **oxycodone (for sale)** for the following reasons:

    - Low ABUK oxycodone API. ABUK or alpha beta unsaturated ketones are impurities FDA has identified concerns with and subsequently requested manufacturers to alter their manufacturing processes to decrease the levels of ABUK in their API. Manufacturing low ABUK material incurs larger manufacturing losses.

    - Increased sales of dosage form manufacturers. The FDA estimated a 12.2% increased demand for oxycodone in 2010.

- OD is recommending an increase in the APQ for **oxymorphone (for sale)** for the following reasons:

    - Increased sales of dosage form manufacturers and exportation requirements. The FDA estimated a 15.7% increased demand for oxymorphone.

    - Product development efforts. 1,012 kg of quota have been assigned to support product development manufacturing efforts (many companies are vying to be the first generic manufacturer of Opana®). Approximately 55% compared to the 1,845 kg quota assigned to support commercial manufacturing efforts.

- OD is recommending an increase in the APQ for **tapentadol** to support a new bulk manufacturer's (b)(4) validation efforts.

- OD is recommending an increase in the APQ for **tetrahydrocannabinols.** While the revised value is higher than the proposed revised 2010 APQ, it is the lower than the initial established 2010 APQ for tetrahydrocannabinols.

- OD is recommending an increase (from zero) in the APQ for **tilidine** to support a new bulk manufacturer's (b)(4) manufacturing requirements.

- The final APQ for **gamma hydroxybutyric acid** will remain the same as the proposed revised APQ value which will cause some contention with (b)(4) and their contract manufacturer (b)(4) who requested the APQ to be adjusted to approximately 79,000 kg. (b)(4) estimates do not take into consideration (b)(4) 2009 year-end inventory, they request more GHB than necessary to meet the legitimate market, and they request inventory allowance larger than what DEA has authorized. (b)(4) has historically been litigious and adversarial with DEA and may continue pursuing further legal action.

Aggregate Production Quota Changes

(all values are in grams unless indicated otherwise)

Controlled Substance	Initial	Final Revised	Initial	Final Revised	Initial	Proposed Revised	Final Revised
Schedule I:	**2008**	**2008**	**2009**	**2009**	**2010**	**2010**	**2010**
Dihydromorphine	2,549,000	2,549,000	2,549,000	3,132,000	3,300,000	3,500,000	3,608,000
Marihuana	4,500,000	4,500,000	4,500,000	4,500,000	4,500,000	11,000	21,000
Tetrahydrocannabinols	312,500	312,500	312,500	312,500	312,500	216,000	264,000
Tilidine	0	0	0	0	0	0	10
Controlled Substance	**Initial**	**Final Revised**	**Initial**	**Final Revised**	**Initial**	**Proposed Revised**	**Final Revised**
Schedule II:	**2008**	**2008**	**2009**	**2009**	**2010**	**2010**	**2010**
4-anilino-N-phenethyl-4-piperidine (ANPP)	0	0	0	0	0	0	1,100,000
Alfentanil	8,000	8,000	8,000	8,000	8,000	6,300	8,000
Amphetamine (for conversion)	5,000,000	5,000,000	5,000,000	7,500,000	6,500,000	6,500,000	7,500,000
Amphetamine (for sale)	17,000,000	17,000,000	17,000,000	17,000,000	17,000,000	17,000,000	18,600,000
Carfentanil	0	0	0	0	0	0	200
Diphenoxylate	828,000	761,000	947,000	947,000	947,000	627,000	827,000
Morphine (for sale)	35,000,000	35,000,000	35,000,000	36,300,000	35,000,000	35,000,000	39,000,000
Noroxymorphone (for sale)	10,000	10,000	10,000	10,000	10,000	5,000	41,000
Opium (tincture)**	0	0	230,000	1,250,000	1,050,000	1,050,000	1,500,000
Oxycodone (for conversion)	4,820,000	4,820,000	3,400,000	4,500,000	4,000,000	4,000,000	5,600,000
Oxycodone (for sale)	70,000,000	70,000,000	77,560,000	94,000,000	88,000,000	88,000,000	105,500,000
Oxymorphone (for sale)	2,400,000	2,000,000	2,000,000	2,570,000	2,570,000	2,570,000	3,070,000
Oxymorphone (for conversion)	11,000,000	12,000,000	12,000,000	12,000,000	12,000,000	12,000,000	12,800,000
Tapentadol	0	0	0	0	0	0	1,000,000
* Oripavine became a new basic drug code December 10, 2007 (72 FR 69618)							
** Opium (powdered) and Opium (tincture) used to be both captured under Opium							
4-anilino-N-phenethyl-4-piperidine (ANPP)	became a schedule II controlled substance August 30, 2010 (75 FR 37295)					-	

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-318F]

Controlled Substances:
Final Revised Aggregate Production Quotas for 2010

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of final aggregate production quotas for 2010.

SUMMARY: This notice establishes final 2010 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA). DEA has taken into consideration comments received in response to a notice of the proposed revised aggregate production quotas for 2010 published June 23, 2010 (75 FR 35838).

EFFECTIVE DATE: (insert date of publication).

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Section 306 of the CSA (21 U.S.C. § 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR § 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant 28 CFR § 0.104.

The 2010 aggregate production quotas represent those quantities of controlled substances

in schedules I and II that may be produced in the United States in 2010 to provide adequate supplies of each substance for: the estimated medical, scientific, research and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks (21 U.S.C. § 826(a) and 21 CFR § 1303.11). These quotas do not include imports of controlled substances.

On June 23, 2010, a notice of the proposed revised 2010 aggregate production quotas for certain controlled substances in schedules I and II was published in the Federal Register (75 FR 35838). All interested persons were invited to comment on or object to these proposed aggregate production quotas on or before July 23, 2010.

Fourteen companies, thirteen DEA registered manufacturers and one non-registrant, commented on a total of 28 schedule I and II controlled substances within the published comment period. Comments received proposed that the aggregate production quotas for alfentanil, amphetamine (for conversion), amphetamine (for sale), codeine (for conversion), codeine (for sale), dextropropoxyphene, dihydromorphine, diphenoxylate, gamma hydroxybutyric acid, hydrocodone, hydromorphone, lisdexamfetamine, meperidine, methadone, methylphenidate, morphine (for conversion), morphine (for sale), nabilone, opium (tincture), oxycodone (for conversion), oxycodone (for sale), oxymorphone (for sale), remifentanil, sufentanil, tapentadol, tetrahydrocannabinols, thebaine and tilidine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements and for the establishment and maintenance of reserve stocks.

DEA has taken into consideration the above comments along with the relevant 2009 year-end inventories, initial 2010 manufacturing quotas, 2010 export requirements, actual and

projected 2010 sales, research, product development requirements and additional applications received. Based on this information, the DEA has adjusted the final 2010 aggregate production quotas for alfentanil, amphetamine (for conversion), amphetamine (for sale), carfentanil, dihydromorphine, diphenoxylate, marihuana, morphine (for sale), noroxymorphone (for sale), opium (tincture), oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), tapentadol, tetrahydrocannabinols, and tilidine.

4-anilino-N-phenethyl-4-piperidine (ANPP) pursuant to DEA's final rule published in the Federal Register on June 29, 2010 (75 FR 37295) will be controlled as a schedule II controlled substance on August 30, 2010. As such, DEA has established an aggregate production quota for ANPP to meet the estimated medical, scientific, research and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks.

Regarding codeine (for conversion), codeine (for sale), dextropropoxyphene, gamma hydroxybutyric acid, hydrocodone, hydromorphone, lisdexamfetamine, meperidine, methadone, methylphenidate, morphine (for conversion), nabilone, remifentanil, sufentanil, and thebaine, DEA has determined that the proposed revised 2010 aggregate production quotas are sufficient to meet the current 2010 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories.

Therefore, under the authority vested in the Attorney General by Section 306 of the CSA (21 U.S.C. § 826), and delegated to the Administrator of the DEA by 28 CFR § 0.100, and redelegated to the Deputy Administrator, pursuant to 28 CFR § 0.104, the Deputy Administrator hereby orders that the 2010 final aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Final Revised 2010 Quotas
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	20 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	10 g
3,4-Methylenedioxymethamphetamine (MDMA)	20 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	3 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	3,000 g
Dihydromorphine	3,608,000 g
Dimethyltryptamine	3 g

Gamma-hydroxybutyric acid	52,156,000 g
Heroin	20 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	1 g
Lysergic acid diethylamide (LSD)	15 g
Marihuana	21,000 g
Mescaline	5 g
Methaqualone	7 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	2 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	16 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	264,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Final Revised 2010 Quotas
1-Phenylcyclohexylamine	2 g
4-anilino-N-phenethyl-4-piperidine (ANPP)	1,100,000 g
Alfentanil	8,000 g
Alphaprodine	2 g
Amobarbital	3 g
Amphetamine (for conversion)	7,500,000 g
Amphetamine (for sale)	18,600,000 g
Carfentanil	200 g
Cocaine	247,000 g

Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	92,000,000 g
Dihydrocodeine	800,000 g
Diphenoxylate	827,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone	55,000,000 g
Hydromorphone	3,455,000 g
Isomethadone	11 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	10,000 g
Lisdexamfetamine	9,000,000 g
Meperidine	6,600,000 g
Meperidine Intermediate-A	3 g
Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	1 g
Methadone	20,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
750,000 g of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 g for methamphetamine (for conversion) mostly for conversion to a schedule III product; and 49,000 g for methamphetamine (for sale)	
Methylphenidate	50,000,000 g
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	39,000,000 g
Nabilone	9,002 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	41,000 g
Opium (powder)	230,000 g
Opium (tincture)	1,500,000 g
Oripavine	15,000,000 g
Oxycodone (for conversion)	5,600,000 g
Oxycodone (for sale)	105,500,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	3,070,000 g
Pentobarbital	28,000,000 g

Phenazocine	1 g
Phencyclidine	14 g
Phenmetrazine	2 g
Phenylacetone	12,500,001 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	67,000 g
Sufentanil	7,000 g
Tapentadol	1,000,000 g
Thebaine	126,000,000 g

The Deputy Administrator further orders that the aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR §§ 1308.11 and 1308.12 shall be zero.

The Office of Management and Budget has determined that notices of aggregate production quotas are not subject to centralized review under Executive Order 12866.

This action does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this action does not have federalism implications warranting the application of Executive Order 13132.

The Deputy Administrator hereby certifies that this action will have no significant impact upon small entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. § 601 et seq. The establishment of aggregate production quotas for schedules I and II controlled substances is mandated by law and by international treaty obligations. The quotas are necessary to provide for the estimated medical, scientific, research and industrial needs of the United States, for export requirements and the establishment and maintenance of reserve stocks. While aggregate production quotas are of primary importance to large manufacturers, their

impact upon small entities is neither negative nor beneficial. Accordingly, the Deputy Administrator has determined that this action does not require a regulatory flexibility analysis.

This action meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

This action will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $126,400,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

This action is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This action will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated:

Michele M. Leonhart
Deputy Administrator

AX:_____
AD:_____
OC:_____
CC:_____
CCR:_____
OD:_____
ODX:_____
OD/D:_____
ODE:_____

ODEQ: (b)(6)

ODE Subject
AD Chron
CCR Chron
CCR Subject
ODE Chron
ODE Circ
ODEQ (b)(6)
OD Chron

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

FEB 25 2009

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, #51-6133
Silver Spring, Maryland 20993

Dear Dr. Woodcock:

The Drug Enforcement Administration (DEA), in accordance with Title 21, Code Federal Regulations § 1303 (21 United States Code (U.S.C.) § 826 and 42 U.S.C. § 242) requests that the Department of Health and Human Services (HHS) provide estimates of the quantities of schedules I and II controlled substances and three list I chemicals which will be required to meet the legitimate medical, scientific and reserve stock needs in 2010 and 2011. Please provide the information by April 1, 2010, so that DEA may use these figures to calculate revised 2010 and initial 2011 aggregate production quotas for publication in the Federal Register.

Each year, the DEA is required to establish limits on the production of schedules I and II controlled substances and three list I chemicals. In order to accomplish this, the DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific and reserve stock needs in 2010 and 2011 for the following controlled substances:

Alfentanil
Amobarbital
Amphetamine
Cocaine
Codeine
Dextropropoxyphene
Difenoxin
Dihydrocodeine
Diphenoxylate
Ephedrine
Fentanyl
Gamma-hydroxybutyric acid
Hydrocodone
Hydromorphone
LAAM
Levorphanol
Lisdexamfetamine
Marijuana
Meperidine
Methadone
Methamphetamine
Methylphenidate
Morphine
Noroxymorphone
Opium (tinctures, extracts, etc., expressed in terms of U.S.P. powdered opium)
Oxycodone
Oxymorphone
Pentobarbital
Phenylpropanolamine
Propiram
Pseudoephedrine
Psilocybin
Remifentanil
Secobarbital
Sufentanil
Tapentadol
Tetrahydrocannabinols
Thebaine

To a significant extent, the DEA relies on medical and scientific information unique to the Food and Drug Administration (FDA), to provide estimates of the actual amounts of these substances which will be required each year. In addition to estimates for the aggregate requirements of the above schedules I and II controlled substances and three list I chemicals, the DEA requests product or company specific information which would assist in the establishment and revision of quotas. Such information includes anticipated new products, discontinued or recalled products, new indications for existing products, new dosage forms, new manufacturing processes, research requirements, and manufacturing problems. Please be assured that such information will be treated as confidential and proprietary. The estimates you provide, along with any comments you have regarding legitimate medical needs, will be greatly appreciated.

DEA also has certain reporting mandates under International Treaties. In accordance with paragraph 4 b) of article 16 of the Convention on Psychotropic Substances, 1971 (1971 Convention), DEA must report the quantities of schedules III and IV psychotropics manufactured in the U.S., the total quantities exported and imported, and the United States assessments or the maximum quantity of schedules III and IV psychotropics that may be imported into the United States Therefore, DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific and reserve stock needs in 2010 and 2011 for the following controlled substances:

Buprenorphine
Etorphine
Halazepam
Mazindol
Pentazocine
Prazepam
Temazepam
Zolpidem

Appropriate members of DEA staff are available to provide any assistance you may need. In order to facilitate the exchange of information, DEA staff is authorized to exchange relevant information directly with designated members of your staff. Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, will act as liaison for all matters concerning these substances. She can be reached by telephone at (b)(6)

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Deputy Chief of Operations
Office of Diversion Control

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

FEB 1 1 2011

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, #51-6133
Silver Spring, Maryland 20993

Dear Dr. Woodcock:

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Each year, the DEA is required to establish limits on the production of schedules I and II controlled substances and three list I chemicals. In order to accomplish this, the DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific and reserve stock needs in 2011 and 2012 for the following substances:

Alfentanil
Amobarbital
Amphetamine
Cocaine
Codeine
Dextropropoxyphene
Difenoxin
Dihydrocodeine
Diphenoxylate
Ephedrine
Fentanyl
Gamma-hydroxybutyric acid
Hydrocodone
Hydromorphone
LAAM
Levorphanol
Lisdexamfetamine
Marijuana
Meperidine
Methadone
Methamphetamine
Methylphenidate
Morphine
Noroxymorphone
Opium (tinctures, extracts, etc., expressed in terms of U.S.P. powdered opium)
Oxycodone
Oxymorphone
Pentobarbital
Phenylpropanolamine
Propiram
Pseudoephedrine
Psilocybin
Remifentanil
Secobarbital
Sufentanil
Tapentadol
Tetrahydrocannabinols
Thebaine

To a significant extent, the DEA relies on medical and scientific information unique to the Food and Drug Administration (FDA), to estimate the amounts of these substances which will be required each year. In addition to estimates for the aggregate requirements of the above schedules I and II controlled substances and three list I chemicals, the DEA requests product or company specific information which would assist in the establishment and revision of quotas. Such information includes anticipated new products, discontinued or recalled products, new indications for existing products, new dosage forms, new manufacturing processes, research requirements, and manufacturing problems. Please be assured that such information will be treated as confidential and proprietary. The estimates you provide, along with any comments you have regarding legitimate medical needs, will be greatly appreciated.

DEA also has certain reporting mandates under international treaties. In accordance with paragraph 4 b) of article 16 of the Convention on Psychotropic Substances, 1971, DEA must report the quantities of schedules III and IV psychotropics manufactured in the United States, the total quantities exported and imported, and the United States' assessment of the maximum quantity of schedules III and IV psychotropics that may be imported into the United States. Therefore, DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific and reserve stock needs in 2011 and 2012 for the following controlled substances:

Buprenorphine
Etorphine
Halazepam
Mazindol
Pentazocine
Prazepam
Temazepam
Zolpidem

My staff is available to provide any assistance your staff may need. In order to facilitate the exchange of information, Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, will act as liaison for all exchanges concerning this matter. She may be reached by telephone at (b)(6) Should you require further information or assistance regarding this matter, please contact me at (b)(6)

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

FEB 2 1 2012

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, #51-633
Silver Spring, Maryland 20993

Dear Dr. Woodcock:

The Drug Enforcement Administration (DEA), in accordance with part 1303 of Title 21 of the Code of Federal Regulations (CFR), 21 United States Code (U.S.C.) § 826, and 42 U.S.C. § 242, requests that the Department of Health and Human Services (HHS) provide estimates of the quantities of schedules I and II controlled substances and three list I chemicals which will be required to meet the legitimate medical, scientific, and reserve stock needs of the United States in 2012 and 2013. Please provide the information by April 1, 2012, so that DEA may use these figures to calculate revised 2012 and initial 2013 aggregate production quotas for publication in the Federal Register.

Each year, DEA is required to determine the total quantity of schedules I and II controlled substances and three list I chemicals to be manufactured to provide for the estimated needs of the United States. In order to accomplish this, DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific, and reserve stock needs in 2012 and 2013 for the following substances:

Alfentanil
Amobarbital
Amphetamine
Cocaine
Codeine
Difenoxin
Dihydrocodeine
Diphenoxylate
Etorphine
Ephedrine
Fentanyl
Gamma-hydroxybutyric acid
Hydrocodone
Hydromorphone
LAAM
Levorphanol
Lisdexamfetamine
Marijuana
Meperidine
Methadone
Methamphetamine
Methylphenidate
Morphine
Nabilone
Noroxymorphone
Opium (tinctures, extracts, etc., expressed in terms of U.S.P. powdered opium)
Oxycodone
Oxymorphone
Pentobarbital
Phenylpropanolamine
Propiram
Pseudoephedrine
Psilocybin
Remifentanil
Secobarbital
Sufentanil
Tapentadol
Tetrahydrocannabinols
Thebaine

To a significant extent, DEA relies on medical and scientific information unique to the Food and Drug Administration to estimate the amounts of these substances which will be required each year. In addition to estimates for the aggregate requirements of the above schedules I and II controlled substances and three list I chemicals, DEA requests any product or company specific information which may assist in the establishment and revision of quotas. Such information includes anticipated new products, discontinued or recalled products, new indications for existing products, new dosage forms, new manufacturing processes, research requirements, and manufacturing problems. Please be assured that such information will be treated as confidential and proprietary. DEA greatly appreciates your assistance in providing these estimates, along with any comments regarding legitimate medical needs.

DEA also has certain reporting mandates under international treaties. In accordance with article 19 of the Single Convention on Narcotic Drugs, 1961, and article 16 of the Convention on Psychotropic Substances, 1971, DEA must report the quantities of internationally controlled substances manufactured in the United States, the total quantities exported and imported, and the United States' assessment of the maximum quantity of controlled substances imported into the United States. Therefore, DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific, and reserve stock needs in 2012 and 2013 for the following controlled substances and substances manufactured from controlled substances:

Buprenorphine
Clobazem
Clonazepam
Diazepam
Lorazepam
Midazolam
Naloxone
Naltrexone
Pentazocine
Zolpidem

My staff is available to provide any assistance you may need in fulfilling this request. In order to facilitate the exchange of information, Christine A. Sannerud, Ph.D., Chief, United Nations Reporting and Quota Section, Office of Diversion Control, will act as the DEA liaison for all exchanges concerning this matter. She may be reached by telephone at (b)(6) Should you require further information or assistance regarding this matter, please contact me at (b)(6)

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

JAN 14 2013

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, #51-633
Silver Spring, Maryland 20993

Dear Dr. Woodcock:

The Drug Enforcement Administration (DEA), in accordance with part 1303 of Title 21 of the Code of Federal Regulations (C.F.R.), 21 U.S.C. § 826, and 42 U.S.C. § 242, requests that the Department of Health and Human Services (HHS) provide estimates of the quantities of schedules I and II controlled substances and three list I chemicals which will be required to meet the legitimate medical, scientific, and reserve stock needs of the United States in 2013 and 2014. Please provide the information by April 1, 2013, so that DEA may use these figures to calculate revised 2013 and initial 2014 aggregate production quotas for publication in the Federal Register.

Each year, DEA is required to determine the total quantity of schedules I and II controlled substances and three list I chemicals to be manufactured to provide for the estimated needs of the United States. In order to accomplish this, DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific, and reserve stock needs in 2013 and 2014 for the following substances:

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Amphetamine
Cocaine
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Difenoxin
Dihydrocodeine
Diphenoxylate
Etorphine
Ephedrine
Fentanyl
Gamma-hydroxybutyric acid
Hydrocodone
Hydromorphone
Levorphanol
Lisdexamfetamine
Marijuana
Meperidine
Methadone
Methamphetamine
Methylphenidate
Morphine
Nabilone
Noroxymorphone
Opium (tinctures, extracts, etc., expressed in terms of U.S.P. powdered opium)
Oxycodone
Oxymorphone
Pentobarbital
Phenylpropanolamine
Propiram
Pseudoephedrine
Psilocybin
Remifentanil
Secobarbital
Sufentanil
Tapentadol
Tetrahydrocannabinols

To a significant extent, DEA relies on medical and scientific information unique to the Food and Drug Administration to estimate the amounts of these substances which will be required each year. In addition to estimates for the aggregate requirements of the above schedules I and II controlled substances and three list I chemicals, DEA requests any product or company specific information which may assist in the establishment and revision of quotas. Such information includes anticipated new products, discontinued or recalled products, new indications for existing products, new dosage forms, new manufacturing processes, research requirements, and manufacturing problems. Please be assured that such information will be treated as confidential and proprietary. DEA greatly appreciates your assistance in providing these estimates, along with any comments regarding legitimate medical needs.

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Buprenorphine
Clobazam
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Diethylpropion
Lorazepam
Midazolam
Naloxone
Naltrexone
Temezapam
Zolpidem

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Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

www.dea.gov

JAN 8 - 2016

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, #51-633
Silver Spring, Maryland 20993

Dear Dr. Woodcock:

The Drug Enforcement Administration (DEA), in accordance with part 1303 of Title 21of the Code of Federal Regulations, Title 21, United States Code, Section 826 (21 U.S.C. § 826), and 42 U.S.C. § 242, requests that the Department of Health and Human Services (HHS) provide estimates of the quantities of schedules I and II controlled substances and three list I chemicals which will be required to meet the legitimate medical, scientific, and reserve stock needs of the United States in 2016 and 2017. Please provide the information by April 1, 2016, so that the DEA may use these figures to calculate revised 2016 and initial 2017 aggregate production quotas for publication in the Federal Register.

Each year, the DEA is required to determine the total quantity of schedules I and II controlled substances and three list I chemicals to be manufactured to provide for the estimated needs of the United States. In order to accomplish this, the DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific, and reserve stock needs in 2016 and 2017 for the following substances:

Alfentanil
Amobarbital
Amphetamine
Cannabidiol
Cocaine
Codeine
Difenoxin
Dihydrocodeine
Diphenoxylate
Ephedrine
Fentanyl
Gamma-hydroxybutyric acid
Hydrocodone
Hydromorphone
Levorphanol
Lisdexamfetamine
Marijuana
Meperidine
Methadone
Methamphetamine
Methylphenidate
Morphine
Nabilone
Noroxymorphone
Opium (tinctures, extracts, etc., expressed in terms of U.S.P. powdered opium)
Oxycodone
Oxymorphone
Pentobarbital
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Pseudoephedrine
Remifentanil
Secobarbital
Sufentanil
Tapentadol
Tetrahydrocannabinols

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The DEA also has certain reporting mandates under international treaties. In accordance with article 19 of the Single Convention on Narcotic Drugs, 1961, and article 16 of the Convention on Psychotropic Substances, 1971, the DEA must report the quantities of internationally controlled substances manufactured in the United States, the total quantities exported and imported, and the United States' assessment of the maximum quantity of controlled substances imported into the United States. Therefore, the DEA requests that HHS provide estimates of the quantities which will be required to meet the legitimate medical, scientific, and reserve stock needs in 2016 and 2017 for the following controlled substances and substances manufactured from controlled substances:

Alprazolam
Buprenorphine
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Diethylpropion
Lorazepam
Midazolam
Naloxone
Naltrexone
Temezapam
Zolpidem

My staff is available to provide any assistance you may need in fulfilling this request. In order to facilitate the exchange of information, Christine A. Sannerud, Ph.D., Chief, United Nations Reporting and Quota Section, Office of Diversion Control, will act as the DEA liaison for all exchanges concerning this matter. She may be reached by telephone at (b)(6)

Sincerely,

Louis J. Milione
Deputy Assistant Administrator
Office of Diversion Control

ODQ Subject (DFN: 630-08)
ODQ Chron
ODQ (b)(6)
OD Chron

OD/DR
OD:
~~OD/D:~~
ODX:
~~ODXL:~~
~~ODXS:~~
~~ODW:~~
ODQ: (b)(6) 7/2016
ODEC (b)(6) 1-6-16
S/:ODQ/FDA/CS Estimates
(DFN:' 630-08 – FDA Annual Estimate Letter)
SBF-CM # ODQ-16-391

(b)(4)

MoxDuo:

- Patented dual opioid: 3/2 fixed ratio of morphine/oxycodone, multiple strengths.
- IR-intended to compete in the $2.5B+ US ($14B global) acute pain market.
- US acute pain market 75M people, 200+M prescriptions; company expects 50% of market.
- Marketed to be better for post-surgical pain than oxycodone, morphine or Percocet.
- Market share expected to grow from the FDA mandated withdrawal of combination narcotics, e.g., Vicodin and Percocet, containing >325mg acetaminophen.
    - 99.9% of all hydrocodone and 26.5% of all oxycodone is used for combination drugs.
    - For 2010 & 2011, 42.5% of hydrocodone/APAP and 6.5% oxycodone/APAP contained >325mg acetaminophen (IMS data).
- CR intended for chronic pain - launch 2015, will compete with Oxycotin (patent expires 2013)

MoxDuo drug product line

- MoxDuo IR (Immediate Release): FDA PDUFA date of June 25th, 2012.
- MoxDuo CR (Controlled Release): Clinical Trials progress: Phase I & II in 2012; Phase III, 2013.
- MoxDuo IV (Intravenous): Phase II.

Strategic Partnerships

(b)(4)

Additional Potential Marketers

(b)(4)

Issues

- Current morphine and oxycodone APQs do not account for the additional material needed for product development from multiple registrants.
- Current oxycodone APQ limit reached.
- Cannot deny product development requests under current regulations (brand or generic).

(b)(4)

- Rate of change in market share ratio from Vicodin/Percocet to MoxDuo unknown.

(b)(4)

Notes

- Within the past 5 years Hydrocodone w/ Acetaminophen >325mg, total sales decreased from 49% to 41% of all hydrocodone combination drugs.
- The only Morphine combination drug (Embeda, morphine/naltrexone) was pulled from the market due to manufacturing issues.
- Codeine: No combination drugs on the market.

United States Government Accountability Office



Report to Congressional Requesters

February 2015

DRUG SHORTAGES

Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved

GAO-15-202

February 2015

DRUG SHORTAGES

Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved

GAO Highlights

Highlights of GAO-15-202, a report to congressional requesters

Why GAO Did This Study

In the last decade, shortages of prescription drugs containing controlled substances, such as narcotics and stimulants, have increased nationwide, preventing providers and patients from accessing essential medications for treatment. Controlled substances are regulated by DEA because of the potential for abuse and addiction. To prevent diversion of controlled substances, DEA sets quotas that limit the amount of certain substances that are available in the United States.

GAO was asked to examine shortages of drugs containing controlled substances. This report examines (1) the trends in such shortages, (2) the effect on patients and providers, (3) DEA's administration of the quota process, and (4) coordination between DEA and FDA to prevent and mitigate shortages. GAO analyzed data from 2001 through 2013 from the University of Utah Drug Information Service, which is generally regarded as the most comprehensive source of drug shortage data, and from 2011 and 2012 from YERS/QMS, which is the official record for the quota process. GAO interviewed officials from DEA, FDA, organizations representing patients and providers, and drug manufacturers. GAO reviewed relevant statutes, regulations, and documents.

What GAO Recommends

DEA should take five actions to improve its management of the quota process; DEA and FDA should quickly update their MOU and agree on steps each will take regarding drug shortages. HHS agreed with the applicable recommendations. DEA neither agreed nor disagreed, but raised multiple objections to this report.

View GAO-15-202. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Shortages of prescription drugs containing controlled substances have increased sharply in recent years; of the 168 shortages reported from January 2001 through June 2013, nearly 70 percent began after 2007. Such shortages lasted for nearly a year, on average. Additionally, many shortages involved generic pain relievers and drugs where there was only one manufacturer.

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), and organizations representing patients and providers report that during shortages of drugs containing controlled substances, patients may receive less effective care, experience medication errors, or not receive treatment at all. They said providers are also affected as they spend time and resources mitigating the effects of shortages, rather than providing care.

The Drug Enforcement Administration (DEA), an agency within the Department of Justice (DOJ), has not effectively administered the quota process that limits the amount of controlled substances available for use in the United States. Each year, manufacturers apply to DEA for quota needed to make their drugs. DEA, however, has not responded to them within the time frames required by its regulations for any year from 2001 through 2014. DEA officials attributed this lack of compliance to inadequate staffing. Manufacturers who reported quota-related shortages cited late quota decisions as causing or exacerbating shortages of their drugs. Additionally, DEA's weak internal controls jeopardize the agency's ability to effectively manage the quota process. For instance, agency officials said that DEA does not conduct quality checks to ensure the accuracy of the data in its Year-End Reporting and Quota Management System (YERS/QMS). GAO estimates that 44 percent of YERS/QMS records in 2011 and 10 percent in 2012 had errors. DEA officials said that 2011 was the first year manufacturers applied for quota electronically and they expected data from 2012 and beyond to be more accurate. DEA also lacks critical management information because it does not have performance measures related to setting quotas, nor does it monitor data to assess its performance. Moreover, DEA does not have reasonable assurance that the quotas it sets are in accordance with its requirements and cannot ensure continuity of its operations, as it does not have protocols, policies, training materials, or other documentation to manage the quota process.

Despite statutory provisions requiring DEA and FDA to coordinate certain efforts to address shortages of drugs containing controlled substances, the agencies have not established a sufficiently collaborative relationship. For example, DEA and FDA disagree about what constitutes a shortage. DEA officials also said that they do not believe FDA appropriately validates or investigates the shortage information it posts on its website and that posting this information encourages manufacturers to falsely report shortages to obtain additional quota. However, FDA reports that it takes steps to investigate and confirm the shortages on its website. Given such barriers to coordination, DEA and FDA cannot effectively act to prevent or alleviate shortages. Although DEA and FDA have a memorandum of understanding (MOU) in place, it has not been revised since the 1970s and they have been working for more than two years to update it. Officials from both agencies said an updated MOU could facilitate information sharing and help prevent and mitigate future shortages of drugs containing controlled substances.

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Abbreviations

ADHD	attention deficit hyperactivity disorder
API	active pharmaceutical ingredient
APQ	aggregate production quota
ARCOS	Automation of Reports and Consolidated Orders System
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DOJ	Department of Justice
DSS	Drug Shortage Staff
EMS	emergency medical services
FDA	Food and Drug Administration
FDASIA	Food and Drug Administration Safety and Innovation Act
GPRA	Government Performance and Results Act of 1993
HHS	Department of Health and Human Services
MOU	memorandum of understanding
UUDIS	University of Utah Drug Information Service
YERS/QMS	Year-End Reporting and Quota Management System

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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February 2, 2015

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate

The Honorable Sheldon Whitehouse
Ranking Member
Subcommittee on Crime and Terrorism
Committee on the Judiciary
United States Senate

In the last decade, shortages of prescription drugs have increased nationwide, preventing providers and patients from accessing medications that are essential for treatment. Some shortages involve drugs that contain controlled substances, such as narcotics, stimulants, and sedatives, which play an important role in health care.[1] For example, anesthesia, which is used to sedate patients, is routinely administered prior to surgical procedures and most patients receive some kind of drug containing a controlled substance during inpatient hospital stays. Emergency medical service (EMS) providers also frequently rely on a variety of drugs containing controlled substances to treat patients experiencing heart attacks, seizures, traumatic injuries, and other medical crises. For example, data from the National EMS Information System, a nationwide repository of information collected by EMS organizations, show that fentanyl and morphine—both narcotics that are used to manage pain—were 2 of the 10 most frequently administered medications by such organizations in 2012. In addition, some drugs containing controlled substances are available by prescription for outpatient use as pain relievers or sleep aids, as well as to treat individuals with attention deficit hyperactivity disorder (ADHD) and anxiety. During shortages, providers—including hospitals, physicians, and pharmacists—may have to use alternative medications, if alternatives are available at all. The Food and Drug Administration (FDA), an agency within the Department of

[1]A controlled substance is one that is included in one of five schedules under the Controlled Substances Act. A controlled substance is placed in a respective schedule based on whether it has a currently accepted medical use in the United States and its potential for abuse and physical or psychological dependence. 21 U.S.C. §§ 802(6), 812.

Health and Human Services (HHS), which oversees the safety and effectiveness of drugs marketed in the United States, considers drug shortages to be a serious public health concern and works to prevent, alleviate, and resolve them.[2]

Despite their medical value, prescription drugs containing these substances have the potential for abuse and psychological and physical dependence. They are therefore required to be regulated by the Drug Enforcement Administration (DEA), an agency within the Department of Justice (DOJ), in accordance with the Controlled Substances Act (CSA). The Centers for Disease Control and Prevention has declared that the United States is in the midst of an epidemic of prescription drug overdose deaths. In 2011, more than 22,000 Americans died from drug overdoses attributable to prescription drugs, and most of those deaths—almost 17,000—were due to prescription pain relievers containing controlled substances. To prevent diversion of controlled substances, DEA maintains a closed system of distribution, which includes limiting the amount of certain controlled substances that are available. To do so, DEA establishes quotas for the maximum amount of each basic class of controlled substance—such as amphetamine or morphine—that can be produced each year in the United States, known as aggregate production quotas (APQ). It also establishes quotas for individual manufacturers, who must apply to DEA to obtain quota for specific classes of controlled substances. In setting quotas, DEA is required to provide for the estimated medical, scientific, research, and industrial needs of the United States.[3]

You raised questions about shortages of drugs containing controlled substances and asked us to examine the effect of such shortages on patients. You also asked us to review DEA's administration of the quota process to understand its potential effects on shortages of drugs containing controlled substances, particularly those used by EMS

[2]We have previously reported on trends in the number of drug shortages and types of drugs most often in shortage, the causes of such shortages, and FDA's ability to respond to them. GAO, *Drug Shortages: FDA's Ability to Respond Should Be Strengthened,* GAO-12-116 (Washington, D.C.: Nov. 21, 2011), and *Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability,* GAO-14-194 (Washington, D.C.: Feb. 10, 2014).

[3]In addition, DEA is also required to provide for lawful export requirements, and for the establishment and maintenance of reserve stocks. 21 U.S.C. § 826; 21 C.F.R. § 1303.11.

providers and to treat ADHD. This report (1) identifies the trends in shortages of drugs containing controlled substances that occurred from January 2001 through June 2013, (2) describes the reported effects of shortages of drugs containing controlled substances on patients and providers, (3) examines DEA's administration of the quota process for controlled substances, and (4) examines DEA and FDA coordination activities to prevent and mitigate shortages of drugs containing controlled substances.

To identify the trends in shortages of drugs containing controlled substances from January 2001 through June 2013, we analyzed University of Utah Drug Information Service (UUDIS) data during this time period.[4] UUDIS data is generally regarded as the most comprehensive and reliable information on drug shortages for the time period we reviewed and are what we used in preparing our 2011 and 2014 reports on drug shortages.[5] For this report we used an extract of the UUDIS dataset used to prepare our 2011 and 2014 reports, which covered shortages from 2001—the first year available from UUDIS—through June 2013. We also examined the characteristics of drugs containing controlled

[4]UUDIS broadly defines a shortage as a supply issue that affects how pharmacies prepare and dispense a product or that influences patient care when prescribers must choose an alternative therapy because of supply issues. Once UUDIS identifies a shortage, it generally does not consider a shortage to be resolved until the drug is available again in all strengths and package sizes from all manufacturers that currently produce the drug. For example, UUDIS could be notified of a shortage involving three manufacturers: Manufacturer A has no product available; Manufacturers B and C still do, but have limited supply of certain package sizes. According to a UUDIS official, UUDIS would consider the shortage to be resolved (1) when Manufacturers A, B, and C all have all strengths and package sizes back in stock; (2) if Manufacturer A decides to discontinue its product, when Manufacturers B and Manufacturer C both have all strengths and package sizes back in stock; or (3) when UUDIS obtains other information indicating that a shortage has been resolved, such as FDA telling UUDIS that Manufacturers B and C have increased supply and all market need has been met. Our analysis focuses on shortages of prescription drugs, so we excluded shortages of over-the-counter drugs, biologics (including vaccines), medical devices, and orally administered vitamins from our analysis even though UUDIS also tracks and includes these shortages in its data.

[5]See GAO-12-116 and GAO-14-194. At the time we did work for our 2011 report, FDA did not have a database containing information on drug shortages. Since then, FDA developed its own database to track shortages. We reported concerns with FDA's management of this database in 2014, see GAO-14-194. For this report, we used the drug shortage data maintained by UUDIS because the time period we reviewed includes years that predate the development of FDA's database. It also allows us to provide information on the trends and characteristics of drug shortages comparable to that which we presented in our 2011 and 2014 reports.

substances that were in shortage at some point from January 2001 through June 2013 and that UUDIS identified as critical shortages because alternative medications were unavailable, the shortages affected multiple manufacturers, or the shortages were widely reported. These critical shortages were a subset of the total number of shortages reported during this time period.[6] For this subset of shortages, we obtained drug shortage bulletins created by UUDIS, which contain national drug codes associated with each shortage.[7] Using these national drug codes, we analyzed Red Book data to determine the product types, routes of administration, and therapeutic classes.[8] We reviewed all UUDIS data for reasonableness, outliers, and consistency, and based on our review we determined that the data were sufficiently reliable for our purposes. Additionally, to give context to and inform these analyses we interviewed officials at the FDA and UUDIS. For this objective as well as our remaining objectives, the scope of our work was limited to prescription drugs, as opposed to over-the-counter or behind-the-counter medications.

To describe the reported effects of shortages of drugs containing controlled substances on patients and providers, we interviewed officials from provider and patient organizations, such as the American Society of Anesthesiologists and Children and Adults with Attention Deficit/Hyperactivity Disorder. We selected provider and patient organizations that represent populations we determined were likely to be affected by shortages of drugs containing controlled substances. The information that we obtained from these organizations is not generalizable to all provider and patient organizations, but provided us with valuable insights. For a complete list of patient and provider organizations we interviewed, see appendix I. We also interviewed officials from FDA, the

[6]These shortages represented 52 percent of all shortages of drugs containing controlled substances reported during this period.

[7]UUDIS creates a drug shortage bulletin for all shortages that it identifies as critical. Each bulletin is publically posted on the American Society of Health-System Pharmacists' website and describes the reason for the shortage; any estimated resupply dates; any related shortages; and the national drug codes associated with the shortage. A national drug code is a unique identifier, though one drug can have multiple national drug codes associated with it. For example, a drug made by one manufacturer, in one strength, but in three package sizes would have a different national drug code for each of the three package sizes. UUDIS does not consistently track the national drug codes associated with shortages that it has determined are not critical.

[8]Red Book is a compendium published by Truven Health Analytics that includes information about the characteristics of drug products.

Office of the Assistant Secretary for Preparedness and Response within HHS, and the National Highway Traffic Safety Administration's Office of Emergency Medical Services. We reviewed relevant documentation from these organizations and agencies, including the results of surveys they had conducted of their constituencies.

To examine DEA's administration of the quota process for controlled substances, we reviewed the CSA and DEA's regulations and other documentation regarding the agency's process for establishing quotas for certain classes of controlled substances with medical use.[9] See appendix II for the specific substance classes subject to quotas that we considered to have medical use. We also interviewed DEA officials about the quota process, including factors that affect the agency's timeliness and responsiveness to manufacturers' quota applications. In addition, we reviewed DEA's administration of the quota process in light of relevant federal standards for internal controls and our prior work related to the establishment of agency performance measures.[10] To examine the timeliness of DEA's quota decisions for certain classes of controlled substances, we reviewed Federal Register notices for APQs for years 2001 through 2014. From our review of Federal Register notices, we were also able to determine when DEA established annual quotas for individual manufacturers from 2001 through 2014, as these types of quota are established after the APQ has been established in the Federal Register. We also analyzed data from the system DEA uses to track and record quota applications and decisions—the Year-End Reporting and Quota Management System (YERS/QMS). We analyzed data for certain controlled substances with medical use from 2011 and 2012, the most recent years for which data were available when we began our work. We

[9]We consider certain classes of controlled substances with medical use to be those substances subject to quotas that are contained in FDA-approved products that are currently marketed for human use.

[10]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999). Among other things, these standards address the need for federal agencies to establish internal controls and to monitor the performance of their programs. The establishment and review of performance measures and indicators is a control activity. Monitoring internal controls allows agencies to assess the quality of performance over time. We have also reported on the importance of establishing performance measures that demonstrate how well a program is achieving its goals. See GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, GAO/GGD-96-118 (Washington, D.C.: June 1996).

analyzed the source documents for a stratified random sample of 440 YERS/QMS records from 2011 and 2012 (15 percent of the total records during these years for certain controlled substances with medical use). We used these source documents to verify YERS/QMS data, each of which includes a manufacturer's quota application for a particular substance and the corresponding decision letter from DEA informing the manufacturer of its quota authorization. We compared the information in these documents with corresponding YERS/QMS records and found many instances of discrepancies between them. We therefore determined the data from YERS/QMS to be unreliable for the purposes of our review, and so we instead are reporting on our analysis of the information contained in the source documents for our sample of YERS/QMS records to determine DEA's timeliness in responding to manufacturers' quota applications. See appendix III for additional information on the sample design and methodology we used to determine the reliability of the data and to report on the source documents. We then compared the timing of DEA's quota decisions, both for the APQs and manufacturers' quotas, to required deadlines in the CSA and DEA's regulations. In addition, we interviewed manufacturers about their experiences with DEA's quota process, including any effect the quota process may have had on shortages of their products. We also reviewed documentation provided by manufacturers about their quota applications and DEA's responses. Specifically, we spoke with 13 dosage form manufacturers, including 7 that had the greatest number of drugs containing controlled substances subject to quota in shortage from January 2010 through June 2013.[11] We also spoke with 2 bulk manufacturers that supplied active pharmaceutical ingredients (API) for some of the drugs containing controlled substances that were in shortage.[12] We identified these manufacturers through our analysis of FDA data on the manufacturer-reported causes of shortages

[11]Dosage form manufacturers produce drugs in finished dosage form, which is a drug product in the form in which it will be administered to a patient, such as a tablet or capsule. Finished dosage forms are manufactured using active pharmaceutical ingredients, such as controlled substances, and excipients, such as fillers or preservatives. An active pharmaceutical ingredient is any element that is intended to provide pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body. An excipient is an inactive ingredient or component that is not the active pharmaceutical ingredient and serves as the vehicle or medium for the active ingredient.

[12]Bulk manufacturers produce API from raw materials for use by dosage form manufacturers in making finished dosage forms for consumption. For example, bulk manufacturers may obtain poppy raw materials to manufacture morphine API.

of drugs containing controlled substances from January 2010 through June 2013, the most recent years for which data were available when we began our analysis. We reviewed FDA's data for reasonableness, outliers, and consistency, and based on our review, determined that the data were sufficiently reliable for our purposes. Lastly, we interviewed DEA and FDA officials about the causes of shortages of drugs containing controlled substances.

To examine DEA and FDA coordination activities to prevent and mitigate shortages of drugs containing controlled substances, we reviewed the relevant provisions of the Food and Drug Administration Safety and Innovation Act (FDASIA) as well as other documentation governing how the two agencies are to coordinate.[13] We interviewed DEA and FDA officials about their coordination activities. In addition, we reviewed our past work related to interagency collaboration and the necessary elements for a collaborative working relationship.[14]

We conducted this performance audit from October 2012 through February 2015 in accordance with generally accepted government auditing standards.[15] Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[13]Pub. L. No. 112-144, tit. X, 126 Stat. 993, 1099-1108 (2012).

[14]See GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies,* GAO-06-15 (Washington, D.C.: Oct. 21, 2005). For that report, we reviewed relevant literature and interviewed experts in the area of collaboration to identify key practices that can help enhance and sustain federal agency collaboration.

[15]Completion of our audit was delayed significantly because of DEA's refusal to comply with our requests for information from and about YERS/QMS for over a year. We requested access to YERS/QMS materials and data starting in January 2013, but did not obtain needed information until March 2014.

Background

DEA's Oversight of Controlled Substances

Within DEA, the Office of Diversion Control is responsible for preventing, detecting, and investigating the diversion of controlled substances. The mission of this Office is dually focused on preventing diversion while ensuring an adequate and uninterrupted supply of these substances for legitimate needs. The CSA requires DEA to maintain a closed system of distribution of controlled substances in the United States from the point of import and manufacture through dispensing to patients or disposal. DEA funds diversion control activities, including the quota process, through fees that it sets for businesses, individuals, or entities that are required to register with DEA to import, export, manufacture, distribute, dispense, or conduct research on controlled substances.[16] The CSA requires that DEA set registration fees at a level that ensures DEA recovers the full costs of operating its Diversion Control Program.[17] DEA adjusts registration fees through the notice and comment rulemaking process and last adjusted registration fees in March 2012.[18]

The CSA places each controlled substance in one of five schedules based on whether the substance has a currently accepted medical use in treatment in the United States, its relative potential for abuse, and the degree of dependence the drug or other substance may cause.[19] Schedule I controlled substances, such as heroin and LSD, have a high potential for abuse and no currently accepted medical use in treatment in

[16]Diversion control activities refer to activities related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals. 21 U.S.C. § 886a(2)(B). See 21 C.F.R. pt. 1301 for more information on DEA's registration requirements and fees.

[17]21 U.S.C. § 886a.

[18]DEA's March 2012 registration fee adjustment took place nearly 6 years after its prior adjustment. Controlled Substances and List I Chemical Registration and Reregistration Fees, 77 Fed. Reg. 15234-15250 (Mar. 15, 2012).

[19]In addition to DEA's role in regulating controlled substances, states may also establish laws that regulate controlled substances. State laws must be in accordance with the CSA, but may be more restrictive.

the United States.[20] Schedule II controlled substances have a high potential for abuse, which may lead to severe psychological or physical dependence, but also have a currently accepted medical use; for instance, amphetamine is a schedule II controlled substance and is used to treat ADHD. As part of the closed system of distribution to prevent the diversion of controlled substances, the CSA requires DEA to establish quotas for each basic class of schedule I and II controlled substances.[21] Quotas are not established for schedule III, IV, and V controlled substances, which have a currently accepted medical use, a lower potential for abuse, and a lower physical and psychological dependence relative to schedule I and II controlled substances.[22]

DEA's Process for Establishing Quotas for Certain Controlled Substances

Each year the Office of Diversion Control establishes three types of quotas for schedule II substances: APQs, bulk manufacturing quotas, and procurement quotas.[23] Within the Office of Diversion Control, the Quota Unit is responsible for calculating and proposing quotas that are then established by the agency.[24]

Aggregate production quotas, which are established for each basic class of schedule I and II substances—such as amphetamine or

[20]Although schedule I substances have no accepted medical use in the United States, DEA issues quotas for these substances for scientific, industrial, and research purposes, including clinical trials. We do not include schedule I substances in our review of DEA's quota process because they have no accepted medical use in the United States.

[21]In addition to each basic class of schedule I and II substances, DEA is also mandated to establish quotas for list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 U.S.C. § 826. In setting quotas for these chemicals, DEA establishes an assessment of annual needs, which is to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. Registrants apply for import quotas to import list I chemicals in to the United States. We did not include quotas for list I chemicals within the scope of this report because DEA officials said that only a small amount of these substances are used to manufacture schedule II substances.

[22]These schedules include drugs such as Tylenol with codeine®, Valium®, and Xanax®.

[23]Although DEA's regulations use the term "individual manufacturing quotas," DEA officials refer to them as "bulk manufacturing quotas." Accordingly, we use the term "bulk manufacturing quotas" throughout our discussion. Companies that obtain bulk manufacturing quotas register with DEA as bulk manufacturers.

[24]In this report, we refer to the Office of Diversion Control's UN Reporting and Quota Section as the Quota Unit.

morphine—specify the maximum amount of each controlled substance that can be manufactured in the United States in a given year to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. APQs limit the amount of bulk materials that may be manufactured or synthesized in the United States, and subsequently available for use in the manufacture of drug products containing schedule I and II controlled substances. In establishing APQs for each basic class of schedule I and II controlled substances, DEA considers information from many sources, including

- manufacturers' production history and anticipated needs;
- estimates from IMS Health on retail consumption based on prescriptions dispensed;[25]
- data from DEA's internal system for tracking controlled substances transactions, known as the Automation of Reports and Consolidated Orders System (ARCOS);
- past histories of quota granted for each substance from YERS/QMS;
- estimates of the projected medical, scientific, and reserve stock needs provided by FDA's Controlled Substances Staff;[26]
- information regarding new and discontinued drug products containing schedule II substances from FDA; and
- data on the diversion of controlled substances, such as information from case seizures and national databases of drug evidence.

By May 1 of each year, DEA is required to propose APQs in the Federal Register for the next year and mail a copy of its proposal to persons registered as bulk manufacturers of the basic class.[27] Any interested person may file comments on or objections to the notice, and, after consideration of such comments or objections, DEA must then establish APQs in the Federal Register and mail a copy of its decisions to

[25]DEA obtains prescription data from IMS Health, a company that collects and analyzes health care data, to determine the number of prescriptions and total amount of drugs purchased by retail establishments for dispensing for each substance.

[26]FDA also uses data from IMS Health to develop its estimates of projected use in the United States.

[27]21 C.F.R. § 1303.11.

manufacturers of the basic class.[28] DEA may increase or decrease the APQ at any point due to fluctuations in demand and other factors, such as changes in accepted medical use of a substance for treatment or availability of raw materials for use in manufacturing.[29] DEA monitors the various data sources used to establish the APQ, as well as an FDA website containing information on drug shortages, to identify any possible changes in supply.[30] Generally, the agency revises the APQ midway through the year to account for any of these changes, as well as to account for any changes in anticipated need communicated by quota applicants. The process for revising the APQ is similar to the one used to establish it. Beginning with 2013 APQs, DEA established an additional 25 percent reserve in APQs in the event of natural disaster or other unforeseen event that could result in substantial disruption to the amount of basic classes of schedule II substances available for manufacture.

Bulk manufacturing quotas limit the amount of a basic class of schedule I or II controlled substance that an individual bulk manufacturer can manufacture through the extraction or synthesis of plant material or other controlled substances. Each bulk manufacturer must apply to DEA to obtain bulk manufacturing quota for a specific substance class and the bulk manufacturing quotas granted to manufacturers in sum cannot exceed the APQs established by DEA.

Procurement quotas limit the amount of a basic class of schedule I or II controlled substance that an individual manufacturer can procure from a manufacturer of bulk raw materials in order to manufacture into dosage forms of a drug or into other substances.[31] The sum of procurement quotas determines the amount of bulk material that needs to be produced.

[28]21 C.F.R. § 1303.11. See e.g., Controlled Substances: Established Aggregate Production Quotas for 2012, 76 Fed. Reg. 78044 (Dec. 15, 2011).

[29]21 C.F.R. § 1303.13.

[30]DEA also monitors letters and telephone calls it receives from individuals who indicate that they cannot get their prescriptions filled for specific products or drugs from their local pharmacies.

[31]We refer to companies that obtain procurement quotas as dosage form manufacturers.

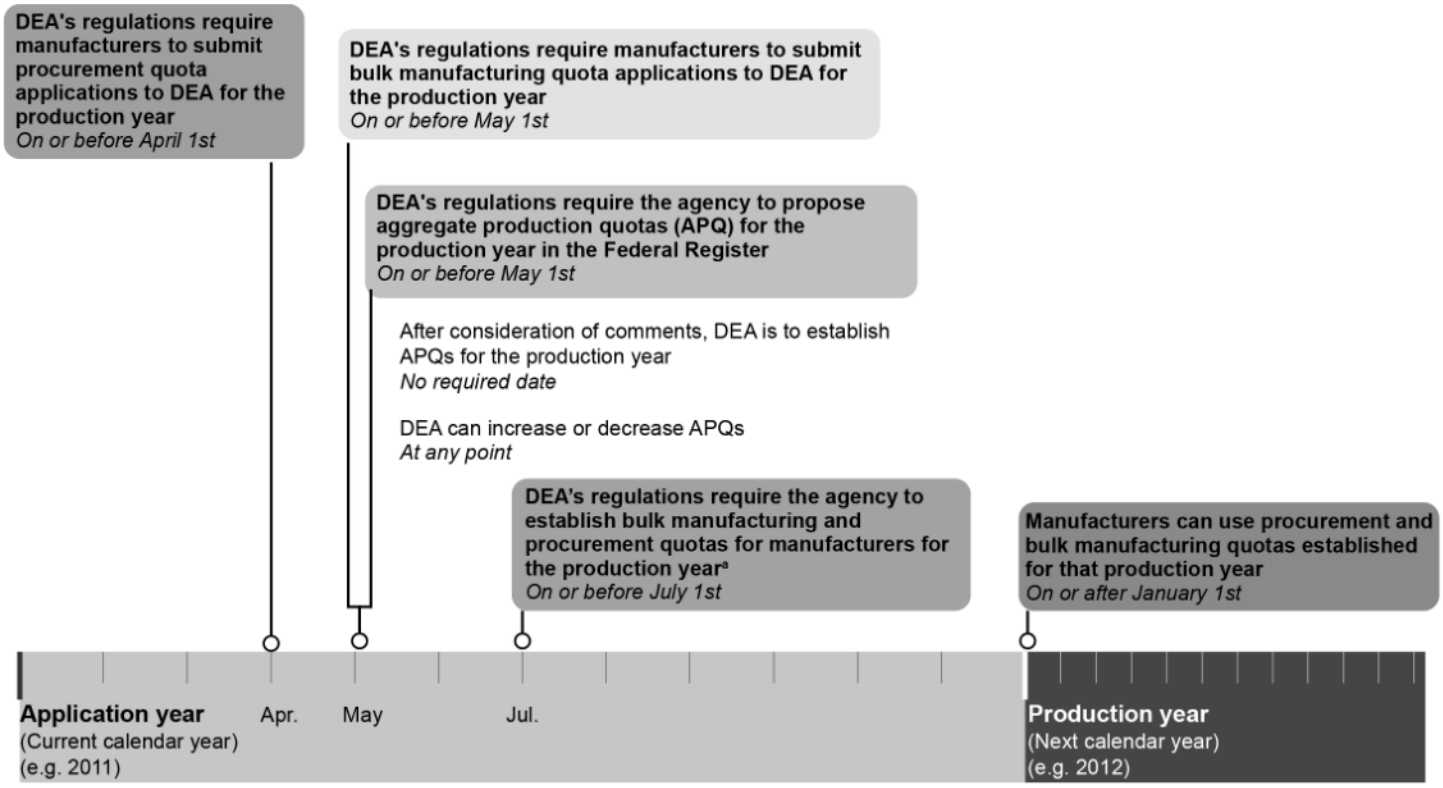
DEA does not have the authority to issue quotas for specific products or to require manufacturers to use their quota for specific products, but rather establishes the quotas for the basic class of controlled substance. For example, DEA may grant a quota of 10,000 grams of amphetamine to a manufacturer, but it is up to the manufacturer to determine how much of that quota will be put towards the various strengths and formulations of its drug products.

In establishing bulk manufacturing and procurement quotas for individual manufacturers, DEA considers the same types of information it uses to establish APQs. However, the agency's focus in reviewing the information is relative to the requesting manufacturer for that particular substance, rather than the total annual need, as is done for the APQ.

The CSA and DEA's implementing regulations designate specific dates by which manufacturers must apply for quotas, as well as dates by which DEA must establish quotas (see fig. 1). Manufacturers apply for quotas in the current year, which we term the application year. Their application is for use of the quota in the next calendar year, which we term the production year. Manufacturers may request a revision to their bulk manufacturing or procurement quota at any point.[32] When manufacturers apply for a revision to their quota during the production year, we term this a supplemental quota application.

[32]21 C.F.R. §§ 1303.12(d), 1303.25(a). DEA also may at any time reduce a manufacturer's bulk manufacturing quota to prevent exceeding the APQ. 21 C.F.R. § 1303.26.

Figure 1: Timeline for Manufacturers to Apply for Quotas and for the Drug Enforcement Administration (DEA) to Propose or Establish Quotas



Source: GAO analysis of the Controlled Substances Act (CSA) and DEA's regulations. | GAO-15-202

Notes: Unused quota from one year cannot be carried over to the following production year. For example, any remaining quota authorized for 2011 cannot be used to obtain controlled substances for procurement quotas and cannot be used to manufacture controlled substances for bulk manufacturing quotas in 2012. A bulk manufacturer, however, may extract or synthesize active pharmaceutical ingredient in one year and hold it in inventory until any subsequent year.

Pursuant to section 1005 of the Food and Drug Administration Safety and Innovation Act, DEA is to review quota requests from manufacturers that relate to shortages of drugs containing schedule II controlled substances and respond within 30 days. Pub. L. No. 112-144, 126 Stat. 993, 1105 (2012) (codified at 21 U.S.C. § 826(h)). Manufacturers can apply to DEA for more quota at any point, but there is no required time frame for DEA to respond to such supplemental quota requests unless a request relates to a drug in shortage.

[a]In contrast to DEA's regulations, the CSA requires DEA to issue bulk manufacturing quotas to manufacturers on or before October 1 for the production year. 21 U.S.C. § 826(c).

DEA launched an electronic system, known as YERS/QMS, in 2008 for manufacturers to submit end of year reports to the agency. Starting in 2011, manufacturers were able to use YERS/QMS to submit quota

applications to the agency electronically.[33] YERS/QMS serves as the official record for the quota process. The system allows DEA to track manufacturers' quota applications—including the date of the quota application, the amount of quota requested, the amount of quota previously authorized by DEA in prior years, and information about the products that will be manufactured with the requested quota—throughout its review process within the Office of Diversion Control. Additionally, YERS/QMS records DEA's decision about how much quota to authorize and the date on which DEA sends a decision letter to the manufacturer notifying it of the agency's quota decision.

FDA's Role in Preventing and Resolving Drug Shortages and Coordination with DEA

Consistent with its mission of protecting public health, FDA established the Drug Shortage Program in 1999—now known as the Drug Shortage Staff (DSS)—to help prevent, alleviate, and resolve shortages. DSS compiles information on drug shortages received from manufacturers and the public, including the reasons for the shortages.[34] FDA defines a shortage as a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.[35] DSS verifies the existence of a shortage by (1) determining if the current demand for a product is stable or increasing based on historical data from IMS Health; (2) contacting all manufacturers of a given drug to investigate supply issues and to obtain information on inventory, manufacturing schedules, and any changes to ordering patterns; (3) evaluating product distribution at the wholesale level, if needed; and (4) assessing information obtained from IMS Health, manufacturers, and wholesalers for the particular product reported to have a potential or actual shortage

[33]Manufacturers can also submit hard copy paper applications by mail, in which case DEA officials will then manually enter the information from the applications into YERS/QMS.

[34]With the enactment of FDASIA, manufacturers must notify FDA at least 6 months prior to the date of a discontinuance or interruption (or as soon as possible if 6 months is not feasible) in the manufacture of a drug that is life supporting, life sustaining, or used to treat debilitating health issues. Pub. L. No. 112-144, § 1001, 126 Stat. at 1099 (codified at 21 U.S.C. § 356c(a)-(b)).

[35]Pub. L. No. 112-144 § 1001, 126 Stat. at 1100 (codified at 21 U.S.C. § 356c(h)(2)). In September 2014, FDA changed its definition of a drug shortage to be consistent with FDASIA. According to FDA, this is not a substantive change in definition and does not alter how FDA works on matters regarding drug shortages. In general, FDA focuses on shortages of medically necessary drugs that have a significant effect on public health.

and for any acceptable alternative products.[36] DSS tracks drug shortages until their resolution, and posts information on its website about current and resolved shortages. FDA also obtains information from the American Society of Health-System Pharmacists, which becomes aware of drug shortages through voluntary reporting from hospitals, pharmacists, and other health care providers. FDA responds to shortages by taking actions within its authority to address the underlying causes and to enhance product availability. For example, FDA may offer feedback on a manufacturers' proposed approach to responding to quality concerns.

FDASIA, enacted in July 2012, contains several provisions related to drug shortages that require coordination between FDA and DEA. When FDA is notified of a supply disruption of a drug that is life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, and that contains a controlled substance subject to quotas, FDASIA requires that FDA request, if FDA determines that it is necessary, that DEA increase quotas applicable to that controlled substance.[37] Similarly, when FDA has determined that a schedule II drug is in shortage in the United States, manufacturers may also make such requests by submitting quota applications and FDASIA requires that DEA respond to these requests from manufacturers within 30 days.[38] Regardless of whether the request came from FDA or manufacturers, if DEA determines that issuing additional quota is not necessary to address a shortage it must provide a written response, which FDA is to post on its website.[39]

Additionally, FDASIA requires both FDA and DEA to describe their coordination on efforts to prevent or alleviate drug shortages in annual reports to Congress.[40] FDASIA also requires FDA to maintain an up-to-

[36]FDA, *Manual of Policies and Procedures, Drug Shortage Management*, MAPP 4190.1, Rev. 2, (Sept. 3, 2014).

[37]Pub. L. No. 112-144, § 1001, 126 Stat. at 1099-1100 (codified at 21 U.S.C. § 356c).

[38]This requirement applies where the manufacturer's request pertains to a schedule II controlled substance that is on the list of drugs in shortage maintained by FDA under section 506E of the Federal Food, Drug, and Cosmetic Act (established by section 1004 of FDASIA). Pub. L. No. 112-144, § 1005, 126 Stat. at 1105 (codified at 21 U.S.C. § 826(h)).

[39]Id. §§ 1001, 1005, 126 Stat. at 1099-1101, 1105 (codified at 21 U.S.C. §§ 356c(e), 826(h)).

[40]Id. §§ 1002, 1006, 126 Stat. at 1102, 1105-06 (codified at 21 U.S.C. §§ 356c-1, 826a).

date list of drugs that it determines to be in shortage, which, subject to public health, trade secret, and confidentiality provisions, must be publicly available.[41] To meet this requirement, FDA posts information about drug shortages on its website, including the name of the drug and the reason for the shortage.

Performance Measures and Internal Controls

Under the Government Performance and Results Act of 1993 (GPRA), as amended by the GPRA Modernization Act of 2010, agencies are statutorily required to prepare annual performance plans that articulate goals for the upcoming fiscal year and must include indicators that the agency will use to measure its performance.[42] Standards for internal control in the federal government and federal guidance on performance management also call for agencies to establish objectives and performance measures for programs that clearly link to agency-wide goals.[43] As our prior work has shown, performance measures are a key tool to help managers assess progress toward the stated agency-wide strategic goals and program-level objectives.[44] Leading agencies seek to establish clear hierarchies of results-oriented performance measures and targets to ensure that the agency is achieving its mission and strategic goals. Such performance measures help agencies make resource decisions and foster accountability to communicate agency progress to Congress and the public.

Internal control, which is synonymous with management control, comprises the plans, methods, and procedures used to ensure an agency is meeting its missions, goals, and objectives, which supports

[41]Id. § 1004, 126 Stat. at 1104-05 (codified at 21 U.S.C. § 356e).

[42]31 U.S.C. § 1115(b).

[43]GAO/AIMD-00-21.3.1.

[44]For example, see our findings in GAO, *Managing for Results: Enhancing Agency Use of Performance Information for Management Decision Making*, GAO-05-927 (Washington, D.C.; Sept. 9, 2005); *Results-Oriented Cultures: Creating a Clear Linkage between Individual Performance and Organizational Success*, GAO-03-488 (Washington, D.C.; Mar. 14, 2003); *Agencies' Annual Performance Plans Under the Results Act: An Assessment Guide to Facilitate Congressional Decisionmaking*, GAO/GGD/AIMD-10.1.18 (Washington, D.C.; February 1998); and *Program Performance Measures: Federal Agency Collection and Use of Performance Data*, GAO/GGD-92-65 (Washington, D.C.; May 4, 1992).

performance-based management.[45] Such controls help agency program managers achieve desired results and provide reasonable assurance that program objectives are being achieved through, among other things, effective and efficient use of agency resources. In addition, internal control standards in the federal government call for agencies to communicate with and obtain information from external stakeholders, compare actual performance to planned or expected results, review performance measures and indicators, compare and assess different sets of data to establish relationships and then take appropriate action, and to document all internal controls, transactions, and other significant events. In addition, we have previously reported on the importance of interagency collaboration.[46] Collaboration can be broadly defined as any joint activity that is intended to produce more public value than could be produced when organizations act alone.

Shortages of Drugs Containing Controlled Substances Rose Sharply After 2007; Many Involved Generic Pain Relievers and Drugs Manufactured by Few Companies

Shortages of drugs containing controlled substances have increased sharply in recent years; such shortages lasted for nearly a year, on average, and the majority of drugs were in shortage multiple times. Half of the shortages of drugs containing controlled substances identified as critical by UUDIS were analgesics (pain relievers) and most involved generic drugs.

[45]GAO/AIMD-00-21.3.1.

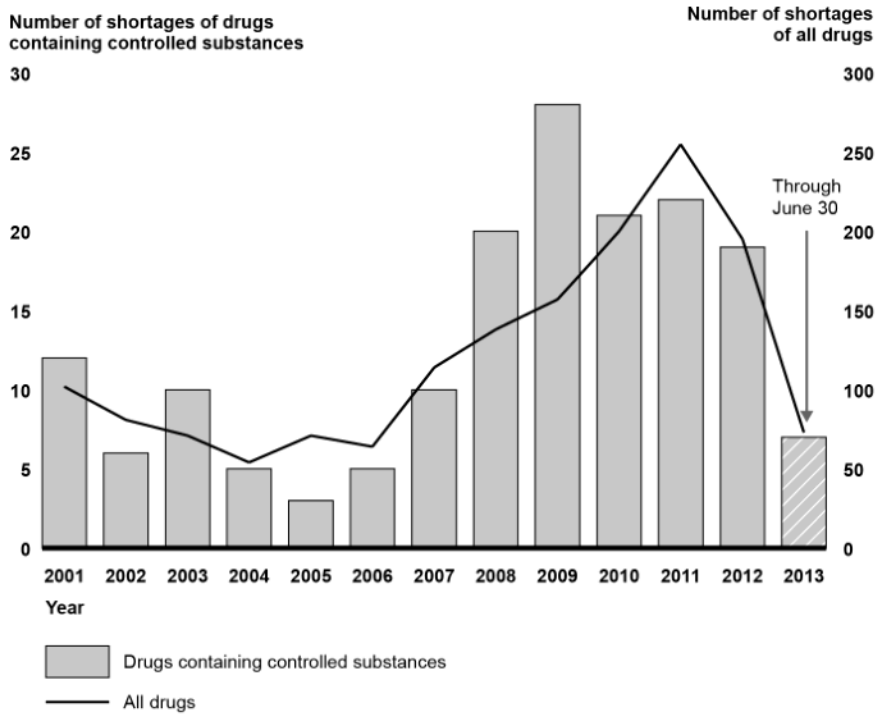
[46]GAO-06-15.

Shortages of Drugs Containing Controlled Substances Have Spiked in Recent Years; Most Were in Shortage Multiple Times and for Nearly 1 Year on Average

Of the 168 shortages of drugs containing controlled substances that were reported from January 2001 through June 2013, nearly 70 percent began between 2008 and 2013.[47] The number of new shortages reported each year peaked in 2009—with 28 that year—and has somewhat declined since then, though the number still remains significantly above pre-2008 levels. (See fig. 2.) The recent increase in these shortages mimics the pattern we have found for shortages of all drugs, which have also sharply increased since 2007 and subsequently declined after peaking in 2011. The 168 shortages of drugs containing controlled substances represent a small percentage of the total 1,575 drug shortages reported from January 2001 through June 2013.

[47]A shortage is counted in the total for "reported" shortages in the year that UUDIS is first notified of the shortage. For example, a shortage reported in July 2010 and resolved in March 2012 would be counted as a reported shortage in 2010. It would not be counted as a reported shortage in either 2011 or 2012.

Figure 2: New Shortages of Drugs Containing Controlled Substances and All Drugs Reported January 2001 through June 2013, by Year



Source: GAO analysis of University of Utah Drug Information Service data. | GAO-15-202

Note: A shortage is counted as "reported" in the year that the University of Utah Drug Information Service is first notified of the shortage. The totals for shortages of all drugs reported for 2007 through 2011 may differ slightly from what we reported in our 2011 report due to minor modifications by the University of Utah Drug Information Service to its data since that report. See GAO-12-116, 16.

The vast majority of shortages of drugs containing controlled substances—96 percent—lasted longer than 1 month and some of these shortages spanned multiple years. (See table 1.) The average duration was nearly 1 year; however, some were much longer. For instance, a single shortage of lorazepam injection, a medication used to treat anxiety, lasted slightly more than 5 years.

Table 1: Summary of the Duration of Shortages of Drugs Containing Controlled Substances, January 2001 through June 2013

Duration of shortages	Number of shortages	Percent[a]	Average duration[a] (in days)
Shortages lasting less than 30 days	6	4	17
Shortages lasting between 30 and 365 days	96	61	160
Shortages lasting more than 365 days	55	35	729
Shortages lasting zero days[a]	11	—	—
Total	**168**	**100**	**354**

Source: GAO analysis of University of Utah Drug Information Service data. I GAO-15-202

Note:

[a]We excluded 11 shortages of the 168 shortages of drugs containing controlled substances identified by the University of Utah Drug Information Service from January 2001 through June 2013 from this analysis because these shortages lasted 0 days, leaving 157 shortages. The majority of these excluded shortages represented manufacturers' decisions to discontinue their production of a drug.

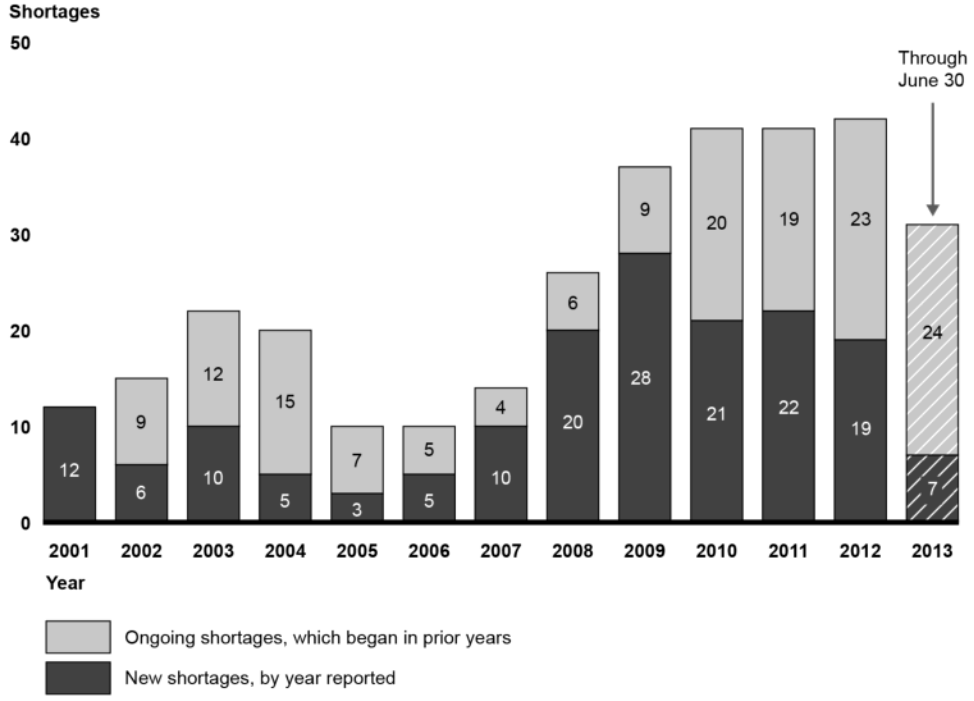
Most shortages—143 of 168—involved drugs that were in short supply multiple times, ranging from two to seven times. Forty-five different drugs containing controlled substances were reported to be in shortage multiple times from January 2001 through June 2013, representing 143 individual shortages. Overall, these 45 different drugs were in short supply for an average of about 3 years. For instance, oxycodone oral solution, a drug that is used to treat moderate to severe pain, was in shortage for the longest combined amount of time over the course of four different shortages, with a combined duration of over 8.5 years.

Drugs containing schedule II substances accounted for more than half of the shortages of drugs containing controlled substances that were reported from January 2001 through June 2013. Fifty-seven percent of shortages involved schedule II substances, while the remaining schedules—schedules III, IV, and V—comprised 15, 26, and 2 percent of shortages, respectively. Shortages of drugs containing schedule II, III, and IV substances ranged on average from 356 days to 359 days. However, shortages of schedule V drugs were shorter, lasting an average of 228 days.

Though the number of shortages reported has declined in recent years, the number of active shortages of drugs containing controlled substances remains high. (See fig. 3.) The active shortage total for each year includes both (1) new shortages reported that year and (2) shortages that started in a prior year that were still ongoing. For example, a shortage reported in July 2010 and resolved in March 2012 would be counted as

an active shortage in three different years (2010, 2011, and 2012). Rather than peaking in 2009, as the number of new shortages reported did, the number of active shortages has remained more or less constant, with 37 to 42 active shortages of drugs containing controlled substances per year from 2009 to 2012. For instance, in 2012, there were 19 new shortages reported that year and another 23 shortages that started in prior years and remained ongoing through some of the year. As of June 2013, there were 31 active shortages of drugs containing controlled substances.

Figure 3: Number of Active Shortages of Drugs Containing Controlled Substances, January 2001 through June 2013, by Year



Source: GAO analysis of University of Utah Drug Information Service data. | GAO-15-202

Note: The active shortage total for each year includes (1) new shortages reported that year and (2) shortages that were reported in a prior year that remained ongoing.

Half of Critical Shortages of Drugs Containing Controlled Substances Were of Pain Relievers and Many Involved Generic Products

Of the 87 shortages of drugs containing controlled substances identified as critical by UUDIS from January 2001 through June 2013, half involved pain relievers (analgesics) (44 of 87). These shortages were identified as critical by UUDIS because alternative medicines were not available, the shortages affected multiple manufacturers, or it received multiple reports of shortages from different provider institutions. There were also shortages of anti-anxiety medications, sedative hypnotic drugs, and stimulants. (See table 2.) All of these types of drugs belong to the broader class of drugs that affect the central nervous system, and are used to treat seizures, manage anxiety, and to provide sedation and pain reduction, among other things.[48]

Table 2: Summary of Critical Shortages of Drugs Containing Controlled Substances by Therapeutic Class, January 2001 through June 2013

Therapeutic class	Number of critical shortages	Percent of critical shortages
Analgesic	44	51
Antianxiety	7	8
Sedative hypnotic	8	9
Stimulant	5	6
Other	23	26
Total	**87**	**100**

Source: GAO analysis of University of Utah Drug Information Service and Truven Health Analytics (Red Book). I GAO-15-202

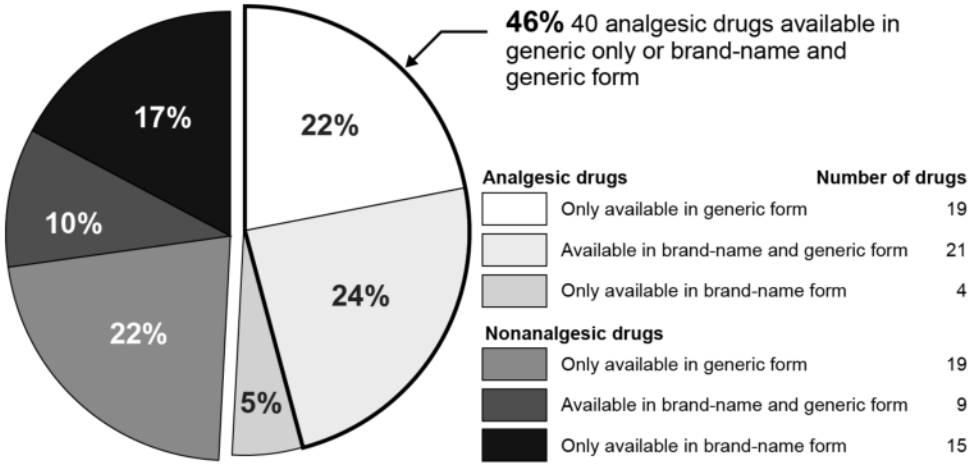
Note: This figure reflects 87 of the 168 (52 percent) shortages of drugs containing controlled substances reported during this time period; it is limited to the shortages the University of Utah Drug Information Service identified as critical. Red Book is a compendium published by Truven Health Analytics that includes information about the characteristics of drug products.

Most critical shortages of drugs containing controlled substances—68 of 87 (78 percent)—involved a generic drug. This 78 percent includes 38 critical shortages of drugs available only in generic form and 30 shortages of drugs available in both brand-name and generic forms. Another 19 critical shortages were of drugs available only in brand-name form (22 percent). Our analysis also showed that 40 critical shortages (46 percent) involved generic pain relievers. These 40 critical shortages include 19 shortages of analgesics only available in generic form

[48]Central nervous system and anesthesia drugs represented the therapeutic class with the highest frequency of all critical drug shortages reported from January 2009 through June 2013. See GAO-12-116 and GAO-14-194.

(22 percent) and 21 shortages of analgesics available in brand-name and generic form (24 percent). (See fig. 4.)

Figure 4: Distribution of Critical Shortages of Drugs Containing Controlled Substances by Therapeutic Class and Product Type, January 2001 through June 2013



Source: GAO analysis of data from the University of Utah Drug Information Service and Truven Health Analytics (Red Book). | GAO-15-202

Note: This figure reflects 87 of the 168 (52 percent) shortages of drugs containing controlled substances reported during this time period; it is limited to the shortages the University of Utah Drug Information Service identified as critical. Non-analgesics include all other therapeutic classes, such as anesthetics and anti-anxiety medications. Red Book is a compendium published by Truven Health Analytics that includes information about the characteristics of drug products.

Most critical shortages of drugs containing controlled substances—79 shortages (91 percent)—involved drugs that were manufactured by four or fewer companies and 39 of those shortages involved drugs manufactured by only one company. The remaining 8 shortages involve drugs that were manufactured by five or more companies (9 percent).

Finally, injectable drugs were in short supply slightly more often than orally administered drugs during this time period, with 44 critical shortages of injectable drugs (51 percent) and 35 critical shortages of orally administered drugs (40 percent). The remaining shortages involved drugs with other routes of administration, such as those administered topically or via the rectum.

Shortages of Drugs Containing Controlled Substances Can Compromise Patient Care and Create Challenges for Providers

According to provider and patient organizations, during shortages of drugs containing controlled substances, patients may receive less effective care, experience medication errors, or not receive treatment at all. Provider organizations also report that providers encounter serious challenges when such drugs are in short supply, requiring them to spend time and resources to mitigate the effects of shortages.

Shortages Can Result in Less Effective Care, Medication Errors, and Delayed or Canceled Treatment

FDA reports that drug shortages can pose a significant threat to the public health by adversely affecting care for patients. According to FDA, drug shortages can delay or deny needed care for patients. Drug shortages can also lead prescribers to use second-line alternatives, which may be less effective or pose additional risks. In addition, provider and patient organizations we spoke with told us that shortages of drugs containing controlled substances have resulted in less effective patient care. For example, representatives from an EMS organization told us that some providers limited the amount of pain medication administered to patients in order to make their supply of the drugs last longer, resulting in patients with unmanaged pain. In addition, some providers often have to use substitutes during shortages that involve undesirable side effects or can be less effective, according to provider organizations.[49] Representatives from the American Society of Anesthesiologists told us that when providers have to use an alternative anesthesia medication that is not the preferred treatment, patients can experience longer recovery times, delayed awakening, or postoperative nausea or vomiting. Medications can affect patients differently and, as a result, finding an effective substitute during a shortage can be complicated. For instance, according to provider and patient organizations focused on mental health issues, providers treating patients with ADHD may need to try different drugs

[49]An American Society of Anesthesiologists' survey revealed that over 95 percent of its members used an alternative medication because of a shortage and another 50 percent modified a procedure in some way because of a shortage. The survey also showed that the anesthesia drugs with the highest reported frequency of shortage were fentanyl and thiopental, both of which are controlled substances, as well as succinylcholine, propofol, and pancuronium, which are not controlled substances. The American Society of Anesthesiologists, *2012 ASA Drug Shortage Survey Results,* accessed January 20, 2015, http://asahq.org/advocacy/federal-activities/regulatory-activity/drug-shortages#Drug%20Shortages%20Survey.

containing other controlled substances and at varied doses to find one that works, although perhaps not as effectively as the patient's usual medication. Even switching from an extended-release formulation to an immediate-release formulation of the same drug can have a significant effect on a child with ADHD if the child's school does not have a nurse to supervise the child taking medication during the day, according to the director of UUDIS. One organization representing patients and families affected by this disorder, Children and Adults with Attention Deficit/Hyperactivity Disorder, found that 18 percent of survey respondents had to change medications during a shortage of ADHD medications. Patients may also be seriously affected by changing to a different route of administration of the same drug during shortages. Patients receiving hospice care or near the end of life may require injections because they cannot swallow a pill for example. Therefore, during a shortage of a morphine injection, clinicians may have to switch the patient to another injectable pain reliever because the patient cannot swallow the morphine tablet, according to the director of UUDIS.

Patients are at increased risk of experiencing medication errors during these shortages. Providers may have to use drugs in unfamiliar dosages or concentrations during shortages of drugs containing controlled substances, which can increase the risk of medication errors and lead to serious consequences for patients. For instance, in its survey of health care practitioners, the Institute for Safe Medication Practices found several instances of overdose and death from providers incorrectly converting doses for pain relievers during a morphine shortage.[50] Errors administering sedatives have also led to patients receiving too much or too little medication, resulting in unintended consciousness during surgery, agitation, and increased recovery times. EMS organizations also noted that the providers they represent are particularly at risk for administering medication incorrectly as they typically have less experience dealing with different medications, doses, or concentrations than hospital-based providers. Additionally, representatives of an EMS organization added that EMS providers deliver care in a mobile environment, which further increases the risk of administering medication incorrectly.

[50]Institute for Safe Medication Practices, *Drug Shortages: National Survey Reveals High Level of Frustration, Low Level of Safety*, accessed October 1, 2012, http://www.ismp.org/newsletters/acutecare/articles/20100923.asp.

Patients may have to delay or forgo care because of shortages of drugs containing controlled substances. For instance, provider organizations told us that providers have had to cancel or delay surgeries and procedures during shortages of anesthesia drugs. EMS associations we spoke with also reported that patients were at risk when drugs that are used to treat seizures were in short supply and there were no available substitutes.

In addition to compromised care, patients faced other hardships. For example, parents spent significant time tracking down ADHD medications that were in shortage for their children, according to provider and patient organizations focused on mental health issues, such as Children and Adults with Attention Deficit/Hyperactivity Disorder and the American Academy of Child and Adolescent Psychiatry. In particular, these organizations reported that some parents of children with ADHD called more than 30 pharmacies to find their children's medication. Representatives of mental health organizations also reported that patients faced increased costs during shortages. Some paid higher prices for their drugs when generic ADHD medications were in short supply and only the more expensive brand-name drug was available. In other instances, patients found they had to visit their physicians more often to obtain new prescriptions when pharmacies with dwindling supplies could only partially fill their orders, which then resulted in additional fees from the physician to obtain a new prescription, according to mental health organizations.[51]

[51]The CSA precludes prescriptions for such schedule II ADHD medications from being refilled, so, according to mental health organizations, patients needed to see their physician more frequently when they were not able to get their prescriptions filled completely. The CSA establishes various requirements that govern prescriptions of controlled substances depending upon the schedule of the drug. For example, schedule II substances, including amphetamine used to treat ADHD, cannot be dispensed without a written prescription of a practitioner, except in emergency situations, and cannot be refilled. 21 U.S.C. § 829(a). Schedule III and IV substances require a prescription; however, the prescription can be filled or refilled for up to 6 months after the date of the prescription and refilled up to five times. 21 U.S.C. § 829(b).

Providers Face Challenges Mitigating the Effects of Shortages of Drugs Containing Controlled Substances

FDA reports and provider organizations told us that shortages of drugs containing controlled substances burden providers, as the providers must spend time and resources addressing such shortages rather than providing care to patients. For example, some providers have had to add full-time staff to manage the effects of shortages and track down medications, according to provider organizations. Officials from a provider organization said that those who could not afford the cost of additional personnel may have had to divert staff from patient care. EMS organizations said that shortages can be particularly challenging for EMS organizations that typically have fewer staff or resources than large hospitals to dedicate to finding drugs that are in short supply. These reports corroborate research on the cost of all drug shortages; researchers at the University of Michigan, in collaboration with the American Society of Health-System Pharmacists, found that the labor costs for managing all drug shortages for U.S. hospitals is approximately $216 million annually.[52]

In trying to mitigate the effects of shortages of drugs containing controlled substances, providers may face situations that pose safety and efficacy concerns, and create ethical dilemmas. For example, providers may opt to turn to expired medications. FDA states that expired medications can be less effective or pose risks due to a change in chemical composition or decrease in potency. In limited cases FDA has exercised enforcement discretion to enable use of expired drugs to alleviate the effect of a shortage. Some states allow the use of expired drugs and providers in those states often pay for expensive tests to assess an expired drug's stability and efficacy, according to provider organizations.[53] Obtaining drugs containing controlled substances in short supply through compounding pharmacies is another avenue providers may take that can pose risks to patients and can cost significantly more than noncompounded drugs.[54] Compounded drugs can raise safety and

[52]R. Kaakeh, B.V. Sweet, C. Reilly, et al., "Impact of Drug Shortages on U.S. Health Systems," *American Journal of Health-System Pharmacy*, vol. 68, no. 19 (2011). This estimate is based on the number of shortages in 2010, when the number of shortages of all drugs was about half of what it was in 2013, according to data from UUDIS.

[53]For instance, in July 2013, Pennsylvania's Bureau of Emergency Medical Services instituted a procedure to allow EMS providers to apply for an exemption that allows them to use certain drugs for 6 months beyond the drugs' expiration date.

[54]Drug compounding is the process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a drug tailored to the needs of an individual patient.

efficacy concerns because the pharmacies that produce such drugs may be exempt from some FDA requirements that apply to drug manufacturers.[55] Provider organizations also said drugs containing controlled substances from compounding pharmacies are significantly more expensive than traditional suppliers and have a shorter shelf live, which can result in wasted product.

EMS providers may face additional challenges during shortages of drugs containing controlled substances, compared to other providers. EMS organizations said that their providers typically obtain medications either through contracts with hospitals or directly from distributors. However, provider organizations said that during periods of short supply, it may be a low priority for hospitals to ensure that EMS providers receive drugs in shortage because hospitals will typically fill their own supply first. EMS organizations added that distributors are more likely to cater to hospitals and other, larger providers because EMS providers are comparatively small purchasers.[56] Additionally, EMS organizations reported some confusion about whether the providers they represent can transfer medications to other affiliated EMS providers because of federal and

[55]Drugs compounded by a licensed pharmacist in a state licensed pharmacy or federal facility, or by a licensed physician, and that meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353a, can qualify for exemptions from the FDA approval requirements, the requirement to label products with adequate directions for use, and the requirement to comply with current good manufacturing practice requirements. The exemptions in section 503A are only available if the licensed pharmacist or licensed physician obtains a valid prescription for an identified individual patient among other things.

Although drug compounding is a traditional component of the practice of pharmacy, concerns have been raised by FDA and others that some pharmacies were going beyond traditional drug compounding for individual patients by producing large quantities of compounded drugs. The Drug Quality and Security Act created a new section 503B of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353b, under which a compounder can register as an "outsourcing facility." Drugs compounded in an outsourcing facility by or under the direct supervision of a licensed pharmacist, and that meet the conditions in section 503B of the Federal Food, Drug, and Cosmetic Act, can qualify for exemptions from the FDA drug approval requirements and the requirement to label products with adequate directions for use. Such outsourcing facilities remain subject to current good manufacturing practice requirements.

[56]The drug distributors we spoke with told us that during a shortage they generally use an allocation system in which customers receive a percentage of past orders, in order to ensure equitable distribution among their customers. However, one distributor said that customers who buy more drugs may receive a higher percentage of their order than other customers though all customers would be limited in the quantities that they receive.

state laws.[57] In addition, the vast majority of EMS providers are governed by state or local clinical protocols and, in some cases, medication formularies designate the specific doses and concentrations of medications that are permitted for use.[58] As a result, EMS providers in those states and localities are likely to continue to grapple with short supplies, unless state laws or regulations enable them to use different medications, doses, or concentrations than what is allowed under existing formularies or protocols.

DEA Has Not Effectively Administered the Quota Process Due to Missed Time Frames and Weak Internal Controls

DEA did not meet its required time frames for establishing quotas for classes of schedule II substances, and manufacturers report that the lack of timeliness has caused or exacerbated shortages of some of their drugs containing controlled substances. Additionally, our work shows that DEA's lack of internal controls, such as controls to ensure data reliability, performance measures, and monitoring of performance, may hinder the agency's ability to ensure an adequate and uninterrupted supply of controlled substances.

[57]EMS providers must comply with federal laws when handling controlled substances, and may also have to comply with a variety of additional state and local requirements. EMS provider organizations reported confusion among EMS agencies about how to comply with federal requirements related to controlled substances. As a result, officials from the Federal Interagency Committee on EMS said they are working with DEA to clarify DEA regulations and guidance that apply to EMS agencies.

[58]Most EMS providers are required to follow certain protocols that govern how they administer care and, in some cases, adhere to medication formularies, both of which can limit the medications used by these providers. State and local governments regulate the practice of EMS by licensing EMS providers and establishing standards of care, including what medications can be administered by EMS providers. According to the 2011 National EMS Assessment, prepared for the Federal Interagency Committee on Emergency Medical Services, 48 states have either state or locally developed patient care protocols for EMS providers (2 states did not provide information). Additionally, 25 states have medication lists or formularies for EMS professionals, according to this assessment.

DEA Did Not Meet Required Time Frames for Establishing Quotas for Schedule II Substances; Manufacturers Reported Quotas Caused or Exacerbated Shortages of Some of Their Products

Our examination of DEA's Federal Register notices proposing and establishing APQs found that DEA has not met its required time frames for more than a decade. Specifically, DEA has not met the time frames provided in its regulations for proposing APQs for classes of schedule II substances and establishing annual bulk manufacturing and procurement quotas for individual manufacturers since at least 2001.

- Proposing APQs: DEA did not propose APQs in the Federal Register on or before May 1st, as required by DEA's regulations, for any year from 2001 through 2014.[59] On average, DEA proposed APQs about 5 months after the May 1 deadline specified in its regulations. Additionally, though there is no requirement for when DEA must establish the APQ in the Federal Register, for 10 of the 14 years from 2001 through 2014, DEA established APQs in the Federal Register in December of the application year, generally in the last two weeks of the year.[60] For one year (2005), DEA established the APQs in the Federal Register in January of the production year. DEA does not inform manufacturers of their quota authorizations until after APQs have been established for the production year; therefore, the date the APQ is established affects when manufacturers receive their quotas.
- Establishing annual bulk manufacturing and procurement quotas: According to our analysis of Federal Register notices, DEA did not meet the requirements specified in the agency's regulations for establishing bulk manufacturing and procurement quotas by July 1, for any year from 2001 through 2014.[61] From our analysis of a random probability sample of YERS/QMS source documents, we estimate that DEA took an average of 182 days in 2011 and 178 in 2012 beyond July 1 to establish annual bulk manufacturing and procurement

[59]21 C.F.R. § 1303.11. The CSA does not designate when DEA is to propose or establish APQs.

[60]We define "application year" as the year in which manufacturers apply for annual quota for the next calendar year. We define "production year" to be the year in which manufacturers can use their quota.

[61]21 C.F.R. §§ 1303.12 and 1303.21.

quotas.[62] In addition to not meeting the time frames in DEA's regulations, our analysis of Federal Register notices found that neither did DEA meet the CSA requirement for establishing bulk manufacturing quotas by October 1 from 2001 through 2013, though it did meet this deadline recently.[63] For 2014 annual bulk manufacturing quotas, DEA established manufacturers' bulk manufacturing quotas in September 2013.

Moreover, manufacturers have expressed concerns about DEA's timeliness in establishing quotas and have asserted that the amount of time it takes DEA to respond to their quota applications has contributed to shortages of some drugs containing controlled substances. We obtained FDA data on the manufacturer-reported causes of 40 shortages of drugs containing schedule II controlled substances from January 2010 through June 2013.[64] These data show that 10 manufacturers reported to FDA that 7 of the 40 shortages of drugs containing schedule II substances during this time period were caused by problems related to quota.[65] The remaining 33 shortages of drugs containing schedule II substances were caused by other factors, such as manufacturing delays, capacity issues, and product quality issues, according to information reported to FDA by manufacturers.[66] After reviewing this information, we contacted representatives from all of these companies. Many told us that DEA's lack

[62]All percentage estimates from the sample of source documents have margins of error at the 95 percent confidence level of plus or minus 10 percentage points or less, unless otherwise noted. All numerical estimates other than percentages have margins of error of plus or minus 10 percent or less of the value of those numerical estimates, unless otherwise noted. Our sample of YERS/QMS source documents includes the entire population of applications submitted by manufacturers that reported shortages caused by quota to FDA and a probability sample of all other applications within each year (2011 and 2012).

[63]21 U.S.C. § 826(c).

[64]The FDA data reflect information reported by manufacturers to FDA that is subsequently analyzed and categorized by the agency.

[65]These 7 shortages were of drugs that included the substance classes of amphetamine, methylphenidate, or oxycodone, and began in either 2010 or 2011. According to FDA's data, there were several instances of shortages of drugs containing each of these substances between January 2010 and June 2013 and some, but not all, were reportedly caused by quotas.

[66]We previously reported that these are the same factors that cause shortages of drugs generally. See GAO-14-194 for more information on the reasons for shortages of all drugs.

of timeliness in establishing manufacturers' quotas has caused or exacerbated shortages of their products containing schedule II substances. In particular, the representatives said that DEA's timing of establishing annual bulk manufacturing and procurement quotas, which has generally been in late December of the application year, after it establishes the APQ, does not provide manufacturers with enough time to plan for production and order the raw material or API needed to start manufacturing their products at the beginning of the production year in January. Representatives from dosage form manufacturers report that these late decisions leave manufacturers operating solely with what is left in their inventory for the first few months of the production year, which may be limited because manufacturers operate in a lean manufacturing environment where they carry as little inventory as possible.

Additionally, manufacturer representatives said that DEA's lack of timeliness in responding to supplemental quota applications submitted during the production year has also caused or exacerbated shortages of their products. Based on our analysis of a probability sample of YERS/QMS source documents, we estimate that it took DEA an average of 58 days to respond to supplemental quota applications in 2011 and 2012. Within the source documents we reviewed, DEA's fastest response to a supplemental application was 7 days and its longest response took about 5 months. While there are no required time frames for DEA to respond to supplemental applications in the CSA or DEA's regulations, as of July 2012, FDASIA has required DEA to respond to manufacturers' quota requests that relate to shortages caused by quotas within 30 days.[67] Although this 30-day time frame was not yet a requirement in 2011 and much of 2012, it is worth noting that it often took longer for DEA to respond, suggesting this requirement could pose a challenge during a future shortage. We estimate that DEA responded within 30 days to 21 percent of supplemental applications in 2011 and 2012. Furthermore, we found that DEA took 10 days longer, on average, to respond to supplemental quota applications submitted by manufacturers that reported shortages caused by quota to FDA in 2011, the year in which these shortages began, than other supplemental applications (see table 3). In 2012, however, we found no statistical difference between the estimated amount of time DEA took to respond to both groups of supplemental applications.

[67]Pub. L. No. 112-144, § 1005, 126 Stat. at 1105 (codified at 21 U.S.C. § 826(h)).

Table 3: The Drug Enforcement Administration's (DEA) Estimated Response Times for Supplemental Applications in Year-End Reporting and Quota Management System (YERS/QMS) Source Documents, 2011 and 2012

YERS/QMS source documents	Applications submitted by manufacturers who reported shortages caused by quota (Y/N)	Average number of days
2011	Y	73
	N	63[a]
2012	Y	51
	N	54[b]
Both years	Y	59
	N	58[c]

Source: GAO analysis of YERS/QMS source documents. I GAO-15-202

Notes: This table reflects our review of a stratified probability sample of 440 source documents from YERS/QMS. This sample included all of the 146 records in 2011 and 2012 that are associated with drug shortages manufacturers reported to the Food and Drug Administration (FDA) were caused by quotas. We consider YERS/QMS records to be associated with these shortages if the record contains a quota application that was (a) submitted by a manufacturer who reported quota caused a shortage of their product to FDA; (b) for a substance that was used in the products reportedly in shortage because of quota; and (c) was submitted during the time of the reported shortage caused by quota. Manufacturers may or may not have reported to DEA that their quota application was related to a shortage. We also analyzed a random sample of 294 records stratified by year that were not associated with any drug shortages reportedly caused by quotas—180 and 114 records from 2011 and 2012, respectively.

[a]The margin of error at the 95 percent confidence level for supplemental applications submitted by manufacturers who did not report shortages caused by quota in 2011 is plus or minus 10.9 percent.

[b]The margin of error at the 95 percent confidence level for supplemental applications submitted by manufacturers who did not report shortages caused by quota in 2012 is plus or minus 13.7 percent.

[c]The margin of error at the 95 percent confidence level for supplemental applications submitted by manufacturers who did not report shortages caused by quota in 2011 and 2012 combined is plus or minus 8.8 percent.

DEA officials acknowledged that the agency has not met the time frames for proposing and establishing quotas, as required by the agency's regulations. DEA officials cited inadequate staffing of the Quota Unit as the reason why DEA has not met its requirements for proposing APQs and establishing manufacturers' bulk manufacturing and procurement quotas for schedule II substances. In particular, DEA officials noted that the agency's workload with respect to quotas has increased substantially and that drug manufacturing has become more complex since the CSA was enacted and DEA's regulations were established in the 1970s. For example, DEA officials said that when the CSA was enacted and DEA's regulations were initially established, dozens of companies applied for quota each year, whereas now hundreds of companies apply for quota. Additionally, DEA reports that manufacturers submit substantially more

applications to DEA than they have in the past. In 2012, for example, DEA received over 3,000 quota applications, and officials said that each application necessitates its own evaluation and analysis for each substance as it relates to the application. In addition to an increasing workload, DEA officials said that the agency has faced hiring challenges. In particular, it has been unable to hire additional qualified scientists for the Quota Unit because DEA has not found candidates with the right skills who are also able to pass the background checks required for employment. They also said that offers to qualified candidates have been declined. DEA officials noted that as of October 2014, the agency was still in the process of trying to hire two additional scientific staff for the Quota Unit, which would increase the staffing level to 12 (8 quota scientists and 4 administrative staff).

DEA officials added that the quality and timeliness of manufacturers' quota applications affects DEA's ability to meet its required time frames for proposing APQs and establishing manufacturers' quotas. For example, DEA estimates that the agency follows up with manufacturers on about half of the quota applications to get clarification on the information provided or to obtain additional information. DEA officials said that manufacturers also continue to revise their annual applications as manufacturing conditions change throughout the year, such as when manufacturers gain or lose business or encounter a manufacturing problem that destroys part of their inventory of controlled substances and they seek to replace what was lost.[68] From our analysis of a probability sample of YERS/QMS source documents, we estimate that although 80 percent of annual applications in 2011 and 65 percent of annual applications in 2012 were submitted in the first two quarters of the application year, another 19 percent of annual applications in 2011 and 22 percent of annual applications in 2012 were submitted in the fourth quarter of the application year. This may represent the first annual application submitted by a manufacturer for the production year or subsequent revisions because YERS/QMS contains both the first annual application submitted and subsequent revisions. DEA officials said that they do not consider manufacturers to be noncompliant with their time frames when they submit annual quota applications after the deadlines. They said they recognize that it is important for manufacturers to submit

[68]DEA's regulations authorize manufacturers to apply for revisions to their quotas at any point. 21 C.F.R. §§ 1303.12(d) and 1303.25(a).

revisions as conditions change, to ensure they receive appropriate amounts of quota. Our review of a sample of YERS/QMS source documents shows that manufacturers often submit annual bulk manufacturing and procurement quota applications throughout the year. Despite this, DEA officials said that they expect the agency will be compliant with its CSA time frames in the future. DEA officials said that moving to an electronic data system for the quota process—YERS/QMS—has helped the agency to be more compliant with its time frames, as well as the reorganization of staff into a separate Quota Unit in 2011.[69] They noted that the agency has already made progress in meeting its CSA-required time frames for establishing annual bulk manufacturing quotas in 2014.

Although DEA acknowledges it has generally not adhered to the quota setting time frames required by the CSA and the agency's regulations in the last 14 years, agency officials do not agree that quotas can cause shortages of drugs containing schedule II substances. In particular, according to DEA, shortages cannot be related to quotas established by the agency because DEA authorizes quotas at the basic class level for a substance—such as amphetamine or morphine. DEA cannot authorize quota for specific drug products containing those substances, as this is precluded by the CSA. DEA officials said the agency has no control over what specific drug products manufacturers actually produce with the quota authorized. For example, if DEA authorized 10,000 grams of morphine to a manufacturer, the manufacturer—and not DEA—then decides how to authorize the quota amongst its various products that contain different formulations, dosage forms, and concentrations.

We cannot confirm whether DEA's lack of timeliness in establishing annual and supplemental quotas has caused or exacerbated shortages. However, by not responding to annual applications in accordance with the time frames required by its regulations or the CSA and by not acting promptly on supplemental applications, DEA may hinder manufacturers' ability to manufacture drugs that contain schedule II controlled substances that may help prevent or resolve a shortage.

[69]DEA officials report that this change is provisional as it is pending finalization.

DEA's Weak Internal Controls Jeopardize Its Ability to Effectively Manage the Quota Process and Ensure an Adequate Supply of Controlled Substances for Legitimate Medical Use

DEA does not have sufficient internal controls to effectively oversee and manage the quota process and therefore may not be able to appropriately respond to quota applications related to shortages when they arise. In particular, DEA does not have adequate controls to ensure the reliability of the YERS/QMS system that it uses to track manufacturers' quota applications and record its quota decisions. DEA officials told us there are no systematic quality checks to ensure that the data in YERS/QMS are accurate, such as electronic checks for data outliers or manual comparisons of YERS/QMS data to source documents (i.e., manufacturers' quota applications and corresponding DEA decision letters) to identify inconsistent information. Instead, DEA officials said that when manufacturers submit their quota applications electronically, YERS/QMS automatically checks to ensure that the manufacturer applying for quota has a valid DEA registration. Additionally, DEA officials said they added an electronic prompt to YERS/QMS that asks manufacturers to reexamine and confirm quota requests that are for smaller amounts than they have already received for the production year. Officials told us that the Quota Unit also reviews the information submitted by manufacturers and will contact them when information entered looks inconsistent or out of the ordinary. DEA also reports that managers verify that the information entered into YERS/QMS by the Quota Unit is accurate. Though DEA takes some steps to ensure the accuracy of its YERS/QMS data, the agency has not systematically checked to make sure that its efforts are sufficient or having the intended effect. Lacking systematic data checks is inconsistent with federal standards for internal control, which calls for agencies to have appropriate control activities in place, such as periodic data checks, to ensure that the data used by the agency for decision making are accurate.[70] Without controls in place to ensure the accuracy of YERS/QMS data, DEA cannot provide reasonable assurance that it has correct information in its official record of the dates and amounts of its quota decisions beyond the individual electronic and hard copies of decision letters it keeps for retention purposes. Further, inaccuracies in YERS/QMS data will also affect the accuracy of future quota applications submitted by manufacturers, as YERS/QMS automatically populates information on quotas previously authorized by DEA from the prior 2 years into a new quota application.

[70]GAO/AIMD-00-21.3.1.

In our review of YERS/QMS data from 2011 and 2012, we found a large number of errors in 2011 and a significant reduction in the number of errors in 2012. Based on our analysis of a probability sample of YERS/QMS data, we estimate that 44 percent of the records in 2011 and 10 percent of the records in 2012, each of which corresponds to one quota application and DEA decision letter, contained at least one data field with incorrect data, such as incorrect dates or amounts of quota requested or authorized.[71] In particular, we estimate that errors in the quota application fields declined substantially in 2012, with, for example, errors in the total amount of quota requested field dropping from 13 percent of records in 2011 to 3 percent of records in 2012. See table 4 for the specific fields in which we found errors in our review for years 2011 and 2012.

[71]This difference is significant with a margin of error at the 95 percent confidence level of plus or minus 10 percentage points.

Table 4: Estimated Percent of Errors in the Drug Enforcement Administration's (DEA) Year-End Reporting and Quota Management System (YERS/QMS)

	Estimated percent of records with errors[a]	
Data fields	**2011**	**2012**
Quota application		
Application year	0%	0%
Company name	1%	0%
Substance name	0%	1%
Quota type	1%	0%
Date submitted	23%	1%
Total amount of quota	13%	3%
Decision letter		
Application year	0%	0%
Company name	1%	0%
Substance name	1%	0%
Quota type	1%	0%
Date mailed	9%	3%
Total amount of quota	5%	2%
Total	**44%**[b]	**10%**[b]

Source: GAO analysis of YERS/QMS data and source documents obtained from DEA. I GAO-15-202

Notes: This table reflects our review of a stratified random sample of 440 source records from YERS/QMS. The sample included all of the 146 records in 2011 and 2012 that are associated with drug shortages manufacturers reported to the Food and Drug Administration (FDA) were caused by quotas. We consider YERS/QMS records to be associated with these shortages if the record contains a quota application that was (a) submitted by a manufacturer who reported quota caused a shortage of their product to FDA; (b) for a substance that was used in the products reportedly in shortage because of quota; and (c) was submitted during the time of the reported shortage caused by quota. Manufacturers may or may not have reported to DEA that their quota application was related to a shortage. We also analyzed a random sample of 294 records stratified by year that were not associated with any drug shortages reportedly caused by quotas—180 and 114 records from 2011 and 2012, respectively.

[a]All percentage estimates have margins of error at the 95 percent confidence level of plus or minus 10 percentage points or less.

[b]Rows may not sum to total because some records have errors in more than one data field. Therefore, such records are counted towards the total number of errors for multiple data fields but count only once for the total number of records with any error.

DEA officials said 2011 was a transitional year for YERS/QMS as manufacturers first started submitting quota applications electronically, and they expected the information for 2012 and beyond to be more accurate. DEA officials noted that they consider the information submitted to YERS/QMS by manufacturers to belong to the manufacturers and therefore DEA officials do not correct this information, even when they learn that it is not accurate. Instead, DEA officials said that they ask

manufacturers to submit a revised application and they mark the original application as withdrawn, as well as make a note in YERS/QMS that the application will be corrected by manufacturers. Nonetheless, we removed applications marked as withdrawn from our analysis and we still found errors in the YERS/QMS data for manufacturers' quota applications, as well as in the data for DEA's quota decisions. As YERS/QMS data is the official record of how much quota is requested by manufacturers and authorized by DEA, maintaining accurate records is important for the management of the quota setting process.

DEA also does not have agency-wide performance measures related to establishing quotas or ensuring an adequate and uninterrupted supply of controlled substances to assess how well the program is carrying out its responsibilities.[72] Federal internal control standards state that performance measures are an important management tool and that such measures provide critical information to managers about agency performance and program outcomes.[73] Such performance information can demonstrate progress toward goals and help program managers determine how to allocate resources among competing priorities. DEA officials said that performance measures related to establishing quotas or ensuring an adequate and uninterrupted supply of controlled substances would be inappropriate because of the complexity of individual quota applications and the difficulty of projecting the number of quota applications for future years. Nonetheless, performance measures related to quotas—such as the percentage of applications that require follow-up by DEA because of missing documentation—are a critical internal control, without which DEA cannot determine if its process for establishing quotas is having the desired outcome of ensuring an adequate and uninterrupted

[72]DEA does have agency-wide performance measures to assess its performance of reducing the diversion of licit drugs, such as the number of scheduled investigations completed each year. We have previously reported on these measures and recommended that DEA reassess its set of performance measures for the Diversion Control Program to identify ways to enhance the measures' link to the outcome of reducing diversion. See GAO, *Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results,* GAO-11-744 (Washington, D.C.: Aug. 26, 2011).

[73]*Standards for Internal Control for the Federal Government* state that the establishment and review of performance measures and indicators is a control activity and that monitoring internal controls allows agencies to assess the quality of performance over time. See GAO/AIMD-00-21.3.1, 14, 20. We have also reported on the importance of establishing performance measures that demonstrate how well a program is achieving its goals. See GAO/GGD-96-118.

supply of controlled substances for legitimate medical use. In the absence of such performance measures, DEA is missing important information for program managers to use when making decisions about program resources and the agency cannot effectively demonstrate program results.

In addition, DEA officials told us that they do not monitor or analyze available data from YERS/QMS to assess its administration of the quota process, which federal standards for internal control state is an important component of managing a program.[74] DEA officials said that the agency does not monitor or analyze these data and that they do not use YERS/QMS to produce aggregate information on timeliness or other performance metrics and the agency has no plans to do so as of October 2014. Absent such analysis, DEA is unable to evaluate its responses to manufacturers' quota applications or to understand the nature of its workload. For example, whereas DEA previously withheld some of the amphetamine APQ to authorize later in the year, officials told us that the agency initially granted more of the amphetamine APQ in 2012 to manufacturers than it had previously, to see if manufacturers would still claim that there was a shortage of their products. However, DEA officials said they did not monitor the effect of this decision, which they said was unprecedented, and they were therefore unsure if it had an effect on shortages or the agency's workload. Officials were unable to say if this change resulted in manufacturers submitting fewer supplemental applications for amphetamine that year. Additionally, DEA officials cited manufacturers' incomplete applications and frequent revisions as affecting the agency's ability to meet its required time frames. However without monitoring or analyzing data to identify how frequently manufacturers submit incomplete and revised applications, DEA lacks information to assess the effect on the agency's workload. This lack of monitoring also prevents DEA from determining whether a few manufacturers are repeatedly submitting incomplete applications or if there is a larger, systemic issue to address. DEA therefore cannot identify appropriate means to help prevent such issues in the future, such as through in-depth training or guidance.

[74] *Standards for Internal Control for the Federal Government* state that managers need to compare actual performance to planned or expected results throughout the organization and analyze significant differences. See GAO/AIMD-00-21.3.1, 13.

Finally, DEA officials told us that the agency does not have protocols, policies, or other documentation to manage how the agency processes quota applications and establishes APQs and annual and supplemental quotas for individual manufacturers.[75] Instead, DEA officials told us that the agency exclusively relies on its regulations and the CSA to serve as guidance on how to conduct these activities. According to federal internal control standards, agencies should have written documentation, such as detailed policies, procedures, and practices, to fit their agency's operations and to ensure that they are built into, and an integral part of, operations. The absence of written guidance may also pose a risk to the consistency of DEA's future operations in the event of staff turnover, changes in administration, or any other disruption that could lead to a loss of institutional knowledge.[76]

The need for detailed policies, procedures, and practices is particularly important because the activities conducted by Quota Unit staff are very complex, requiring staff to weigh data from at least five different sources and to make recommendations about how to authorize the APQ among various manufacturers. Having additional guidance for these activities is key to help ensure that staff in the Quota Unit process applications consistently and that they are adhering to DEA's regulations and the CSA when setting quotas. For instance, Quota Unit staff analyze and reconcile data from multiple sources in order to recommend quotas that meet estimated legitimate medical need. One such data source is ARCOS, DEA's system for tracking the distribution of controlled substances, which DEA uses in determining how much quota to authorize. Officials told us that there are many instances in which ARCOS data are unreliable and therefore it may contradict information from other sources used by quota scientists, such as the sales information manufacturers provide in their

[75]*Standards for Internal Control for the Federal Government* state that all internal controls, transactions, and other significant events need to be clearly documented, and the documentation should be readily available for examination. The documentation should appear in management directives, administrative policies, or operating manuals and may be in paper or electronic form. See GAO/AIMD-00-21.3.1, 15.

[76]We have previously reported on the risk to the management and operational continuity at agencies due to a lack of written policies and procedures. See, for example, GAO, *Social Security Disability: Management Controls Needed to Strengthen Demonstration Projects,* GAO-08-1053 (Washington, D.C.: Sept. 26, 2008).

quota applications.[77] Although quota scientists may be faced with contradictory information, it is left to the discretion of the Quota Unit staff to determine how to reconcile conflicting data sources, as there are no written policies or guidance and this level of detail is not included in DEA's regulations or the CSA. Moreover, DEA officials told us that the reliability of different data sources can vary based on the substance and the quota applicant. They noted that in some cases, manufacturer-reported sales data may not be as reliable as data on the number of retail prescriptions dispensed, whereas for a different substance or quota applicant, the reverse may be true. Nonetheless, despite the need to consider data sources differently relative to the substance class or quota applicant, there is nothing in the CSA or DEA's regulations about how to do this and DEA has no additional guidance on the matter.

Additionally, when asked how they train new staff if there is no written guidance about the quota process, DEA officials said that they train new Quota Unit staff about the CSA and DEA's regulations through on-the-job training and using presentations created for industry. There are no specific documents developed for the exclusive purposes of training new staff. DEA officials said that the presentations for industry give new Quota Unit staff an overview of the quota process and that everything else must come from on-the-job training, as each function within the Quota Unit is unique and each quota application is different from the next. DEA officials told us that they ensure consistency in their decision-making by having the Deputy Assistant Administrator of the Office of Diversion Control review and authorize every quota decision that is made. However, given the volume of quota applications that DEA processes each year—over 3,000 in 2012—it is unreasonable to expect that the Quota Unit staff can make consistent decisions with no written guidance. Similarly it is not reasonable to assume that one senior manager can devote sufficient time to review these many staff decisions and ensure that quotas are set in accordance with DEA's regulations and the CSA. Further, the lack of written guidance poses a risk to the continuity of the agency's operations should personnel leave or be reassigned.

[77]In the course of our work, DEA officials told us that ARCOS data were unreliable unless verified by DEA officials against source documents located at registrants' place of business.

DEA and FDA Have Not Established a Sufficiently Collaborative Relationship, Which Could Hinder Their Abilities to Effectively Coordinate and Address Future Shortages

FDASIA contains provisions that require DEA and FDA to coordinate their activities where additional quota may be needed to address a shortage of a drug containing controlled substances, though no such opportunity has occurred since the law's enactment in 2012. In addition, FDASIA requires each agency to report to Congress annually describing the coordination between the two agencies on efforts to prevent or alleviate shortages. Although both agencies report that their working relationship has improved in recent years—namely by establishing a point of contact at DEA who is responsible for coordinating with FDA's DSS—the agencies' use of essential collaborative practices to enhance their abilities to successfully coordinate to resolve or mitigate shortages has been limited.[78] We have previously identified key practices that agencies need for enhanced and sustained collaboration, including defining and articulating a common outcome and establishing compatible policies, procedures, and other means to operate across agency boundaries.[79] Running throughout these practices are a number of factors, such as trust, that are important elements for a collaborative working relationship.

One barrier to effective coordination between the two agencies is that DEA and FDA have not defined and articulated a common outcome related to shortages of drugs containing controlled substances. FDASIA gives FDA the authority to create and maintain a list of drug shortages.[80] However, the two agencies sometimes disagree about whether a shortage exists. This is a fundamental concern because FDASIA also contains provisions that require the two agencies to work together to address shortages of drugs subject to quotas. According to DEA, FDA has posted shortages on its website when, from DEA's perspective, there is no shortage. DEA often views drugs containing the same substance class as viable substitutes for one another, even when the drugs are different strengths or formulations. Officials told us that there is no shortage, from DEA's perspective, as long as there is quota available to

[78]Collaboration can be broadly defined as any joint activity that is intended to produce more public value than could be produced when the organizations act alone, including coordination.

[79]See GAO-06-15.

[80]Pub. L. No. 112-144, § 1004, 126 Stat. at 1104-05 (codified at 21 U.S.C. § 356e) (directing the Secretary of Health and Human Services to "maintain an up-to-date list of drugs that are determined by the Secretary to be in shortages in the United States" among other things).

manufacture a given controlled substance, regardless of which manufacturers are producing the product and which strengths or formulations are available. For instance, DEA would not consider there to be a shortage of 1 milliliter vials of hydromorphone in the 10 milligram/milliliter concentration if the 5 milliliter vials were still available. Separately, FDA evaluates potential substitutes on a case by case basis to determine whether drugs are clinically interchangeable in order to assess if there is enough supply of a drug to meet demand. To determine clinical interchangeability, FDA states that it relies upon clinical expertise from within the agency, as well as consultation with outside medical professional associations. For example, for ADHD drugs, both the immediate release and extended release formulations are needed and are not substitutes for each other. According to FDA, some patients are well maintained on the extended release formulation alone, some patients require the immediate release formulation at certain points in the day to treat their specific symptoms, and some patients require both the extended release formulation as well as the immediate release formulation at specific times of the day to control their symptoms. FDA may or may not consider drugs of different strengths or formulations to be substitutes for one another and FDA's determination about whether drugs are clinically interchangeable has not always aligned with DEA's perspective, leading DEA to assert that some of the shortages listed on FDA's website are not actual shortages. By not reaching an agreement about what constitutes a drug shortage, the agencies are lacking a key practice of effective coordination and it is unclear if they will be able to work together to respond to shortages of drugs containing controlled substances caused by quotas.

The agencies' collaboration is further impaired by a lack of trust on the part of DEA regarding the shortages listed on FDA's drug shortage website. DEA officials told us that they do not believe FDA appropriately validates or investigates the shortages it lists on its website, which they believe encourages abuse by manufacturers and distributors. Specifically, DEA officials said that they are concerned that manufacturers may falsely report shortages to FDA when they do not receive the amount of quota they requested, rather than because there are actual supply disruptions. As DEA does not consider FDA to have independently confirmed the existence of a shortage, DEA officials said that it considers FDA's website to be an incentive for manufacturers to file self-serving and misleading reports. As a result, despite the fact that DEA officials told us they monitor FDA's website, they still consider it to be neither useful nor accurate for DEA's purposes. When we spoke to FDA about its drug shortage website, officials told us that the agency takes multiple steps to verify the existence

of a shortage before placing it on its website, including confirming the supply disruption with the manufacturer of the product, checking with manufacturers of related products to confirm that they cannot cover the decrease in supply, and analyzing market sales data to compare current supply with historical demand.[81]

Another barrier to effective collaboration is the lack of compatible policies, procedures, and other means to operate across agency boundaries, including mutually agreed upon time frames for DEA to respond if FDA notifies DEA of a shortage caused by quota. Although FDA established policies and procedures in September 2014 for requesting a quota adjustment from DEA if it determines that it is necessary to address a shortage, DEA officials said that the agency has not and does not plan to establish formal policies or procedures to coordinate the agency's response with FDA.[82] Such actions are not consistent with key practices for effective collaboration. It is important to note that while FDASIA directs DEA to respond within 30 days to manufacturers that request additional quota pertaining to a drug in shortage that is on FDA's drug shortage list, the law does not specify how quickly DEA must respond to a request from FDA to address a shortage of a life-sustaining drug and the agencies do not have an agreement in place regarding this matter. A time frame for DEA to respond to an FDA request is particularly important, given that FDA has determined that there is a shortage of a life-sustaining drug that an increase in quota is necessary to address, and DEA may not necessarily agree with FDA's determination of a shortage. Federal standards for internal control also state that communicating information within a specified time frame that enables entities to carry out their responsibilities is an important control activity.[83] DEA officials told us that the notifications it received from FDA prior to FDASIA were not useful. These notifications included copies of manufacturers' quota applications and FDA's assessment that the application was, or could be, related to a shortage. DEA maintained that, because FDA was not providing it with any new information, FDA's notifications were not helpful. Further, DEA

[81]For more information on the steps that FDA takes to verify the existence of a drug shortage see GAO-14-194.

[82]See FDA, *Manual of Policies and Procedures, Drug Shortage Management*, MAPP 4190.1 Rev. 2 (Sept. 3, 2014).

[83]See GAO/AIMD-00-21.3.1, 18.

officials said that the applications may or may not be related to a shortage from DEA's perspective.

Finally, both agencies stated that they are subject to restrictions on exchanging the proprietary information they receive from drug manufacturers. Both agencies agree that sharing such information with one another would be helpful in preventing and mitigating shortages of drugs containing controlled substances. For example, DEA officials said that it would be helpful to be informed in advance of FDA's decisions about upcoming drug approvals that may help alleviate a shortage. According to DEA, this could provide it with early notification about the need to quickly verify information provided by manufacturers in quota applications for drugs that appear to be nearing FDA approval. DEA officials added that such information sharing would make it easier for the two agencies to communicate about drug shortages and quotas in a meaningful way.

Although DEA and FDA have long had memorandums of understanding (MOU) in place, these documents do not address the topic of drug shortages. The agencies have been working for more than 2 years on developing a new MOU, which would replace the original documents that were executed in the 1970s. As of January 20, 2015, the new MOU had not been finalized and the two agencies report that they are continuing to work towards outlining mutually agreeable terms. Officials from both agencies explained that they expect the new MOU would establish the terms for sharing and safeguarding the proprietary information that they are currently prohibited from exchanging and that may ultimately allow the agencies to work together more effectively to address shortages. However, DEA officials said that they do not expect the new MOU to specify what types of information may be shared, including information related to a shortage of a drug containing controlled substances or the time frames for sharing such information. FDA officials indicated that once the new MOU is in place the two agencies will still need to take additional steps before they can begin to share information, such as developing a work plan for sharing information related to shortages of drugs containing controlled substances. As the agencies will need to take additional steps before they can begin exchanging information related to shortages after the MOU is in place, it is uncertain whether FDA and DEA will be able to expeditiously address shortages of drugs containing controlled substances, should one occur in the near future.

Conclusions

Prescription drugs containing controlled substances are routinely used in inpatient, outpatient, and emergency settings. DEA is responsible for preventing, detecting, and investigating the diversion of these substances, while nonetheless ensuring an adequate and uninterrupted supply for legitimate needs. Because DEA maintains a closed system of distribution that limits the availability of certain substance classes by establishing aggregate production, bulk manufacturing, and procurement quotas, the agency's management of the quota process is of critical importance to public health.

Our work shows that DEA is not well prepared to expeditiously respond to future shortages. DEA has not met its required time frames for establishing quotas for more than a decade. DEA also lacks sufficient internal controls to ensure the reliability of the data it uses to establish quotas, which we found led to errors in its data system. Moreover, DEA does not monitor the data it collects and has no established performance measures related to either setting quotas in a timely manner or ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical use. Its lack of written policies and procedures for a complex process poses a risk to the continuity of its future operations.

Because FDA also plays a vital role in preventing, mitigating, and resolving drug shortages, its collaboration with DEA is key to responding to shortages. FDA adopted the definition of a drug shortage that is specified in FDASIA and was assigned authority to maintain the list of drugs in shortage. Moreover, FDASIA directs the two agencies to work together to coordinate certain activities related to shortages. However, DEA and FDA are not able to effectively collaborate due to fundamental disagreement over whether any given shortage exists. DEA has made it clear it does not trust FDA's information, as it does not consider many of the shortages that FDA verifies to be legitimate. In addition, DEA has not developed any formal policies or procedures to coordinate its response to a shortage with FDA. The two agencies have been operating under an MOU that has been unchanged for about 40 years and that does not address the topic of drug shortages. Although it is under revision, this process began over 2 years ago and remains incomplete. Despite FDASIA's provisions directing the two agencies to coordinate and report on their responses to drug shortages, it is not clear that the new MOU will facilitate this. Given that the agencies have indicated that they will still need to take additional steps before they can begin exchanging information after the MOU is in place, they may not be able to provide a quick response should a shortage occur in the near future.

While we cannot establish a causal relationship between shortages of drugs containing controlled substances and DEA's management of the quota setting process, the shortcomings we have identified prevent DEA from having reasonable assurance that it is prepared to help ensure an adequate and uninterrupted supply of these drugs for legitimate medical need, and to avert or address future shortages. This approach to the management of an important process is untenable and poses a risk to public health.

Recommendations for Executive Action

To ensure that DEA is best positioned to administer the quota process to ensure an adequate and uninterrupted supply of controlled substances for legitimate medical use and respond to shortages of drugs containing controlled substances, we recommend that the Administrator of DEA take the following five actions:

- establish controls, including periodic data checks, to ensure that the YERS/QMS data accurately reflect both manufacturers' quota submissions and DEA's decisions;
- establish performance measures for DEA related to quotas and ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical use;
- monitor and analyze YERS/QMS data to assess DEA's administration of the quota process;
- establish internal policies for processing quota applications and setting aggregate, annual, and supplemental quotas to ensure that staff conduct these activities consistently and in accordance with the CSA and agency's regulations; and
- expeditiously establish formal policies and procedures to facilitate coordination with FDA as directed by FDASIA, including a specific time frame in which DEA will be expected to respond to FDA requests to expedite shortage-related quota applications.

To strengthen DEA's and FDA's ability to respond to shortages of drugs containing controlled substances, we recommend that the Administrator of DEA and the Commissioner of FDA take the following two actions:

- promptly update the MOU between the two agencies, and
- either in the MOU or in a separate agreement, specifically outline what information the agencies will share, and time frames for sharing such information, in response to a potential or existing drug shortage.

Agency Comments and Our Evaluation

We provided a draft of this report for comment to HHS and DOJ. In addition, we provided excerpts of this report to UUDIS. We received written comments from HHS and DEA, which are reproduced in full in appendix IV and V, respectively. Both agencies also provided technical comments, which we incorporated as appropriate. UUDIS did not have any comments.

HHS agreed with the two recommendations applicable to FDA. Specifically, it agreed with our recommendation that it promptly update its MOU with DEA. It also agreed with our recommendation that it and DEA should specifically outline what information they will share and the time frames for doing so, in response to a potential or existing drug shortage. HHS also stated that FDA is actively working to finalize the new MOU with DEA.

DEA did not explicitly agree or disagree with the seven recommendations we made to it, but commented on each. In some instances, its comments indicate that it is either supportive of strengthening its management of the quota process and improving coordination with FDA, or that it has already taken steps consistent with our recommendations. In one instance, it did not respond directly to our recommendation. DEA also raised multiple objections to our work and described what it characterized as flaws and weaknesses in our draft report. In particular, DEA stated concerns with (1) our understanding of quotas, (2) definition of a shortage, (3) the title of our draft report, (4) our methods of conducting investigation and data analysis, and (5) our conclusions.

Understanding of quotas. DEA stated that we fail to understand that it does not have the authority to issue quotas for individual dosage forms and that it cannot require a manufacturer to manufacture or distribute its products, whether API or final dosage form. This report reflects these facts, specifically stating that “DEA does not have the authority to issue quotas for specific products or to require manufacturers to use their quota for specific products.” DEA concluded that because the agency does not have this authority, its quota decisions have no effect on the availability of individual dosage forms containing substances that are subject to quotas. We disagree with this conclusion because manufacturers must receive authorization from DEA to obtain controlled substances subject to quotas, and so the amounts of quota authorized by DEA and the timing of its decisions directly affect when manufacturers are able to obtain the substances necessary to manufacture their products. We understand that manufacturers are ultimately responsible for what they manufacture with

the quota authorized by DEA, but their decisions are made within the confines of the quota granted by DEA.

Definition of a shortage. DEA stated that our draft report is misleading because we fail to account for the fact that the definition of a "shortage" means different things to different entities. DEA suggested that our approach is flawed because we focus on individual drug products rather than the basic class of controlled substances. We do so because this is the level that affects patients and providers. Thus, we used data from UUDIS and FDA, both of which track shortages of individual drug products. UUDIS is regarded as the most comprehensive and reliable source of drug shortage information between January 2001 through June 2013 and FDA has been mandated by statute to identify and monitor drug shortages. Drugs within the same substance class are not necessarily clinically interchangeable, according to FDA and UUDIS. For example, as we describe in this report, there can be significant implications for patients who have to switch from an extended-release formulation to an immediate-release formulation of the same drug and patients who have trouble swallowing may not be able to use a tablet formulation if an injection is in short supply.

Additionally, DEA criticized our use of FDA's revised definition of a drug shortage, which FDA adopted in September 2014. DEA stated that this definition, which FDA adopted to be consistent with FDAISA, is "materially different" from the definition FDA used from 2006 through 2012. DEA implied that, by doing so, our analysis was flawed in that we inappropriately applied the new definition to our analysis of YERS/QMS records from 2011 and 2012—a period predating FDA's revised definition. We disagree. Our analysis of certain YERS/QMS records was premised on particular shortages of drugs containing controlled substances that occurred between January 2010 and June 2013. We collected data from FDA beginning in October 2012 to specifically identify the manufacturer-reported causes of shortages of drugs containing controlled substances. We completed our collection of FDA's data in August 2013. We could not have applied FDA's revised definition of a drug shortage to our efforts as, at that time, the revised definition was not yet adopted by FDA. We requested the YERS/QMS source documents, including the entire population of records in 2011 and 2012 that were associated with drug shortages manufacturers reported to FDA that were caused by quotas, in June 2014. Therefore, FDA's revised definition had no bearing on our YERS/QMS analysis. However, we include and discuss FDA's revised definition in this report as it is relevant to FDA's and DEA's implementation of FDASIA provisions that require coordination between

both agencies in response to certain drug shortages. It is also important to note that, although DEA asserts that FDA's revised definition is "materially different" than its prior one, as we note in this report, FDA does not consider the revised definition to be substantively different nor does it alter how FDA works to resolve drug shortages.

With respect to DEA's and FDA's different views on when a shortage exists, our report explicitly recognized that DEA and FDA are not able to effectively collaborate due to this fundamental disagreement. In fact, this was the basis for our recommendation that DEA and FDA take steps to improve the coordination required of them under FDASIA.

Title of our draft report. DEA stated that the title of our draft report was inconsistent with the our findings: (1) that a causal relationship could not be established between shortages of drugs containing controlled substances and DEA's lack of timeliness in establishing annual and supplemental quotas and (2) that we could not prove that DEA's collaboration with FDA would hinder their collective abilities to effectively coordinate regarding future shortages. We disagree with DEA's conclusion that the quota process and its collaboration with FDA play no role in, and cannot cause or exacerbate, drug shortages. As this report shows, DEA does not use effective approaches for managing the quota process or collaborating with FDA. We continue to believe that DEA should improve its administration of the quota process and enhance coordination with FDA to be in a position to fulfill its statutory responsibilities. Nevertheless, we modified the title of this report to emphasize the need for process and collaboration improvements, rather than the link between drug shortages and the process and collaboration shortcomings.

Method of conducting investigation and data analysis. DEA stated that our methodology was flawed because we did not attempt to independently determine whether there were shortages of drugs subject to quotas and whether quotas actually caused such shortages. In its comments, DEA stated that two of its data systems—ARCOS and YERS/QMS—would have provided us with such information. This stance contradicts information that DEA consistently provided throughout the course of our work, and we disagree with DEA's position for several reasons.

- First, we sought to obtain ARCOS and YERS/QMS data from DEA early in our review and were met with strong opposition from agency officials. We requested ARCOS data in order to track the drugs that

manufacturers reported to be in shortage to examine their movement through the supply chain before, during, and after the reported shortage and YERS/QMS data to analyze DEA's timeliness and responsiveness in authorizing quota. DEA officials said that ARCOS is used to monitor the diversion of drugs and it is not used nor intended to be used to identify shortages of specific drugs. DEA officials also told us that there is too much complexity in the supply chain to perform a meaningful analysis and that it would be inappropriate to use ARCOS data for our purpose. DEA officials also insisted that supplying us with ARCOS data would be burdensome and an inefficient use of their agency's resources. Similarly, DEA officials objected to providing us with the YERS/QMS data we requested. As DEA stated in its comments, negotiations to obtain these data were "protracted and contentious." Our audit was ultimately delayed for over a year as we attempted to obtain these ARCOS and YERS/QMS data. However, following the intervention of senior DOJ management officials, DEA eventually provided the requested information from both ARCOS and YERS/QMS.

- Second, although DEA indicated in its comments that ARCOS and YERS/QMS data could have provided us with a "full view" of the distribution of schedule II controlled substances throughout the supply chain, this is inconsistent with information the agency provided throughout the course of our work and what we ultimately found through our analyses. DEA officials repeatedly informed us that, apart from their concerns with providing us with the ARCOS data, they objected to our planned analysis because of significant and inherent inaccuracies in the data. Agency officials explained that, because the ARCOS data are self-reported by registrants, the data contain many errors, particularly in the quantity field that records the number of packages, weight, or volume being reported in each transaction. DEA officials told us that they consider these data to be so unreliable they only use data from ARCOS as a preliminary tool when beginning diversion investigations, and that they must ultimately verify the data against source documents available at the registrants' business locations. DEA advised us that ARCOS data were unreliable; however, to maintain our independence, it was necessary for us to obtain a sample of data to complete our own assessment.

  Once we obtained the requested data from both ARCOS and YERS/QMS, we conducted a preliminary analysis on each data set. We identified significant data reliability issues with both sets of data and determined that both ARCOS and YERS/QMS were unreliable for our purposes. Specifically, regarding ARCOS, our analysis of the data sample identified drastically different numbers of transactions and

amounts reported as transferred between manufacturers and distributors for any given quarter between 2010 through 2012. Both manufacturers and distributors are required to report the number of transactions of these substances and the amounts transferred to ARCOS, so we would therefore expect that the number of transactions and amounts reported as transferred between both groups to be similar. DEA officials could not provide explanations for these inconsistencies. In addition, it was not possible for us to use source documents to verify all of the transactions in our sample because it was beyond the two year retention requirement for registrants' original documentation for many of the transactions. Because our tests on the sample we obtained showed the ARCOS data to be unreliable for our purposes, there was no point in further analyzing ARCOS data or in requesting additional data.

Our assessment of YERS/QMS also determined that these data were not reliable for our purposes. However, we were able to analyze a sample of YERS/QMS data by taking certain methodological steps. Specifically, to correct for the errors that we found in the data, we analyzed the information contained in the source documents for our sample of YERS/QMS records for certain fields. Overall this sample represented about 15 percent of the total YERS/QMS records that we obtained from DEA in 2011 and 2012.[84] We found a significant number of errors in the data from 2011 (44 percent overall) and less in the data from 2012 (10 percent overall). Although we had correct information from the source documents, we determined that it was not appropriate for us to use all of the fields contained in those documents because we continued to identify inconsistencies, including in the source documents themselves. For instance, within the source documents associated with a particular supplemental application—a manufacturer's supplemental quota application and DEA's decision letter—the manufacturer may have requested the additional amount of quota it was seeking (e.g., an additional 500 grams in addition to 500 grams it previously received), but DEA's corresponding decision letter authorized the total amount of quota for that year (e.g., 1,000 grams). Therefore, it would appear that DEA authorized 200 percent of the quota requested in this case, according to the source documents, when in fact it authorized 100 percent of the request. Due to these

[84]According to DEA officials, YERS/QMS data prior to 2011 were not available and our data request was made before 2013 was complete.

inconsistencies, we did not pursue analyzing the amount of quota that DEA authorized for manufacturers in 2011 and 2012. DEA states in its comments that we should have analyzed the amounts of quota authorized by DEA for the substance classes that had drugs in shortage in 2011 and 2012 to verify the manufacturers' claims that quotas caused or exacerbated shortages. However, the data reliability concerns we identified within the quota amount fields, particularly for 2011 data when 6 of the 7 quota related shortages began, prevented the feasibility of a meaningful analysis.

In addition to criticizing our methodology for not fully utilizing data from YERS/QMS and ARCOS to independently establish causation between a specific shortage and the quotas DEA established for a basic class of schedule II controlled substance, DEA stated that our draft report was misleading because of our extensive description of the nature and magnitude of drug shortages of all controlled substances and their consequences. We do so because the scope of this report is not limited to drugs containing controlled substances that are subject to quota, but includes other prescription drugs containing controlled substances. It is important to note that we identify specific examples of shortages of schedule II drugs that are subject to quota—such as morphine, fentanyl (anesthesia), amphetamine and methylphenidate (ADHD drugs)—and the impact of these shortages on patients and providers in this report. As we note in this report, quota was not reported to be the primary cause of all shortages of drugs that contain schedule II substances. Indeed, not all drugs containing controlled substances are subject to quota. Other primary causes included manufacturing delays, capacity issues, and product quality issues, which are the same factors that cause shortages of drugs generally. However, because the availability of quota could be a factor in shortages of those drugs that do contain controlled substances subject to quota, we considered it both necessary and relevant to include such information. We therefore provide FDA data on the manufacturer-reported causes of shortages of their products containing schedule II substances, including quota.

Lastly, we believe that DEA may have misconstrued the intent of our study. DEA implies that our purpose was to evaluate whether it authorized adequate amounts of quota and whether manufacturers provided adequate justification for their quota requests. However, our purpose was to examine the trends and characteristics of drug shortages of controlled substance and their affect on patients and providers, as well as assess DEA's administration of the quota process, including its internal controls and compliance with required time frames. The purpose of our

study was not to determine whether DEA's decisions were correct or manufacturers' justifications were sufficient. In using ARCOS and YERS/QMS data, we sought to obtain information about where certain controlled substances were in the supply chain before, during, and after a shortage and DEA's timeliness and responsiveness in responding to manufacturers' quota applications. Data reliability concerns with both data sets prevented us from fully accomplishing such analyses.

Our conclusions. DEA stated that our conclusions unfairly link the quota process to diminished patient care by describing the trends of shortages of drugs containing controlled substances and then evaluating DEA's administration of the quota process that only applies to a subset of those substances. These are two separate issues. This report does not say, nor do we believe, that quotas are the sole cause of shortages of drugs containing schedule II substances. However, we disagree with DEA's contention that the actions it takes in setting quotas at the class level would have no bearing on the drug products that are made with those substances. The shortcomings that we identified in DEA's administration of the quota process prevent it from having reasonable assurance that it is providing for an adequate and uninterrupted supply of these drugs for legitimate medical need, and calls into question DEA's ability to avert or address future shortages of medically necessary products. We agree that there are many factors that affect and ultimately cause drug shortages and include these in this report. However, simply because not all drugs that have been in shortage are subject to quotas does not mean that quotas cannot cause, contribute to, or exacerbate shortages of drugs containing schedule II substances.

DEA also questioned our conclusion that by not acting promptly to respond to supplemental quota applications, it may hinder manufacturers' ability to produce schedule II drugs that may help prevent or resolve a shortage. DEA said this is not possible because manufacturers' business decisions are involved. We recognize that manufacturers must apply for quota, and then use it to manufacture and ultimately distribute the appropriate drugs for there to be any impact on drug shortages. However, DEA's actions also play a part when quota is involved. DEA's lack of timeliness in responding to manufacturers' supplemental quota applications—taking nearly 60 days on average—for both shortage and non-shortage related applications is problematic and not in the interest of public health. We continue to believe DEA should implement our recommendations to ensure that it is positioned to comply with the statutorily mandated time frame of responding to applicable requests within 30 days.

DEA's response to our recommendations. Regarding our first recommendation that DEA establish controls to ensure that the YERS/QMS data accurately reflect both manufacturers' quota submissions and DEA's decisions, DEA described existing flags and reviews in place to ensure the information that is entered by manufacturers and DEA staff is accurate. While we understand that DEA takes some steps to help ensure the accuracy of YERS/QMS data, it does not perform sufficient checks to ensure the accuracy of the information. For example, DEA does not compare a sample of YERS/QMS data to the source documents (manufacturer's application and DEA decision letter) to identify if its existing checks are adequate. Although the accuracy of the data improved from 2011 to 2012, we nonetheless found a 10 percent error rate in the 2012 data. In particular, some of the fields with the highest rates of error in the 2012 data were in the fields for the amount of quota requested or authorized, which have implications for the availability of controlled substances subject to quota. We continue to believe that taking additional steps to reduce this error rate, as we recommended, is important.

Regarding our second recommendation to establish performance measures related to quotas, DEA said it recognizes the value in establishing performance measures for personnel who review quota applications. While we agree that it can be useful to develop performance measures for personnel, our recommendation is intended to be more expansive than that and should include performance measures at the program or agency level. For example, as we note in this report, DEA could set goals and then measure the number of manufacturers who submit incomplete or revised quota applications, both factors that DEA cited as affecting its ability to meet its required time frames. DEA could also establish goals and track the percentage of annual applications that DEA responds to in accordance with its required time frames. It is important that DEA set such measures to assess its performance in achieving its mission of ensuring an adequate and uninterrupted supply of controlled substances as it does for its diversion-related mission.

For our third recommendation about monitoring and analyzing YERS/QMS data, DEA said it agrees that such actions are important to ensuring proper administration of the quota process. DEA also provided examples of how the agency uses YERS/QMS data in setting APQs and bulk manufacturing and procurement quotas. However, the agency did not commit to using the data to monitor its administration of the quota process or its performance. Such information could be of vital importance to determine the feasibility of potential performance measures, as we

recommended, or to evaluate DEA's efforts in meeting its performance measures once developed, such as the extent to which DEA is meeting its required time frames for responding to annual quota applications.

In response to our fourth recommendation that DEA establish internal policies for processing quota applications, DEA stated that it has already established such policies and procedures. However, the agency did not provide documentation of such policies and procedures despite repeated requests. To the contrary, DEA officials told us that the agency relies exclusively on its regulations and the CSA in establishing APQs and manufacturers' quotas. As we state in this report, this is inconsistent with federal standards for internal control, and we believe that policies are still needed because of the complexity of the work involved in setting quotas.

In response to our fifth recommendation that DEA expeditiously establish formal policies and procedures to facilitate coordination with FDA as directed by FDASIA, DEA stated that it will follow the requirements of FDASIA to respond to FDA's requests within 30 days. However, FDASIA does not specify a time frame in which DEA must respond to FDA's requests to increase quota; this 30-day time frame is only applicable to requests that DEA receives from manufacturers. Furthermore, DEA has not historically met its required time frames for establishing quotas from either the CSA or its regulations. Therefore, we believe that policies and procedures are needed to establish such a time frame and specify how DEA will respond to such a request from FDA. We understand that DEA has received no such request from FDA since the enactment of FDASIA; however, we believe that it is imprudent to wait for a shortage that has serious implications for public health before determining how to proceed.

Regarding our sixth recommendation that DEA promptly update the MOU with FDA, DEA stated that it had begun negotiating the terms of the new information sharing agreement when this review began in 2012, which we note in this report. DEA said that the final version of this MOU has been routed for signature within the agency as of December 2014.

Lastly, in response to our seventh recommendation that, either in the MOU or in a separate agreement, DEA and FDA specifically outline what information the agencies will share and the time frames for sharing such information in response to a potential or existing drug shortage, DEA noted that it has already engaged in discussions with FDA to determine the specific procedures for sharing drug shortage related information pursuant to FDASIA. We believe that reaching a specific agreement on information sharing will be beneficial to both agencies.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of the Department of Health and Human Services and the Attorney General, and other interested parties. In addition, the report will be available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at crossem@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix VI.



Marcia Crosse
Director, Health Care

Appendix I: List of Provider and Patient Organizations Interviewed

Provider Organizations

1. American Academy of Child and Adolescent Psychiatry
2. American Academy of Pediatrics
3. American College of Emergency Physicians
4. American Hospital Association
5. American Psychiatric Association
6. American Society of Anesthesiologists
7. American Society of Health-System Pharmacists
8. Association of Critical Care Transport
9. Institute for Safe Medication Practices
10. International Association of Fire Chiefs
11. National Association of Boards of Pharmacy
12. National Association of Emergency Medical Technicians
13. National Association of State EMS Officials
14. National Community Pharmacists Association

Patient Organizations

1. Children and Adults with Attention Deficit/Hyperactivity Disorder
2. National Alliance on Mental Illness

Appendix II: Classes of Schedule II Controlled Substances with Medical Use

The Drug Enforcement Administration (DEA) establishes quotas on the quantity of schedule II substance classes that may be produced in the United States in any given calendar year.[1] We consider classes of schedule II controlled substances with medical use to be those substances that are contained in Food and Drug Administration (FDA) approved products currently marketed for human use, and are not considered precursors, reference standards, or metabolites, as reported by DEA.[2] Those substance classes include the following:

Alfentanil	Hydromorphone	Opium
Amobarbital	Levorphanol	Oxycodone
Amphetamine	Lisdexamfetamine	Oxymorphone
Cocaine	Meperidine	Pentobarbital
Codeine	Methadone	Remifentanil
Dihydrocodeine	Methamphetamine	Secobarbital
Diphenoxylate	Methylphenidate	Sufentanil
Fentanyl	Morphine	Tapentadol
Hydrocodone	Nabilone	

[1]DEA also establishes quotas for schedule I substances, but we did not include them in our report because such substance classes have no currently accepted medical use in treatment in the United States.

[2]A precursor is a chemical that is transformed into another compound as in the course of a chemical reaction. For example, the controlled substance noroxymorphone is a precursor used to manufacture opiates. A metabolite is a substance produced during metabolism or a result of metabolism. For example, the substance ecgonine is a metabolite of cocaine as it is generated in the extraction of cocaine from coca leaf.

Appendix III: Scope and Methodology – Analysis of the Year-End Reporting and Quota Management System Data

As part of our work examining the Drug Enforcement Administration's (DEA) quota process, we analyzed data from DEA's Year-End Reporting and Quota Management System (YERS/QMS) for certain controlled substances with medical use to assess the reliability of the system and DEA's timeliness in responding to manufacturers' quota applications. This appendix provides further detail on our methods for determining the reliability of the data and analyzing the data.

To determine the reliability of data from DEA's YERS/QMS, DEA provided data from the system for 2011 and 2012, the most recent years for which data were available when we began our analysis. We discussed these data with the officials responsible for maintaining YERS/QMS and examined the data for obvious errors and values outside of expected ranges. We removed applications that were marked as "withdrawn," as DEA does not authorize quota for these applications.[1] We also removed applications that appeared to be duplicates, which we identified by searching for applications that had the same registrant, drug, date submitted, and quota type (e.g., bulk manufacturing or procurement). We searched for applications that had the word "duplicate" in the notes field of YERS/QMS as well, which DEA uses to record additional information about quota applications. Additionally, we removed applications that were not for schedule II substance classes with medical use.[2]

We then selected a sample of 442 records, from the total of 2,982 records, from YERS/QMS to verify against source documents, each of which includes a manufacturer's quota application for a particular substance and the corresponding DEA decision letter informing the manufacturer of its quota authorization (see table 5). This sample included the entire population of records in 2011 and 2012 that are associated with drug shortages manufacturers reported to the Food and Drug Administration (FDA) were caused by quotas, of which there were 146. We consider YERS/QMS records to be associated with these shortages if the record contains a quota application that was (a) submitted by a manufacturer who reported to FDA that quota caused a shortage of its product; (b) for a substance that was used in the

[1]DEA told us that manufacturers often withdraw an application if it has an error or if a manufacturer loses a contract and no longer needs quota for a particular substance.

[2]See appendix II for the list of schedule II substances that we consider to have medical use.

products reportedly in shortage because of quota; and (c) was submitted during the time of the reported shortage caused by quota. For instance, if a manufacturer reported a shortage of a drug containing a controlled substance to FDA beginning in 2011 and ending in 2012, and said that the shortage was caused by quota issues, we considered all applications from that manufacturer for that controlled substance in 2011 and 2012 to be related to a shortage reportedly caused by a quota issue. We also selected a random sample of 296 records stratified by year—182 and 114 records from 2011 and 2012, respectively. We included more records from 2011 because we believed those records would be harder for DEA to locate, as DEA told us that there were a larger percentage of hard-copy applications, as opposed to electronic applications, in 2011 than 2012. Because we followed a probability procedure based on random selections, our sample is only one of a large number of samples that we might have drawn. Since each sample could have provided different estimates, we express our confidence in the precision of our particular sample's results as a relative margin of error based on a 95 percent confidence interval (e.g., plus or minus 10 percentage points). This is the interval that would be expected to contain the actual population value for 95 percent of the samples we could have drawn.

Table 5: Records Sampled from the Drug Enforcement Administration's Year-End Reporting and Quota Management System (YERS/QMS) for Schedule II Substances with Medical Use

	Number of records in population	Number of records in sample
Records associated with shortages reportedly due to quota (2011 and 2012)	146	146
Records not associated with shortages reportedly due to quota (2011)	1,419	182
Records not associated with shortages reportedly due to quota (2012)	1,417	114
Total	**2,982**	**442**

Source: GAO analysis of YERS/QMS data. I GAO-15-202

From our sample of 442 YERS/QMS records for which we requested source documents from DEA, we analyzed source documents for 440 records. DEA officials said that they could not locate documents for one record and another record was found to be ineligible based on our review. Noncertainty sample sizes were inflated to account for an expected location rate of 50 percent for 2011 and 80 for 2012, to assure enough located files would be available for analysis. Because DEA told us that some paper applications had been put into storage due to office renovations and were difficult to retrieve, we assumed we would not be able to locate the full sample of records. DEA officials told us that there were more paper records—as opposed to electronic records—submitted

in 2011 than 2012. Based on that information, we assumed a lower location rate in 2011 than 2012. In order to estimate population quantities, we analyzed our sample data using survey analysis software that accounts for our stratified random selection design and uses analysis weights in order to make the results of our sample representative of all YERS/QMS applications for schedule II substances with medical use in 2011 and 2012.

In order to confirm that we were comparing the source documents to the correct record in YERS/QMS, we matched the documents based on the manufacturer and substance, and at least one of the following fields: date application was submitted; total amount requested; date decision letter was mailed; and total amount authorized.[3] Using this methodology, we were able to match 440 records in our sample. To verify the accuracy of the YERS/QMS data for these 440 records, we compared the data in YERS/QMS against the information in DEA's source documents (quota applications and decision letters). We used the following fields in the quota application to validate or correct the data in YERS/QMS: quota year, company name, substance name, quota type (e.g., bulk manufacturing or procurement), the date submitted, and total amount requested. We used the following fields in the decision letters provided by DEA to validate or correct the data in YERS/QMS: quota year, company name, substance name, quota type (e.g., bulk manufacturing or procurement), date mailed, and total amount authorized. We calculated the number of fields with errors (e.g., number of errors in the date submitted field) and the number of records with errors (i.e., a record with an error in any field). We also weighted the results of our error calculations in order to make the results representative of all YERS/QMS records in 2011 and 2012. Based on our review of these source documents, we determined that the YERS/QMS data we obtained from DEA were unreliable for our purposes.

Because of the reliability concerns with the YERS/QMS data, we used the information contained in the 440 YERS/QMS source documents for our analysis of DEA's timeliness in responding to manufacturers' quota applications and when manufacturers submitted annual quota applications. In order to separate annual applications and supplemental

[3]DEA matched source documents to the corresponding YERS/QMS records for 8 of the 440 records for which they provided source documents.

applications, which have different requirements for timeliness, we considered annual applications to be applications submitted in the year prior to when the quota would be used (e.g., an application submitted in May 2010 for 2011 quota). Applications submitted in the same year as when the quota would be used were considered supplemental. For annual applications, we analyzed DEA's compliance with the required deadlines in the Controlled Substances Act and DEA's regulations, including how often DEA met the deadlines for our sample of records and how many days passed when it did not meet the deadlines.[4] We also analyzed when manufacturers submitted their annual quota applications. For supplemental applications, we analyzed the amount of time that it took DEA to respond to supplemental applications in our sample. We used a two-tailed t-test to determine whether there was a statistical difference in the amount of time DEA took to respond to supplemental applications submitted by manufacturers that reported shortages due to quota compared to all other supplemental applications. For our analysis of these 440 YERS/QMS source documents, we express our confidence in the precision of our particular sample's results the same way in which we did for our analysis of the errors in the YERS/QMS data, as we described above.

[4]See 21 U.S.C. § 826(c); 21 C.F.R. §§ 1303.12 and 1303.21.

Appendix IV: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

DEC 29 2014

Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Controlled Substances: Better Management of the Quota Process and Enhanced Coordination between DEA and FDA Needed to Address Drug Shortages" (GAO-15-202).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: CONTROLLED SUBSTANCES: BETTER MANAGEMENT OF THE QUOTA PROCESS AND ENHANCED COORDINATION BETWEEN DEA AND FDA NEEDED TO ADDRESS DRUG SHORTAGES (GAO-15-202)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

GAO Recommendation

To strengthen the Drug Enforcement Administration's (DEA) and the U.S. Food and Drug Administration's (FDA) ability to respond to shortages of drugs containing controlled substances, we recommend that the Administrator of DEA and the Commissioner of FDA promptly update the memorandum of understanding (MOU) between the two agencies and either in the MOU or in a separate agreement, specifically outline what information the agencies will share, and timeframes for sharing such information, in response to a potential or existing drug shortage.

HHS Response

HHS concurs with this recommendation and is actively working to finalize the new MOU with the DEA.

Appendix V: Comments from the Drug Enforcement Administration

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

DEC 2 9 2014

Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Crosse:

The Drug Enforcement Administration (DEA) provides the following comments to the Government Accountability Office (GAO) report entitled "*Controlled Substances: Better Management of the Quota Process and Enhanced Coordination between DEA and FDA Needed to Address Drug Shortages*" (GAO-15-202).

It is important to note that the titled conclusion of the report is inconsistent with the GAO finding that it cannot establish either a "causal relationship between shortages of drugs containing controlled substances and DEA's management of the quota setting process" (Draft, p. 45) or that DEA coordination with the U.S. Food and Drug Administration (FDA) adversely affected the availability of drug products containing controlled substances.[1]

Introduction

The DEA agrees that prescription drug abuse is a nationwide epidemic and more must be done to prevent, detect, and deter the diversion of pharmaceutical controlled substances that supply drug addiction and abuse. The DEA role in this effort is as the primary agency responsible for coordinating the drug law enforcement activities of the United States. The Diversion Control Program (DCP) is a strategic component of the DEA's law enforcement mission. The DEA Office of Diversion Control administers the DCP and implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, but are collectively referred to as the "Controlled Substances Act" or the "CSA." The CSA and its implementing regulations are designed to prevent, detect, and deter the diversion of controlled substances and listed chemicals into the illicit market while

[1] See Draft, p. 34 (stating GAO "cannot confirm whether DEA's lack of timeliness in establishing annual and supplemental quotas has caused or exacerbated shortages"); p. 40 (stating "DEA and FDA have not established a sufficiently collaborative relationship, which *could* hinder their abilities to effectively coordinate *future* shortages") (emphasis added).

establishing the total quantity of each basic class[2] of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. This is a delicate balance.

One way that DEA provides for the estimated medical, scientific, research, and industrial needs of the United States is to establish an aggregate, nationwide quota for each basic class of schedule I and II controlled substance (referred to as the Aggregate Production Quota, or "APQ") and to authorize individual quotas (referred to as manufacturing quota and procurement quota). It is important to understand that DEA authorizes quota only at the manufacturer level for those entities that manufacture active pharmaceutical ingredients (API), those entities that manufacture substances into dosage forms, and those entities that repackage or re-label drug products that contain schedule I or II controlled substances. Once the aggregate quota is established and a particular manufacturer is

[2] "Basic class" means, as to controlled substances listed in Schedules I and II:
(1) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in §1308.11(b) of this chapter;
(2) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.11(c) of this chapter;
(3) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.11(d) of this chapter;
(4) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
(i) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;
(ii) Apomorphine;
(iii) Codeine;
(iv) Etorphine hydrochloride;
(v) Ethylmorphine;
(vi) Hydrocodone;
(vii) Hydromorphone;
(viii) Metopon;
(ix) Morphine;
(x) Oxycodone;
(xi) Oxymorphone;
(xii) Thebaine;
(xiii) Mixed alkaloids of opium listed in §1308.12(b)(2) of this chapter;
(xiv) Cocaine; and
(xv) Ecgonine;
(5) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in §1308.12(c) of this chapter; and
(6) Methamphetamine, its salts, isomers, and salts of its isomers;
(7) Amphetamine, its salts, optical isomers, and salts of its optical isomers;
(8) Phenmetrazine and its salts;
(9) Methylphenidate;
(10) Each of the substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.12(e) of this chapter. 21 C.F.R. § 1300.01(b).

authorized to manufacture a specific amount of a basic class of controlled substance, DEA cannot require the manufacturer to manufacture API or a specific drug product, or distribute that substance down through the supply chain. Furthermore, a bulk manufacturer may extract or synthesize API in an authorized calendar year, and hold it in inventory until any subsequent calendar year. Of equal importance, the CSA prohibits DEA from establishing quotas in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance. 21 U.S.C. § 826(a). These limitations are critical to understanding the effect that quota can have on the availability of a specific drug product at the retail level or at the emergency medical service (EMS) provider level. The failure to appreciate these limitations is the fatal flaw in the GAO report.

Another fundamental weakness in the GAO report is the failure to account for the fact that "shortage" means different things to different entities, and without accounting for this distinction, the GAO report is misleading with respect to the effect that the DEA quota process can have on patient care. To identify trends in shortages of drugs containing controlled substances, GAO analyzed University of Utah Drug Information Service (UUDIS) data. UUDIS broadly defines a "shortage" as a supply issue that affects how pharmacies prepare and dispense a product or that influences patient care when prescribers must choose an alternative therapy because of a supply issue. A UUDIS "critical shortage" occurs when alternative medications are unavailable, the shortages affect multiple manufacturers, or the shortages are widely reported. In addition, UUDIS information is based on national drug codes (NDCs) rather than the basic class of controlled substance contained within a specific drug product. NDCs are identifiers that are unique to a particular manufacturer, drug product, dosage form, dosage strength, and package size. Accordingly, a single basic class of controlled substance will be represented by many different NDCs. Statistics and analysis based on the NDC, rather than the basic class of controlled substance, could dramatically distort the actual number of shortages that could be attributed to quota.

From September 2006 through July 2012, the FDA defined a "drug shortage" as a "situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level."[3] (FDA CDER MAPP 6003.1, Sept. 26, 2006). FDA changed their definition in September 2014 to align with the definition in the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) to "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." Although this new definition is materially different from the definition applicable during the period in review (2011 and 2012), the GAO report uses the 2014 definition in its analysis.

In contrast to the UUDIS and FDA, which view shortages in the context of patient-level availability, DEA views shortages in the context of manufacturer-level quota. Accordingly, a shortage within DEA's jurisdiction is the lack of sufficient quota available for bulk or dosage form manufacturers to manufacture a basic class of a schedule I or II controlled substance. This perspective is the result of the CSA prohibition against establishing quotas in terms of individual

[3] The GAO report discusses DEA's concern with the reliability of information posted on FDA's drug shortage website. During the period under review, DEA was concerned that FDA did not adhere to the applicable definition of "drug shortage" because FDA was listing drug products in shortage when clinically interchangeable drug products were available. Other inaccuracies included reporting that some distributors experienced a shortage due to quota or lack of API, yet distributors do not receive quota.

pharmaceutical dosage forms prepared from or containing a controlled substance, together with the mandate to limit the supply of controlled substances available for diversion, and the inability to require a manufacturer to manufacture a specific API or drug product or require the distribution of controlled substance drug products downstream. Accordingly, if alternative forms of a drug product are available (e.g., brand, generic, or other clinically interchangeable drug products), or if manufacturers have quota authorization, the DEA cannot remedy any patient-level shortage (e.g., inadequate supply at the retail level or EMS provider level) by increasing the aggregate or authorizing more quota at the manufacturer level. GAO fails to emphasize and account for these fundamental distinctions in its review of the potential effect of the quota process on the availability of drug products containing schedule II controlled substances.

Some simplified examples can illustrate how the above distinctions can skew shortage conclusions. If there is an unmet patient need for hydromorphone 10 mg/mL, 1 mL vials, UUDIS and FDA would qualify it as a shortage. However, DEA would not consider there to be a shortage within its jurisdiction if the 10 mg/mL, 5 mL vials are available. Similarly, DEA would not consider there to be a shortage if the brand name version of a particular drug product is unavailable, if the generic version of the drug product is available. Also, there would be no shortage in DEA's jurisdiction if there is hydromorphone quota available in the APQ (i.e., the annual APQ has not been exhausted) and manufacturers are not requesting additional quota, or if manufacturers with authorized hydromorphone quota are not manufacturing their quota allotment or are not distributing the manufactured hydromorphone downstream.

Further comments regarding the GAO report are focused on the following three main areas and are discussed below: method of conducting investigation; method of data analysis; and GAO conclusions.

Method of conducting investigation:

Generally, the Congressional requesters sought to "better understand the impact of DEA quotas on patients with emergency medical and critical care conditions and traumatic injuries, and the extent to which DEA policies and regulations may impede the ability of physicians and health care providers to mitigate a shortage of a drug on any of the applicable schedules." Specifically, GAO was asked to particularly focus on shortages of drugs containing controlled substances used by EMS providers and to treat attention deficit hyperactivity disorder (ADHD). GAO did not evaluate the flow of specific controlled substances from the point of quota request and authorization to manufacture, or from the point of manufacture to distribution to the retail level, using available data from the Automation of Reports and Consolidated Orders System (ARCOS) and Year End Reporting and Quota Management System (YERS/QMS).

GAO was aware of which manufacturers self-reported shortages to FDA claiming the shortage was due to quota, and which specific drug products were reported in shortage due to quota, yet GAO did not investigate each manufacturer's quota allotment or usage, the manufacturer's manufacturing and distribution practices, whether the manufacturer provided adequate justification for quota, or if the manufacturer asked for quota before or after reporting the shortage. In fact, GAO did not attempt to determine whether "shortages" actually existed because of a lack of quota. GAO was not without the tools to determine the answer to this question. After a protracted and contentious

negotiation regarding the data that DEA could release to GAO to conduct this investigation, DEA and GAO reached an agreement wherein DEA provided specified information from ARCOS and YERS/QMS. ARCOS and YERS/QMS data could have provided GAO with a full view of the distribution of schedule II controlled substances by manufacturers and distributors, from the point of bulk manufacture, to dosage form manufacture, and down to distribution to the retail level. Instead, GAO simply reported manufacturers' anecdotal complaints about the quota process' effect on shortages.

Amphetamine is a schedule II controlled substance and is used to treat ADHD, among other things, and it was reported to be in shortage during the review period. GAO requested ARCOS information pertaining to 17 specific NDCs, all of the amphetamine basic class. However, the 17 requested NDCs represented only a small fraction of the available market supply. The DEA estimated that there were 48 other amphetamine-containing drug products, 25 of which were manufactured and distributed during the period under review. GAO did not request ARCOS data on the other available amphetamine-containing products on the market, and GAO did not discuss in its report any findings relative to the 17 requested NDCs. The ARCOS information, combined with information from YERS/QMS, is crucial to determining whether sufficient API was manufactured, whether the API was distributed downstream by bulk manufacturers, whether dosage form manufacturers were manufacturing drug products in accordance with their quota applications, whether dosage form manufacturers were distributing drug products downstream and if so, where, and whether controlled substances were being held at the manufacturer level or destroyed rather than placed into the supply chain.

DEA is confident that a review of ARCOS and YERS/QMS data would have established that DEA's administration of the quota process did not cause or exacerbate any shortages of drug products used to treat ADHD in 2011. In 2011, DEA increased the APQ for amphetamine salts by 6,700 kg. A review of the ARCOS and YERS/QMS data for amphetamine salts showed that manufacturers subsequently requested, and DEA authorized, only a very small percentage of this increase. In addition, a significant number of amphetamine dosage units were destroyed throughout 2011, as well as a substantial amount of raw material, and millions of dosage units of ADHD drug treatment products still remained at the distributor and retail level at the end of 2011.

Close review of the ARCOS data would have also refuted manufacturers' assertions about the effects of DEA's timing to establish quotas. For example, manufacturer representatives reported to GAO that the timeline for establishing quotas does not provide manufacturers with enough time to plan for production and order the raw material or API needed to start manufacturing their products at the beginning of the production year. Representatives reported to GAO that they operated solely with what is left in their inventory for the first few months of the production year, "which may be limited because manufacturers operate in a lean manufacturing environment where they carry as little inventory as possible." (Draft, p. 30). This statement from manufacturers is conflicting. Manufacturers complained that they do not have sufficient inventory because of quota and must operate on what is solely remaining in inventory, but then go on to state their business choice to operate in a lean environment where they carry as little inventory as possible. Even so, manufacturers may manufacture API and procure raw material at any time during the year, and not distribute it until the next calendar year because DEA regulations provide for an inventory allowance.

In addition, a review of ARCOS data would have been critical to determining whether the DEA's processing of supplemental quota applications in 2011 caused or exacerbated FDA-reported drug shortages, as alleged by manufacturers. (Draft, p. 30-31). GAO's probability sample of YERS/QMS source documents showed that it took DEA an average of 58 days to respond to supplemental quota applications in 2011 and 2012. (Draft, p. 30-31). GAO also reported that it took DEA 10 days longer, on average, to respond to supplemental quota applications submitted by manufacturers that reported shortages caused by quota in 2011. However, as discussed above, a review of ARCOS and YERS/QMS information would have established that amphetamine manufacturers only sought authorization to manufacture a very small percentage of the mid-year increase.

Method of Data Analysis:

The report's extensive description of the nature and magnitude of shortages (Draft, p. 17) is misleading as it uses a very broad definition of "shortage," using data from two different sources to quantify and explain the consequences of shortages, and then ties these consequences to the very small number of schedule II drug product "shortages" without ever establishing causation between the specific shortage and the quotas for the specific basic class of controlled substance.

GAO found that approximately 10% (168 of 1,575) of the UUDIS shortages from January 2001 through June 2013 involved drug products containing a controlled substance (Draft, p. 17); of these, 57% (96) involved drug products containing schedule II controlled substances (Draft, p. 19), or approximately 6% (96 of 1,575) of the total number of UUDIS shortages. Because UUDIS information is presented according to NDC rather than the basic class, the results (96 shortages of schedule II controlled substances from 2001 to 2013) can dramatically distort the actual number of shortages that could have been attributed to lack of quota in a particular basic class of controlled substance. The results can also be misleading because UUDIS counts a shortage as a period of time; as a result, 45 different drugs containing controlled substances were reported to be in shortage multiple times from January 2001 through June 2013, representing 143 individual shortages. (Draft, p. 19). The data could also be distorted by the fact that GAO analyzed data from YERS/QMS for 2011 and 2012, rather than 2001 to 2013. Analyzing the information regarding the specific drug products and the specific basic class of controlled substance represented by the 96 NDCs, as well as the calendar year that the substances were reported in shortage would have helped to determine the role, if any, that quota played in any shortage.

GAO also reported that critical shortages represented 52% (87 of 168) of all shortages of drugs containing controlled substances. (Draft, p. 4, n.6; p. 21). Of the 87 shortages containing controlled substances identified as critical by UUDIS from January 2001 through June 2013, half (44 of 87) involved pain relievers (analgesics). (Draft, p. 20-21). Analgesics can be controlled in schedule II, III, IV, or V. However, GAO does not state whether these products contained schedule II controlled substances subject to quota, or schedule III through V controlled substances not subject to quota. This information, along with the NDCs and basic class of controlled substance involved, would be important in determining the role, if any, quota played in any shortage, particularly with respect to the UUDIS "critical shortages," because the applicable criteria (alternative medications are unavailable, the shortages affect multiple manufacturers, or the shortages are widely reported) are more likely to implicate quota than a standard shortage (a supply issue that affects how pharmacies

prepare and dispense a product or that influences patient care when prescribers must choose an alternative therapy because of a supply issue).

Even so, for the period January 2010 to June 2013, GAO reported that there were 40 FDA-reported shortages of drug products containing schedule II controlled substances, and of those, only seven were alleged to have been caused or exacerbated by quotas. (Draft, p. 30). The remaining 33 reported shortages of drugs containing schedule II controlled substances were caused by other factors that cause shortages of drugs generally such as manufacturing delays, capacity issues, and product quality issues. (Draft, p.30). GAO does not state whether any of these seven shortages occurred during the period in review, 2011 and 2012, nor does GAO indicate which basic class of controlled substance was involved, or whether each shortage involved a different basic class of controlled substance or if a single basic class of controlled substance was involved in several reported shortages. However, GAO contacted the 10 manufacturers that reported the seven shortages from January 2010 to June 2013, and reported that "many" manufacturers stated DEA's lack of timeliness in establishing quotas caused or exacerbated shortages of their drug products. It does not appear that GAO verified these statements with the data it obtained from YERS/QMS or ARCOS. Rather, the cause of these self-reported shortages was substantiated by collecting anecdotal information from manufacturers.

Some drug products specifically mentioned in the report were in shortage due to reasons other than quota. For example, beginning in 2010, a major manufacturer of injectable drug products containing controlled substances voluntarily shut down certain of its production lines and slowed the release of products in certain manufacturing facilities as a result of certain quality issues cited by the FDA. Such interruptions adversely impacted, and continue to adversely impact, the manufacturer's ability to manufacture and sell its products. The availability of all injectables were adversely affected, including substances specifically mentioned in the GAO report as having significant deleterious effects on patient care as a result of shortage, such as fentanyl, hydromorphone, and morphine—all schedule II substances subject to quota. Review of the quota data would have shown that when new manufacturers submitted quota applications to meet the new demand, DEA verified with FDA the supply disruption and acted quickly to authorize quota to the new manufacturers.

In addition, some drug products emphasized by GAO when it reported the effects of drug shortages on treatment and patient care were not drug products subject to quota. For example, GAO references an American Society of Anesthesiologists' survey regarding the effects of drug shortages on anesthesiologists. (Draft, p.24, n.49). The highest frequency of reported shortages were fentanyl (66%), thiopental (40%), succinylcholine (21%), propofol (19%), and pancuronium (15%). As discussed above, fentanyl shortages were due to manufacturing issues. Thiopental is a schedule III controlled substance and thus not subject to quotas; and the remaining three substances are non-controlled substances. In another example, lorazepam injection is a schedule IV controlled substance, and GAO highlighted the adverse consequences of its shortage, indicating that a single shortage of it lasted slightly more than 5 years. (Draft, p. 18). Another consideration GAO ignores is that the benzodiazepines are primarily imported and not manufactured in the United States. Finally, GAO reports that oxycodone oral solution (Draft, p.19), a drug GAO reports is used to treat moderate to severe pain, was in shortage for the longest combined amount of time from January 2001 through June 2013. However, certain oxycodone oral solution drug products were not FDA-approved drugs and could not be lawfully manufactured or distributed until FDA approval in

September, 2014.

GAO Conclusions:

Failure to utilize the available information as discussed above, and failure to evaluate and analyze the causes of specific controlled substance shortages lead to an analysis that unfairly linked the quota process to diminished patient care. Even though GAO could not find that shortages occurred because of a lack of quota or because of DEA's administration of the quota process, GAO makes several inferences about a relationship between drug shortages and the quota process. This was accomplished because GAO begins its report with identifying trends in shortages from January 2001 through June 2013, and then examines DEA's administration of the quota process, thereby suggesting the effect of the quota process on shortages. However, GAO only evaluated quota data for 2011 and 2012, and its evaluation is not generalizable to other years.

As discussed above, only seven of 40 FDA-reported shortages of drug products containing schedule II controlled substances were alleged to have been caused or exacerbated by quotas. GAO reports that it cannot confirm that DEA's lack of timeliness caused or exacerbated shortages. However, the tools were available to GAO to refute the specific claims that DEA's administration of the quota process caused or exacerbated shortages.

DEA is confident that its administration of the quota process did not affect a shortage during the period in review because drug product shortages are not limited to products that contain schedule II controlled substances. In fact, for the period January 2010 to June 2013, only 18% (7 of 40) of FDA-reported schedule II drug product shortages implicated quotas. Also, UUDIS data shows that from January 2001 through June 2013, approximately 43% of all reported controlled substance shortages were present in schedule III through V drug products, where quotas are not involved. (Draft, p. 19). In addition, GAO found that, from January 2001 through June 2013, the number of new controlled substance shortages reported each year peaked in 2009 and then declined. (Draft, p. 17-18; fig. 2). The increase in these shortages mimics the pattern found for shortages of all drugs, indicating that the same factors affecting shortages of all drugs are also the same factors affecting shortages of drugs containing controlled substances. It is more likely that a common denominator (or a combination of common denominators) are effecting the similar patterns in shortages amongst controlled substances and non-controlled substances; as well as amongst schedule II controlled substances and schedule III through V controlled substances.

GAO concluded that by not acting "promptly" on supplemental applications, DEA may hinder manufacturers' ability to manufacture schedule II drugs that may help prevent or resolve a shortage. However, as explained above, even if DEA increased the APQ or authorized additional manufacturing or procurement quota, manufacturers must apply for it and actually use it to manufacture the drug products in shortage, and then distribute those products downstream—activities that DEA cannot compel.

DEA Response to Recommendations:

GAO Recommendation (1): Establish controls, such as periodic data checks, to ensure that the YERS/QMS data accurately reflect both manufacturers' quota submissions and DEA's decisions.

Response: The GAO report found that the data error rate was substantially improved from the initial year the process became electronic to the second year (2011 to 2012), dropping from 45% to 10%. (Draft, p. 35). DEA has established policies and procedures to ensure data is accurate. In order to determine the timeliness of responses to submitted requests, there are a number of computer-generated dates, including date submitted, date assigned for review, and date review complete. In order to determine accuracy in quota values being requested and granted there are a series of system-generated flags in YERS/QMS. The flags guide and verify data provided by applicants; and there are flags for internal review, including when a quantity greater than requested is entered. Managers review worksheets for accuracy in summarizing the analysis of the data and supporting documentation provided by the applicant. They then verify that the values contained in the working documents are accurately entered into YERS/QMS. Upon final authorization, managers close the application in YERS/QMS after ensuring that the dates mailed are entered as the authorization letters are scanned and sent to the applicant (via email and U.S. Postal mail). YERS/QMS has a flag to ensure that the date entered is correct.

GAO Recommendation (2): Establish performance measures for DEA related to quotas and ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical use.

Response: DEA recognizes the value in establishing performance measures for personnel reviewing quota applications and will determine whether performance is measurable with regard to processing quotas. Many factors determine how quickly and how accurately a quota application is reviewed and a quota recommended. For example, a single quota application is for one specific basic class; however, each quota request may involve quota for more than one specific drug product containing that basic class. The reasonable amount of time to evaluate each application is highly dependent on how many different factors affect a single request.

GAO Recommendation (3): Monitor and analyze YERS/QMS data to assess DEA's administration of the quota process.

Response: DEA agrees that monitoring and analyzing YERS/QMS data is important to ensuring proper administration of the quota process. The YERS/QMS data are integrally related for manufacturing and procurement quotas applications and responses. The data are reviewed and monitored constantly when analyzing each quota application. For example, with the APQ set as the maximum of each basic class to be manufactured each year, the quota review process of every manufacturing quota application checks the APQ, amounts issued, pending and remaining. In addition, the manufacturing quota data are analyzed and used with other sources to establish and revise the annual APQs.

GAO Recommendation (4): Establish internal policies for processing quota applications and setting aggregate, annual, and supplemental quotas to ensure that staff conduct these activities consistently and in accordance with the CSA and agency's regulations.

Response: DEA has established policies and procedures for staff administering the quota

procedures. In addition, beginning with 2013 APQs, DEA included an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. DEA expects that maintaining this reserve in the aggregate production quotas will mitigate adverse public affects if an unforeseen event results in substantial disruption to the amount of controlled substances available to provide for legitimate public need.

GAO Recommendation (5): Expeditiously establish formal policies and procedures to facilitate coordination with FDA as directed by FDASIA, including a specific timeframe in which DEA will be expected to respond to FDA requests to expedite shortage-related quota applications.

Response: DEA shall follow the requirements of FDASIA to respond to requests within 30 days. It should be noted that no special requests for expedited quota review have been forwarded to DEA since enactment of FDASIA in July, 2012. As previously conveyed to GAO, DEA and FDA began negotiating the terms of a new information sharing agreement before this engagement commenced. As of December 15, 2014, the final memorandum of agreement has been routed for signature within DEA.

GAO Recommendation (6): Promptly update the MOU between the two agencies.

Response: As previously conveyed to GAO, DEA and FDA began negotiating the terms of a new information sharing agreement before this engagement commenced. As of December 15, 2014, the final memorandum of agreement has been routed for signature within DEA.

GAO Recommendation (7): Either in the MOU or in a separate agreement, specifically outline what information the agencies will share, and timeframes for sharing such information, in response to a potential or existing drug shortage.

Response: As previously conveyed to GAO, DEA and FDA began negotiating the terms of a new information sharing agreement before this engagement commenced. As of December 15, 2014, the final memorandum of agreement has been routed for signature within DEA. DEA and FDA have engaged in discussions to determine the specific procedures by which information regarding drug shortages shall be exchanged, pursuant to FDASIA. These procedures will be memorialized in a mutually agreeable workplan.

Conclusion:

There can be no doubt that drug shortages adversely affect the public health. Drug shortages occur across the continuum of pharmaceutical characteristics, e.g., brand, generic, controlled, non-controlled, over-the-counter, dosage forms and dosage strengths, analgesics, sedatives, stimulants. Shortages can be caused by a variety of factors, as GAO previously reported in 2011 and 2014. Determining the relationship between retail and EMS level drug product shortages and manufacturing quota is a multifaceted undertaking that particularly requires an understanding of controlled substance manufacturing and distribution practices, an appreciation of how competitive contractual agreements affect the actions of manufacturers, distributors, and patent owners, and how

these dynamics influence the annual forecasting of quota need.

DEA remains committed to establishing production quotas for each basic class of controlled substance in schedule II to be manufactured each year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Accordingly, DEA appreciates the GAO finding that it cannot establish a causal relationship between shortages of drugs containing controlled substances and DEA's management of the quota setting process.

Should you have any questions regarding this matter or our comments, please contact Michael A. Dixon, Acting Deputy Chief Inspector, Office of Inspections, at (202) 307-4007.

Sincerely,

FOR

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Richard P. Theis
Director, Audit Liaison Group
Internal Review and Evaluation Office
Justice Management Division

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7114 or crossem@gao.gov

Staff Acknowledgments

In addition to the contact named above, Geri Redican-Bigott, Assistant Director; Zhi Boon; Jessica Farb; Cathleen Hamann; Rebecca Hendrickson; Tom Jessor; Eileen Larence; Jan Montgomery; Lisa Motley; Leslie Powell; Dan Ries; Janet Temko-Blinder; Sonya Vartivarian; and Eric Wedum made key contributions to this report.

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Congressional Relations	Katherine Siggerud, Managing Director, siggerudk@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548
Public Affairs	Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, DC 20548



Please Print on Recycled Paper.

Page 1453

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

Page 1454

Withheld pursuant to exemption

(b)(5);(b)(6)

of the Freedom of Information and Privacy Act

Page 1455

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

Page 1456

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(b)(5)

of the Freedom of Information and Privacy Act

Page 1457

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(b)(5)

of the Freedom of Information and Privacy Act

Page 1458

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(b)(5);(b)(6)

of the Freedom of Information and Privacy Act

2016 Accuracy Study in the DEA's Year-End Reporting and Quota Management System

Issue:

In June 2016, a follow-up study on the accuracy of DEA's Year-End Reporting and Quota Management System was conducted and found 0.01% errors overall.

Background (paragraph excerpted from the 2014 GAO Report):

The 2014 GAO report on the YERS/QMS found that the data error rate was substantially improved from the initial year the process became electronic to the second year (2011 to 2012), dropping from 45% to 10%. DEA acknowledged policies and procedures to ensure data is accurate. In order to determine the timeliness of responses to submitted requests, there are a number of computer-generated dates, including date submitted, date assigned for review, and date review complete. In order to determine accuracy in quota values being requested and granted there are a series of system-generated flags in YERS/QMS. The flags guide and verify data provided by applicants; and there are flags for internal review, including when a quantity greater than requested is entered. Managers review worksheets for accuracy in summarizing the analysis of the data and supporting documentation provided by the applicant. They then verify that the values contained in the working documents are accurately entered into YERS/QMS. Upon final authorization, managers close the application in YERS/QMS after ensuring that the dates mailed are entered as the authorization letters are scanned and sent to the applicant (via email and U.S. Postal mail). YERS/QMS has a flag to ensure that the date entered is correct. (Source: GAO 15- 202).

Data Review and Analysis:

Between March and May 2016, a random sample of 146 quota applications from YERS/QMS were reviewed and compared to the corresponding DEA Decision letter. These 2016 quota applications included 108 procurement quota applications, 26 manufacturing quota applications and 12 import quota applications. The same data fields that GAO used in their report were reviewed (GAO Report 15-202, Table 4, page 38). The applications that were submitted by the DEA Registered manufacturer into the YERS / QMS applications were compared to the data entered by the DEA staff member and the Decision Letter that was sent in response to the DEA Manufacturer.

The estimated percent of records with errors revealed an overall error rate of 0.01% in the category of "Total Amount of Quota" in the Decision Letter. All other data fields in the Quota Applications and the Decision Letters were determined to be 0%.

The estimated percent of records with errors are presented in Table 1 below.

Results:

Table 1: Estimated Percent of Errors on the DEA's Year End Reporting and Quota Management System (YERS/QMS)

Estimated percent of records with errors	
Data fields	**2016**
Quota Application	
Application year	0%
Company name	0%
Substance name	0%
Quota type	0%
Date submitted	0%
Total amount of quota	0%
Decision Letter	
Application year	0%
Company name	0%
Substance name	0%
Quota type	0%
Date mailed	0%
Total amount of quota	0.01%
Total	**0.01%**

Conclusions:

As all users of the YERS /QMS continued to transition and learn the new online system, error rates reached minimal levels. Since the 2014 GAO Report, ODQ was able to provide presentations and online demos to the DEA registrants at DEA manufacturer meetings and recently reinstituted Pharmaceutical Training Seminars. The presentations from these meeting and the YERS / QMS User Guides are posted on the DEA Office of Diversion website. Increased familiarity with the system and an understanding of what data is required for the online forms and as supporting documentation, decreased the errors on the applications submitted by the DEA registrants. With more complete and accurate applications, there were no discrepancies to document in YERS or the outgoing Decision letters.

Looking beyond the YERS / QMS launch and initial transition years (2011 and 2012), the dramatic improvements in accuracy after moving to an online quota application system are strikingly apparent.

Pharmaceutical Training Seminar – 2016
Online Quota Applications



UN Reporting and Quota Section
ODEquota@dea.usdoj.gov
(202) 307-7184

Why the Switch from Paper?

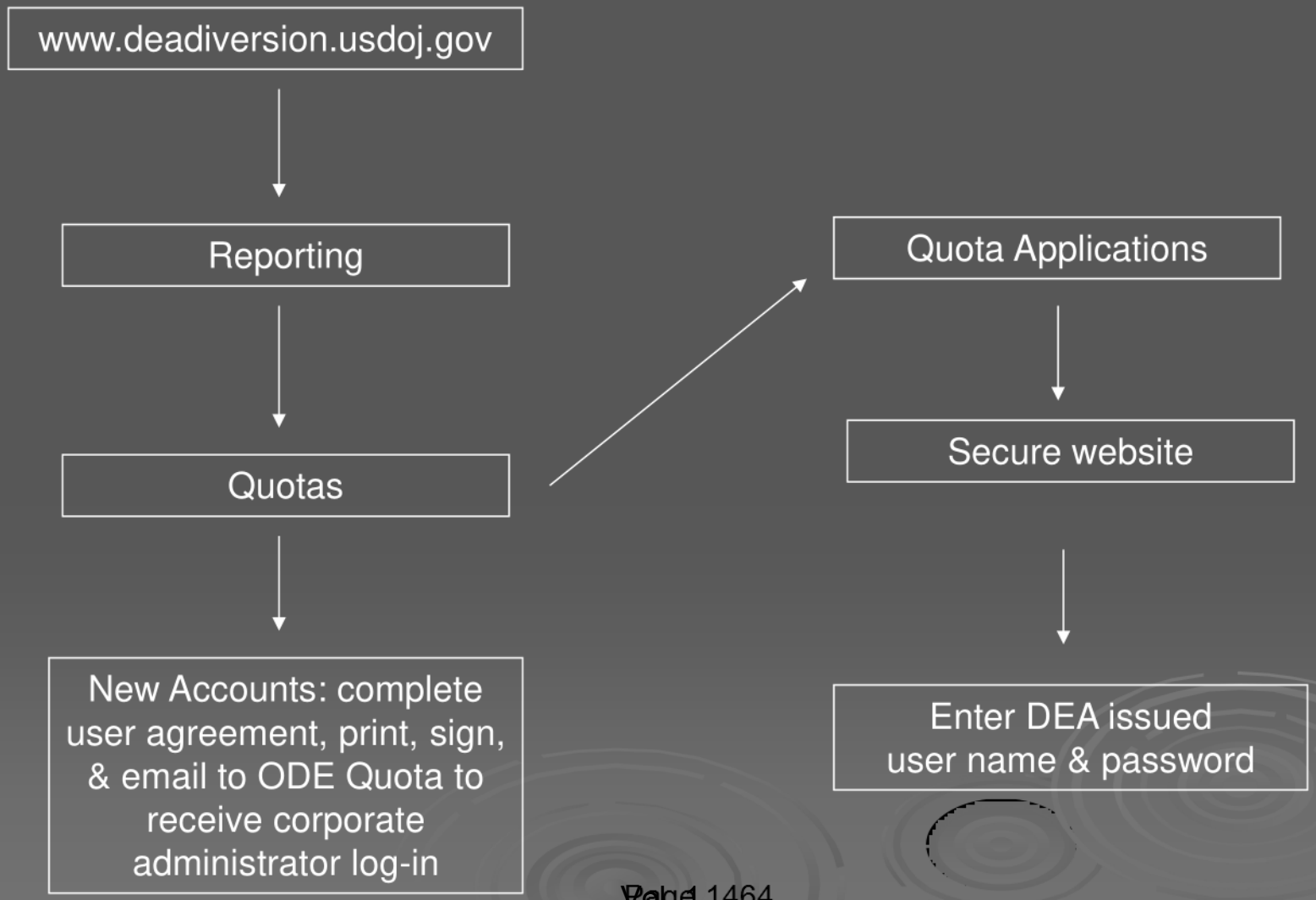
- OPM requested we go paperless (2011 est.)

- Benefits
  - Provides secure web-based database system
  - Verifies registration as active and current
  - Preloads your available drug codes, historical data
  - Performs calculations
  - Lists confirmation and status
  - Expedites process

Please Note

- Procurement applications due by April 1
- Import applications due by April 1
- Manufacturing applications due by May 1
- Adjustments to any quota can be requested throughout the year
- Quantities should expressed as:
  - Anhydrous acid, base or alkaloid
  - GRAMS

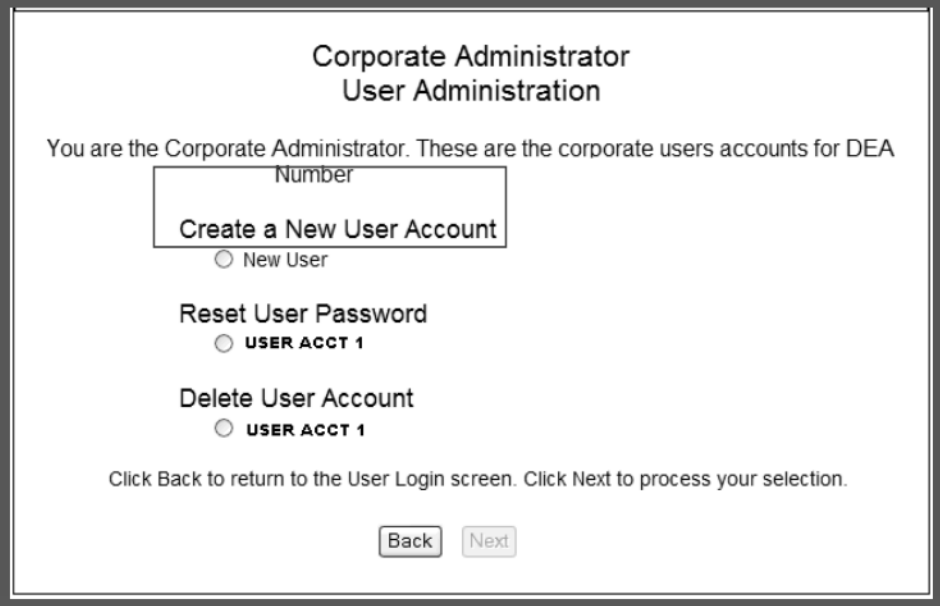
Accessing Quota Applications



Corporate Administrator Login



Create New Corporate User Account







Corporate User Login



Corporate User Login Confirmation



Report Selection Menu



Online Quota Application

Must request specific isomers for:

- Amphetamine
  - d-amphetamine
  - l-amphetamine
  - d,l-amphetamine
- Methamphetamine
  - d-methamphetamine
  - l-methamphetamine
  - d,l-methamphetamine
- Tetrahydrocannabinols
  - Delta-9-THC
  - All Other Tetrahydrocannabinols

Online Quota Application

"For Sale" vs. "For Conversion"

- Codeine
- D-Amphetamine
- D-Methamphetamine
- Diphenoxylate
- Hydrocodone
- Morphine
- Noroxymorphone
- Oxycodone
- Oxymorphone

Online Quota Application

For Sale: substance used to manufacture products containing same basic class which is bought from the bulk manufacturer.

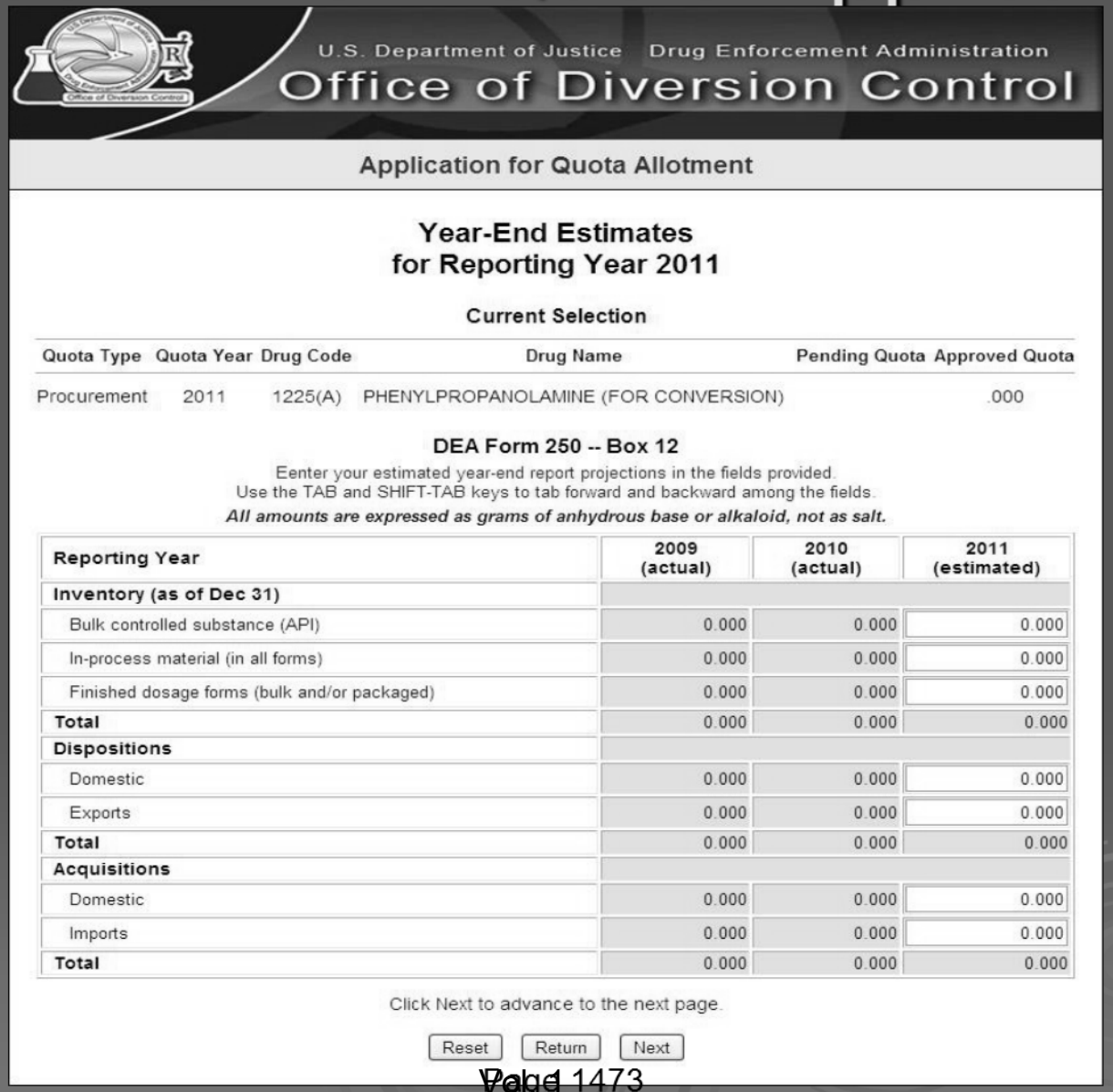
- involves ~95% of the quota applications

ex: Codeine (for sale) ⟶ codeine/APAP

For Conversion: substance used to synthesize a different basic class.

ex: Codeine (for conversion) ⟶ hydrocodone

Procurement Quota Application



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Year-End Estimates for Reporting Year 2011

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225(A)	PHENYLPROPANOLAMINE (FOR CONVERSION)		.000

DEA Form 250 -- Box 12

Eenter your estimated year-end report projections in the fields provided.
Use the TAB and SHIFT-TAB keys to tab forward and backward among the fields.

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.

Reporting Year	2009 (actual)	2010 (actual)	2011 (estimated)
Inventory (as of Dec 31)			
Bulk controlled substance (API)	0.000	0.000	0.000
In-process material (in all forms)	0.000	0.000	0.000
Finished dosage forms (bulk and/or packaged)	0.000	0.000	0.000
Total	0.000	0.000	0.000
Dispositions			
Domestic	0.000	0.000	0.000
Exports	0.000	0.000	0.000
Total	0.000	0.000	0.000
Acquisitions			
Domestic	0.000	0.000	0.000
Imports	0.000	0.000	0.000
Total	0.000	0.000	0.000

Click Next to advance to the next page.

Reset Return Next

Quota Allotment Categories



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Quota Request for Reporting Year 2011

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225(A)	PHENYLPROPANOLAMINE (FOR CONVERSION)		.000

Quota History
(DEA Form 250 -- Box 11)

Enter the *total* value for your quota allotment request in the field provided.
All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.

--- History (Approved) ---			--- Current Request ---
2008	2009	2010	2011
0.000	0.000	0.000	

Quota Allotment Request by Category

Sub-divide your total quota request by category.
You must provide a value for *at least one* category, and the sum of the categories must equal the total quota request.
Use the TAB and SHIFT-TAB keys to tab forward and backward among the fields.

Commercial Manufacturing :
Product Developement :
Packaging :
Replacement :
Transfer :
Total :

Click Next to advance to the next page.

Reset Back Next

Quota Allotment Categories

- Commercial Manufacturing
  - Conversion to other substances
  - Dosage form
- Product Development
  - All stages leading to FDA approval
    - Laboratory scale
    - Scale up
    - Exhibit
    - Stability

Quota Allotment Categories

- Packaging
  - Packaging/Repackaging
  - Labeling/Relabeling
- Replacement
  - Case-by-case basis for commercial mfg
- Transfer
  - Bulk API
  - In-process material
  - Finished dosage units

Quota Allotment Categories



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Report Selection Menu

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	.000

Sub-Reports Selection

In order to complete your application for quota allotment, you will need to provide additional information using the sub-reports below. To fill out a sub-report, click the Report Link to advance to the corresponding report form. If the color of the sub-report link is gray, it means there are sub-reports already on file. You may review and/or update these by clicking the link. You will not be able to advance to the next page until all required sub-reports have been completed.

Required / Optional	Current Request	Report Link
Optional		Commercial Manufacturing Converted Substances (DEA Form 250 -- Box 13)
Optional	894.000	Commercial Manufacturing Dosage Forms (DEA Form 250 -- Box 14)
Required	984.000	Product Development (DEA Form 250 -- Box 14)
Required	543.000	Packaging (DEA Form 250 -- Box 14)
Required	151.000	Replacement
Required	484.000	Transfer

If you have completed all required sub-reports, click Next to continue.

Back Next

Commercial – Conversions

Basic Class To Be Manufactured
(DEA Form 250 -- Box 13)

To convert PHENYLPROPANOLAMINE (FOR CONVERSION) to another substance, select the substance from the list. If the target substances is not in the list, either contact DEA to have the substance added to your registration, or select "Users Choice" (the last entry).

--- Listed in Alphabetical Order (Select One) ---

Drug Name	Drug Code	2009 (actual)	2010 (actual)	2011 (estimated)	% Yield (estimated)

Fill in the fields above and click Submit.

Reset Submit

Summary

Remove	Drug Name	Drug Code	2009 (actual)	2010 (actual)	2011 (estimated)	% Yield (estimated)
○	Vraxoin	0000	.000	.000	2,524.002	252.24

To remove an entry, click the Remove radio button.

Next

Commercial - Dosage Forms

Dosage Form Data
(DEA Form 250 -- Box 14)
Quota Requested: 894.000

If you intend to manufacture dosage forms from PHENYLPROPANOLAMINE (FOR CONVERSION), fill out the fields below and click Submit. You may create as many individual dosage forms as necessary.

* Name	* Mkt Auth	* Used 2009	* Used 2010	* Est. 2011

The * symbol denotes a required field. Number fields must be a valid number between 0 and 999,999,999.999 inclusive.

Reset Submit

Summary

Remove	Name	Mkt Auth	Used 2009	Used 2010	Est. 2011
○	Traylopanifaphryn	Department of Agriculture	5121	1321	1231

To remove an entry, click the Remove radio button.
Click Next to return to the Report Selcetion Menu.

Next

Product Development

Dosage Form Data
(DEA Form 250 -- Box 14)
Quota Requested: 984.000

If you intend to manufacture PHENYLPROPANOLAMINE (FOR CONVERSION) into dosage forms, fill out the fields below and click Submit. You may create as many individual dosage forms as necessary.

* Name	* Strength	* Units/Batch	* # Batches	* Purpose	* Qty	* Completion Time

The * symbol denotes a required field. Number fields must be a valid number between 0 and 999,999,999.999 inclusive.

Reset Submit

Summary

Remove	Name	Strength	Units/Batch	# Batches	Purpose	Qty	Completion Time
○	Calafrin	23 gm	125	521	Nausea	132	2 months

To remove an entry, click the Remove radio button.
Click Next to return to the Report Selcetion Menu.

Next

Labeling & Packaging

Package Form Data
(DEA Form 250 -- Box 14)
Quota Requested: 543.000

If you intend to segment PSEUDOEPHEDRINE (FOR CONVERSION) into packages, fill out the fields below and click Submit. You may create as many individual package forms as necessary.

* Name	* Strength	* Units / Pkg	# Pkgs	* Purpose	* Qty

The * symbol denotes a required field. Number fields must be a valid number greater than 0 and less than 1,000,000,000.000.

Reset Submit

Summary

Remove	Name	Strength	Units / Pkg	# Pkgs	Purpose	Qty
○	Protaxis	121	35	56	Resale	251

To remove an entry, click the Remove radio button.
Click Next to return to the Report Selcetion Menu.

Next

Replacement

Replacement Data
Quota Requested: 151.000

If you intend to request Replacment quota for PHENYLPROPANOLAMINE (FOR CONVERSION), fill out the fields below and click Submit.

* Destruction Date

* Explanation

Please provide an explanation of what was destroyed and why. You must submit appropriate documentation including DEA Form 48 and DEA Form 522 if a reverse distribution was used. Summarize what was destroyed (ie. commercial batches, product development samples and retains, bulk API, etc.) and the reason for disposal.

The * symbol denotes a required field. Number fields must be a valid number between 0 and 999,999,999.999 inclusive.

Reset Submit

Summary

Remove	Destruction Date	Explanation
◉	Jan 21, 2011	Batch became contaminated.

To remove an entry, click the Remove radio button.
Click Next to return to the Report Selcetion Menu.

Next

Transfer

Transfer Data
Quota Requested: 151.000

If you intend to transfer PHENYLPROPANOLAMINE (FOR CONVERSION), fill out the fields below and click Submit. You may create as many individual Transfer forms as necessary.

* DEA Number

* Explanation

Please provide details of transfers, ie. what will be transferred, the purpose of the transfer, etc.

The * symbol denotes a required field. Number fields must be a valid number between 0 and 999,999,999.999 inclusive.

Reset Submit

Summary

Remove	DEA Number	Explanation
○	RL0401187	Required the further analysis of product in outside independent study.

To remove an entry, click the Remove radio button.
Click Next to return to the Report Selcetion Menu.

Next

Summary



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Final Summary

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225(A)	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	.000

Year-End Report Data

	2009 (actual)	2010 (actual)	2011 (estimates)
Inventory	0.000	0.000	1,272.000
Acquisitions	0.000	0.000	100.000
Dispositions	0.000	0.000	69.000

Quota Allotment Request by Category

Comm Man	Prod Dev	Replacements	Transfers	Total
894.000	984.000	151.000	484.000	2,513.000

Remarks

Click Submit to transmit your data to DEA.
Click Return to go back to the Year-End Estimates page to modify any part of this request.

Return Submit

Summary



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Summary Confirmation

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225(A)	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	.000

Confirmation

You have successfully submitted a Quota Allotment Request for the substance noted above. Your reference number is:

108035

You may contact DEA via email at ODE.Quota@USDOJ.gov concerning this transaction. Be sure to include the reference number in the subject line of all such correspondence.

If you find a need to amend this request, you may do so by selecting this same substance from the Main Selection Menu. At that time all data entry fields will be pre-populated with values from your latest request.

Printing Options

You are required by law to retain a copy of this Request for Quota Allotment for a period of seven years after the date of the initial request. Click the Print button below and you will be able to print or archive the resultant PDF report.

Print

Return Exit

Status Report



U.S. Department of Justice Drug Enforcement Administration

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Application for Quota Allotment

Quota Request Status

The following table lists substances for which you have formally requested a quota allotment, and the status of your application. Multiple requests for the same substance are sorted sequentially by Drug Name within Quota Type.

A date in the Date Approved field indicates the date the request was approved. Requests that have not been approved yet show as "Pending."

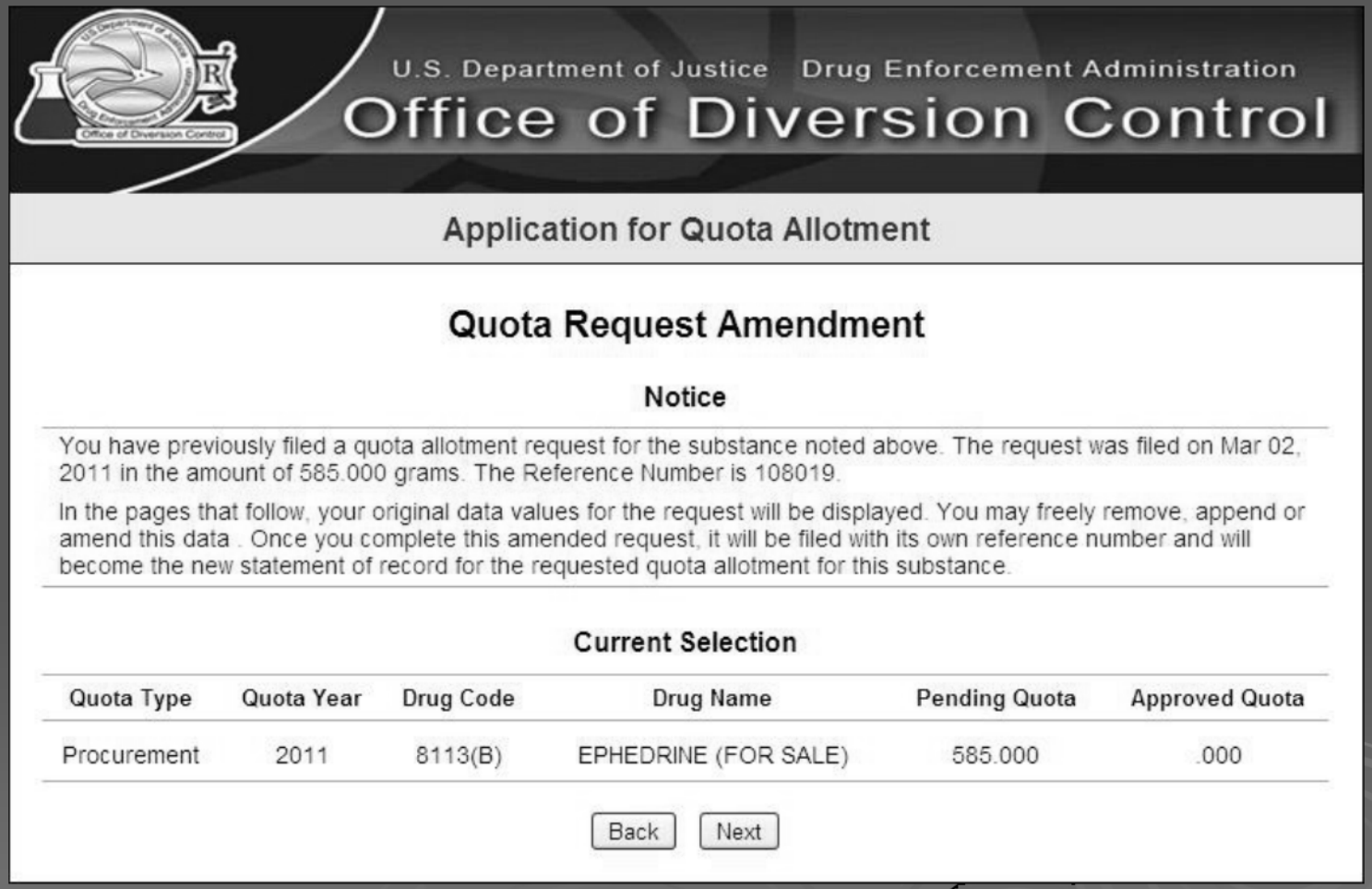
Requests may be amended by returning to the Main Selection Menu and selecting the substance from the list.

To view the request as a PDF report, click the Request ID link.

Quota Type	Quota Year	Date Submitted	Drug Code	Drug Name	Quota	Date Approved	Request ID
PRO	2011	Mar 2, 2011	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	Pending	108035
PRO	2011	Mar 30, 2011	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	Pending	108166
PRO	2011	Mar 4, 2011	1225	PHENYLPROPANOLAMINE (FOR SALE)	4,410.000	Pending	108076
PRO	2011	Mar 4, 2011	8112	PSEUDOEPHEDRINE (FOR CONVERSION)	5,545.000	Pending	108074

Back Print

Quota Amendments



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Quota Request Amendment

Notice

You have previously filed a quota allotment request for the substance noted above. The request was filed on Mar 02, 2011 in the amount of 585.000 grams. The Reference Number is 108019.

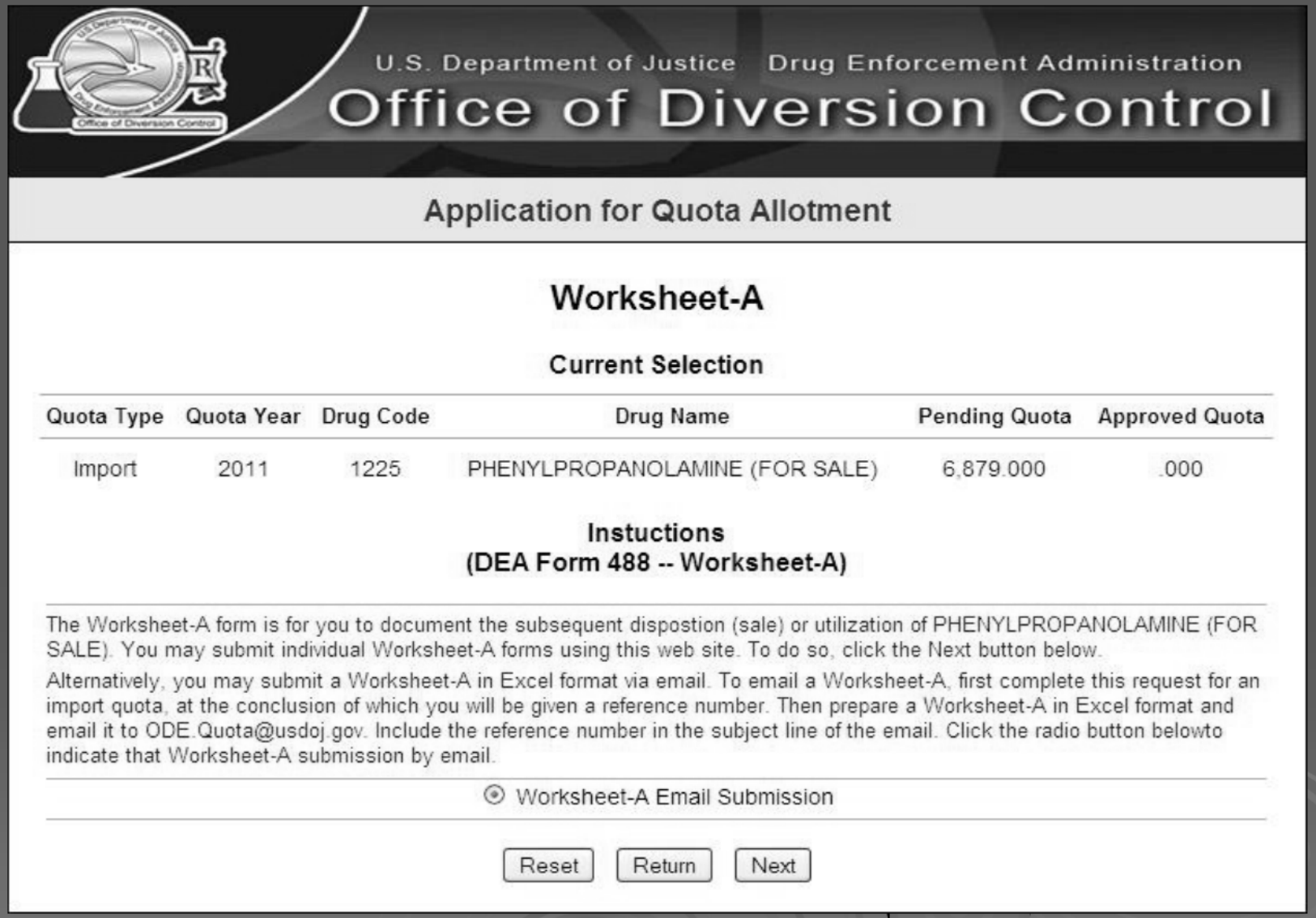
In the pages that follow, your original data values for the request will be displayed. You may freely remove, append or amend this data . Once you complete this amended request, it will be filed with its own reference number and will become the new statement of record for the requested quota allotment for this substance.

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	8113(B)	EPHEDRINE (FOR SALE)	585.000	.000

Back Next

List 1 Import quota


U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Worksheet-A

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Import	2011	1225	PHENYLPROPANOLAMINE (FOR SALE)	6,879.000	.000

Instuctions
(DEA Form 488 -- Worksheet-A)

The Worksheet-A form is for you to document the subsequent dispostion (sale) or utilization of PHENYLPROPANOLAMINE (FOR SALE). You may submit individual Worksheet-A forms using this web site. To do so, click the Next button below.

Alternatively, you may submit a Worksheet-A in Excel format via email. To email a Worksheet-A, first complete this request for an import quota, at the conclusion of which you will be given a reference number. Then prepare a Worksheet-A in Excel format and email it to ODE.Quota@usdoj.gov. Include the reference number in the subject line of the email. Click the radio button belowto indicate that Worksheet-A submission by email.

◉ Worksheet-A Email Submission

Reset Return Next

List 1 Import quota

Worksheet-A

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Import	2011	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)	12.000	.000

Worksheet-A Data
(DEA Form 488 -- Worksheet-A)

* DEA Number :
* Name of Comapany :
* Address :
* Phone :
* Fax :
* Email :
* Contact Person :
* Quantity to be sold (as grams of anhydrous base) :
* Provide documentation for Quantity to be sold (purchase orders, supply agreements, etc) :
* Intended Use : ○ Sale / Product Launch ○ Product Development / Research ○ Other (explain)

The * symbol denotes a required field. Number fields must be a valid number between 0 and 999,999,999.999 inclusive.

Fill in the fields above and click Submit.

Reset Submit

List 1 Import quota

Summary

○ Remove

DEA Num : ####
Company Name : dFGHFYT
Address : HFGGGYYJK,GYFJYYU CTGBD BGFSHDFJKSD
Phone : 256-515-4422
Fax : 121-142-4448
Email : NCBHXJH@GMAIL.COM
Contact : SHJAGYSG
Quantity to be sold : 5,226.000
Supporting docs : GJKEYU
Intended Use : Other
Intended Use Explain : FJDSIOUFRW

To remove an entry, click the Remove radio button.
To return to the Worksheet-A Selection Menu, click Return.

Next

Questions?

UN Reporting and Quota Section
ODEquota@dea.usdoj.gov
(202) 307-7184

-CITE-

21 USC Sec. 826 01/22/02

-EXPCITE-

TITLE 21 - FOOD AND DRUGS
CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL
SUBCHAPTER I - CONTROL AND ENFORCEMENT
Part C - Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

-HEAD-

Sec. 826. Production quotas for controlled substances

-STATUTE-

(a) Establishment of total annual needs
The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(b) Individual production quotas; revised quotas
The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a) of this section. The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

(c) Manufacturing quotas for registered manufacturers
On or before October 1 of each year, upon application therefore by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) Quotas for registrants who have not manufactured controlled substance during one or more preceding years
The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

(e) Quota increases
At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

(f) Incidental production exception
Notwithstanding any other provisions of this subchapter, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II as incidentally and necessarily result from the manufacturing process used for the manufacture of a controlled substance with respect to which its manufacturer is duly registered under this subchapter. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances.

-SOURCE-

(Pub. L. 91-513, title II, Sec. 306, Oct. 27, 1970, 84 Stat. 1257; Pub. L. 94-273, Sec. 3(16), Apr. 21, 1976, 90 Stat. 377.)

-REFTEXT-

REFERENCES IN TEXT

Schedules I and II, referred to in text, are set out in section 812(c) of this title.

-MISC2-

AMENDMENTS

1976 - Subsec. (c). Pub. L. 94-273 substituted "October" for "July".

EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, but with Attorney General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91-513, set out as a note under section 801 of this title.

-SECREF-

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 823, 824, 842 of this title.

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[CITE: 21USC826]

Section 826. Production Quotas for Controlled Substances

(a) Establishment of total annual needs

The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(b) Individual production quotas; revised quotas

The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a) of this section. The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

(c) Manufacturing quotas for registered manufacturers

On or before October 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the

manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) Quotas for registrants who have not manufactured controlled substance during one or more preceding years

The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance or ephedrine, pseudoephedrine, or phenylpropanolamine during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

(e) Quota increases

At any time during the year any registrant who has applied for or received a manufacturing quota for a basic class of controlled substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

(f) Incidental production exception

Notwithstanding any other provisions of this subchapter, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II or ephedrine, pseudoephedrine, or phenylpropanolamine as incidentally and necessarily result from the manufacturing process used for the manufacture of a controlled substance or of ephedrine, pseudoephedrine, or phenylpropanolamine with respect to which its manufacturer is duly registered under this subchapter. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances or chemicals.

(g) Reference to ephedrine, pseudoephedrine, or phenylpropanolamine

Each reference in this section to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(Pub. L. 91-513, title II, Sec. 306, Oct. 27, 1970, 84 Stat. 1257; Pub. L. 94-273, Sec. 3(16), Apr. 21, 1976, 90 Stat. 377; Pub. L. 109-177, title VII, Sec. 713, Mar. 9, 2006, 120 Stat. 264.)

References in Text

Schedules I and II, referred to in text, are set out in section 812(c) of this title.

Amendments

2006--Subsec. (a). Pub. L. 109-177, Sec. 713(1), inserted "and for ephedrine, pseudoephedrine, and phenylpropanolamine" after "for each basic class of controlled substance in schedules I and II".

Subsec. (b). Pub. L. 109-177, Sec. 713(2), inserted "or for ephedrine, pseudoephedrine, or phenylpropanolamine" after "for each basic class of controlled substance in schedule I or II".

Subsec. (c). Pub. L. 109-177, Sec. 713(3), inserted "and for ephedrine, pseudoephedrine, and phenylpropanolamine" after "for the basic classes of controlled substances in schedules I and II".

Subsec. (d). Pub. L. 109-177, Sec. 713(4), inserted "or ephedrine, pseudoephedrine, or phenylpropanolamine" after "that basic class of controlled substance".

Subsec. (e). Pub. L. 109-177, Sec. 713(5), inserted "or for ephedrine, pseudoephedrine, or phenylpropanolamine" after "for a basic class of controlled substance in schedule I or II".

Subsec. (f). Pub. L. 109-177, Sec. 713(6), inserted "or ephedrine, pseudoephedrine, or phenylpropanolamine" after "controlled substances in schedules I and II", "or of ephedrine, pseudoephedrine, or phenylpropanolamine" after "the manufacture of a controlled substance", and "or chemicals" after "such incidentally produced substances".

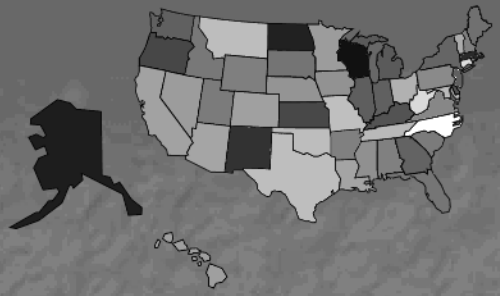
Subsec. (g). Pub. L. 109-177, Sec. 713(7), added subsec. (g). 1976--Subsec. (c). Pub. L. 94-273 substituted "October" for "July".

Effective Date

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, but with Attorney General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91-513, set out as a note under section 801 of this title.

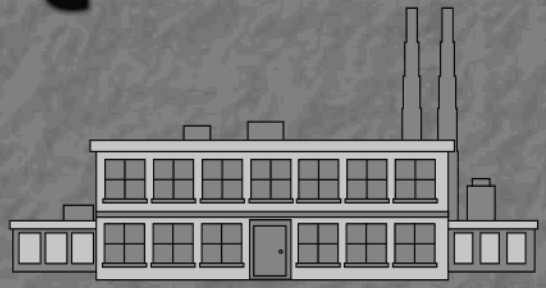
Coordination With United States Trade Representative

Pub. L. 109-177, title VII, Sec. 718, Mar. 9, 2006, 120 Stat. 267, provided that: "In implementing sections 713 through 717 and section 721 of this title [amending this section and sections 830, 842, 952, 960, and 971 of this title], the Attorney General shall consult with the United States Trade Representative to ensure implementation complies with all applicable international treaties and obligations of the United States."





QUOTAS



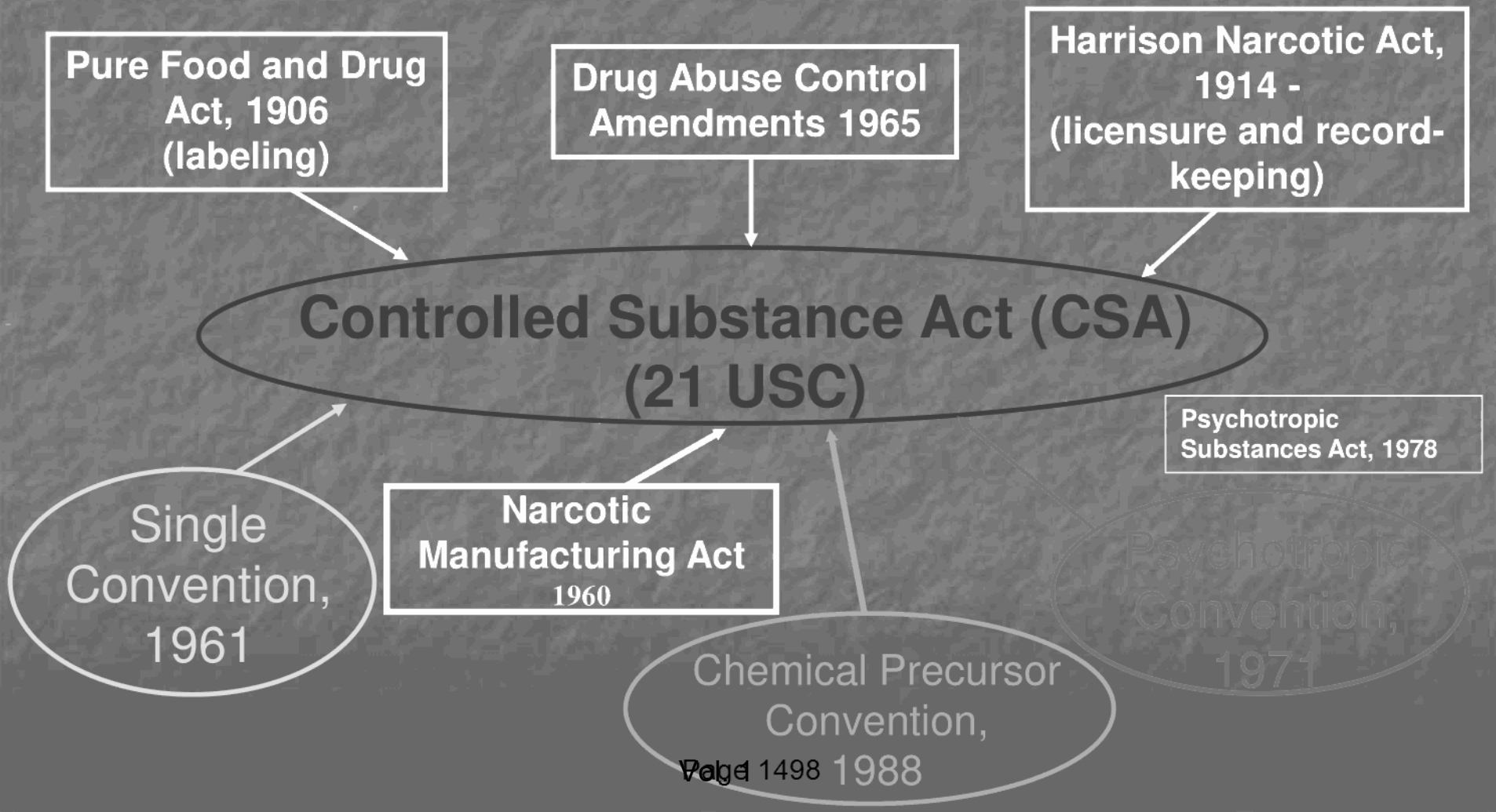
Drug Enforcement Administration

Office of Diversion Control

UN Reporting and Quota Section

Pharmaceutical Training Seminars

CSA - Historical Perspective:



Levels of Drug Control

- Schedule I (CI) – NEED QUOTA (MFG)
  - Substances with high abuse potential and no medical utility (most restrictive)
- Schedule II (CII)- NEED QUOTA (MFG)
  - Substances with high abuse potential and medical utility
- Schedule III, IV and V (CIII, CIV, CV)–
  - Substances with medical utility in the U.S. and high (CIII) to progressively lower levels of abuse potential, dependence profile and regulatory controls
- Ephed, Pseudo & PPA (List 1)- NEED QUOTA (MFG/IMPORT)
  Substances used for manufacture of cough & cold medicines and vet products. Can also be used for illicit manufacture of methamphetamine & amphetamine

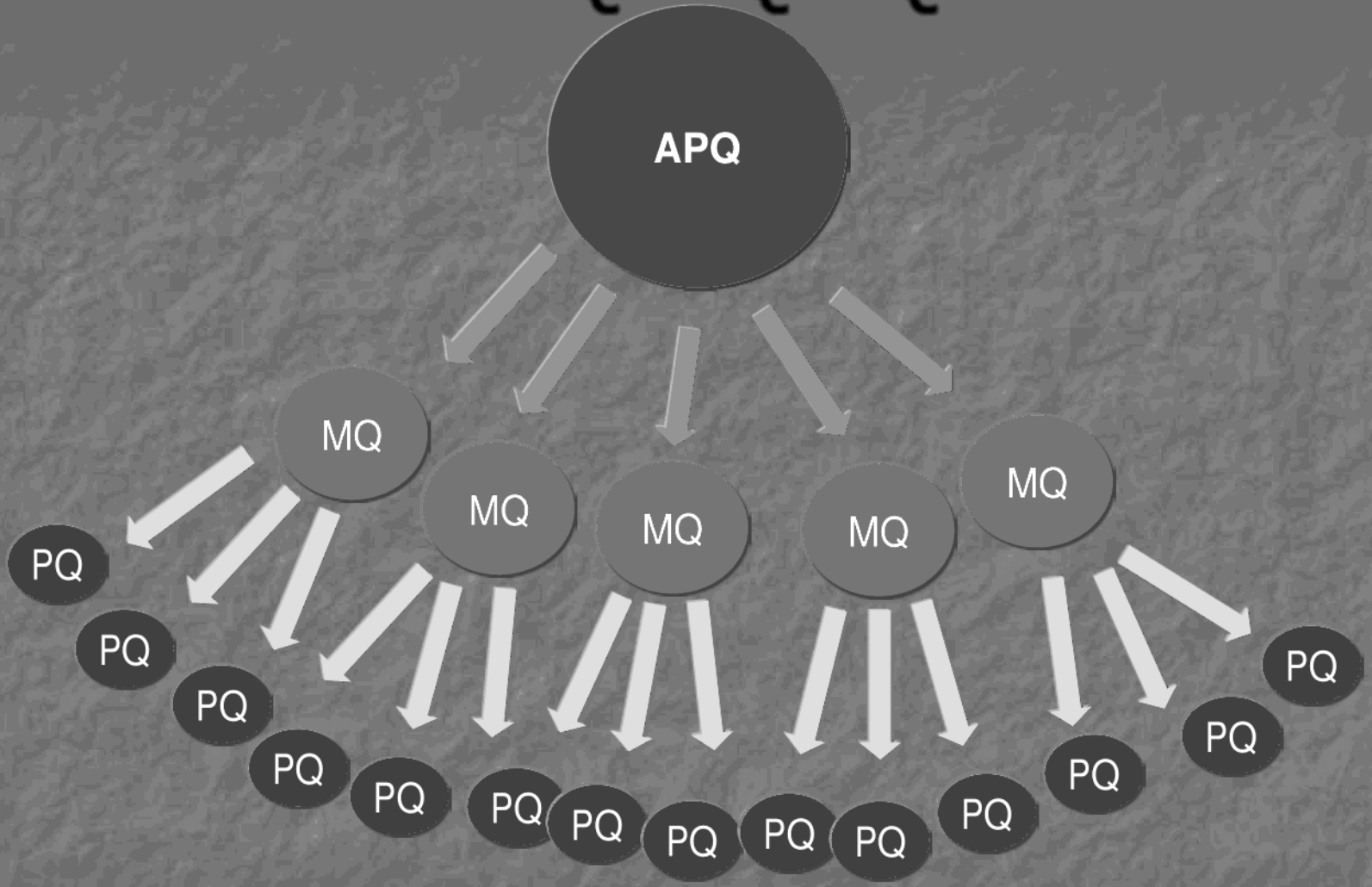
Purpose of Quotas

- Provide for legitimate need of Schedule I and II controlled substances and three list 1 chemicals (E, PE, and PPA)
- Restrict the manufacture and procurement to those manufacturers registered by DEA
- Limit the quantity of drugs in Schedule I and II, and three list 1 chemicals (E, PE, PPA) which may be manufactured or produced in U.S.
- Provide adequate inventories

Quota Requirements Schedule I and II Controlled Substances

- Aggregate Production Quotas (21 CFR 1303.11 and 1303.13)
- Individual Manufacturing Quotas (21 CFR 1303.21 through 1303.27)
- Procurement Quotas (21 CFR 1303.12)

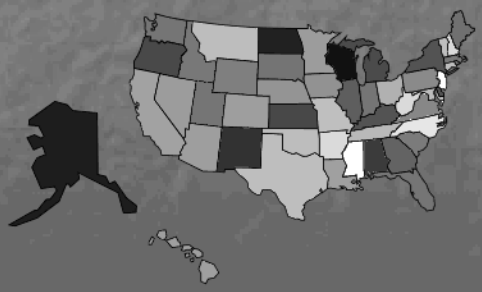
APQ-MQ-PQ



*Packaging/Labeling are not counted against the APQ/AAN

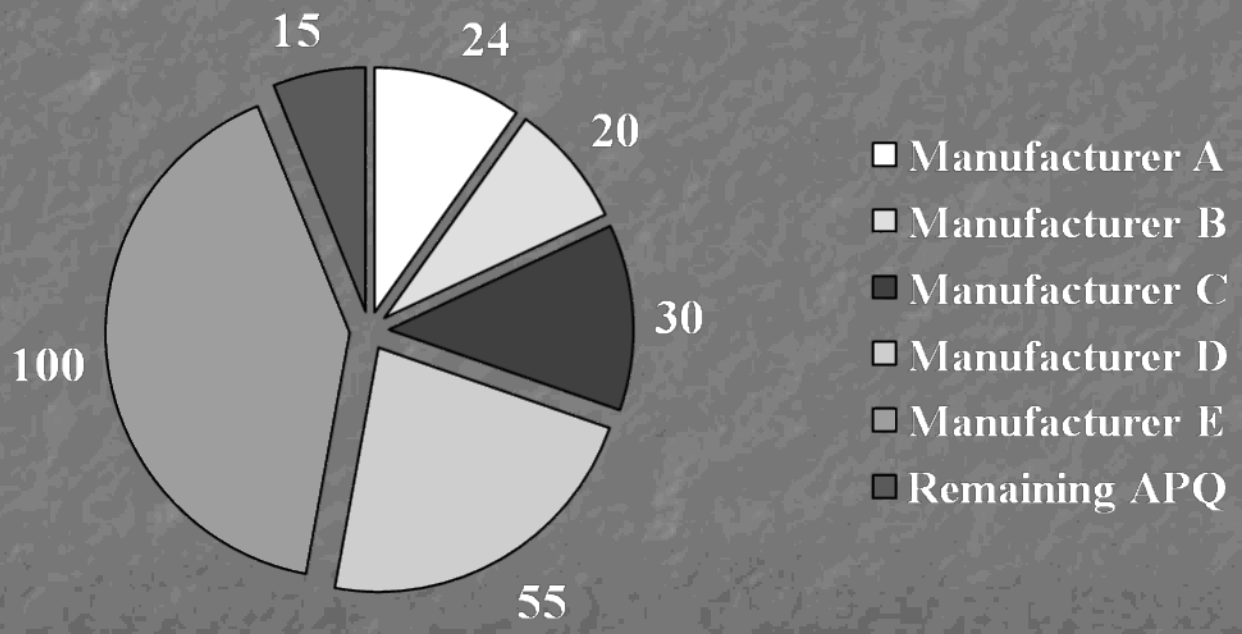
Aggregate Production Quotas

- Upper limit of national production
- Established annually with one revision
- Federal Register notices required
- Schedules I and II controlled substances (basic classes)

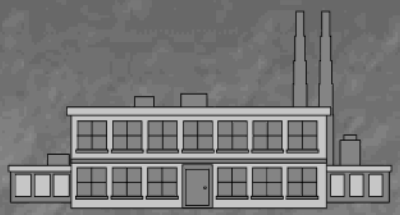


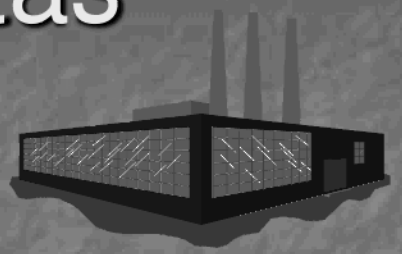
Relationship Between Aggregate and Manufacturing Quotas

APQ = 244 kg



Manufacturing Quotas

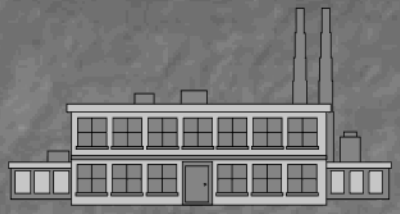


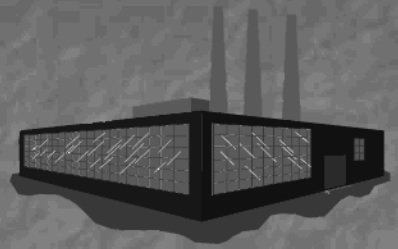


Bulk manufacturers of Schedules I and II controlled substances whose methods include:

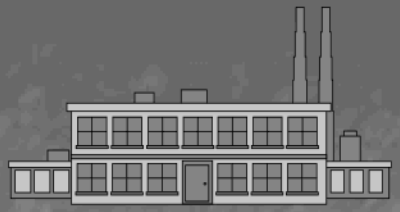
- Extraction from plant material i.e. coca leaf, opium, poppy straw concentrate
- Synthetic routes i.e.
  - hydrocodone from codeine
  - Controlled from non-controlled substance/chemical

Manufacturing Quotas

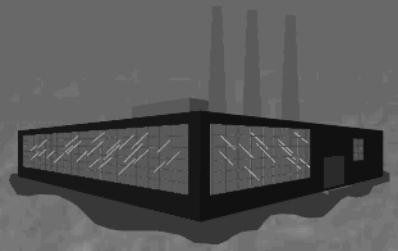




- Establish maximum amount which may be manufactured in a calendar year
- DEA registered bulk manufacturers cannot exceed manufacturing quota
- Establish guidelines for inventory allowances

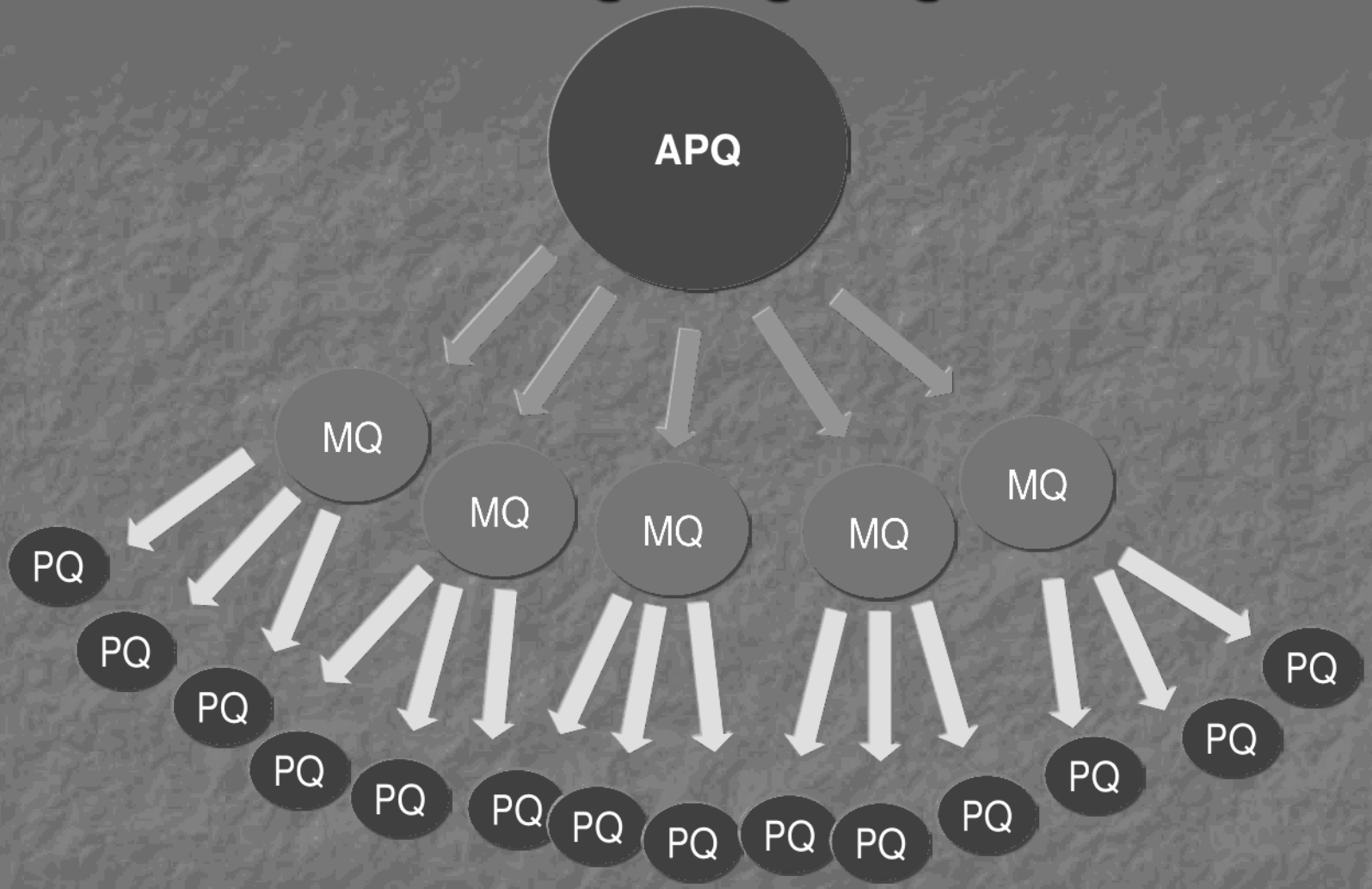


Manufacturing Quota Inventory Allowance



- 21 CFR 1303.24
- 50% of average net disposals for current and preceding year for current manufacturers
- 50% of reasonably estimated net disposal for current year for new manufacturers
- During calendar year may not exceed 65% of estimated net disposal
- Exceeding 65% will suspend quota until inventory is less than 60% of net disposals

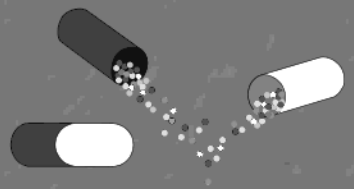
APQ-MQ-PQ



*Packaging/Labeling are not counted against the APQ/AAN

Procurement Quotas

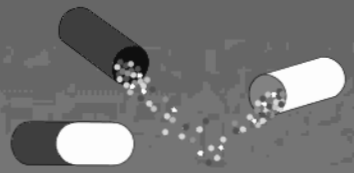
- Manufacturers who procure a Schedule I or II controlled substance, or List 1 chemical for the purposes of:
  - Converting bulk API into finished dosage forms
  - Formulating products such as
    - FDA approved pharmaceuticals
    - Exempt chemical preparations
    - Reference standards
  - Packaging, repackaging, labeling or re-labeling a commercial container or dosage form



PQ always received for these activities

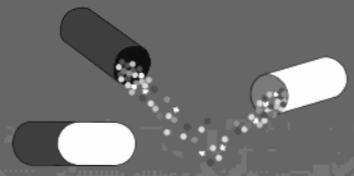
Procurement Quotas





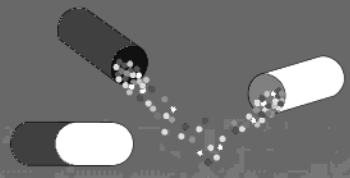
- DEA registered manufacturers
- Establishes maximum amount which may be acquired in a calendar year
- Certification of adequate quota needed to place order (21 CFR 1303.12(f))
- Cannot exceed procurement quota
- Sum of procurement quotas determines amount of bulk material to be produced

Procurement Quota Frequently Asked Questions



- Registration number changed
  - New Quota is needed to receive inventory of old registration
  - New Quota is needed to continue activity under new registration
  - Must submit new quota applications online once all necessary drug codes have been added to registration
  - QUOTA DOES NOT TRANSFER

Procurement Quota Frequently Asked Questions

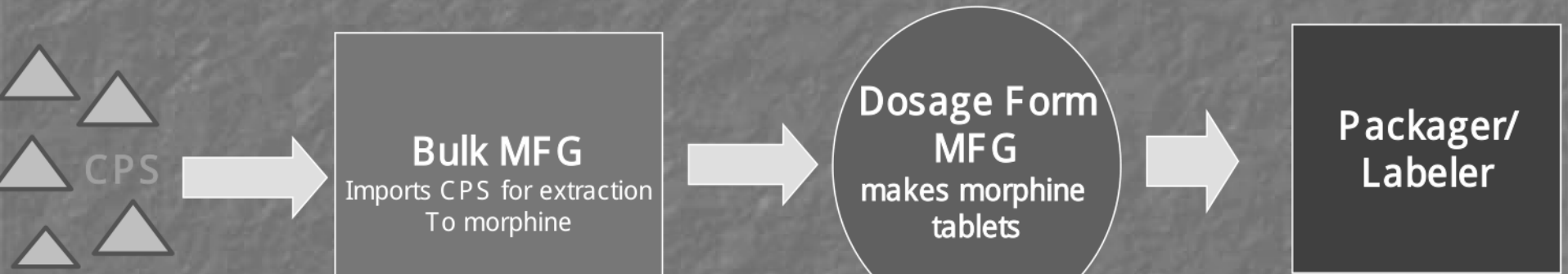


- Analytical exempted Standards
  - No quota is needed as per 21 CFR 1303.12(e)(2).
- Research
  - No quota needed for research registration per 21 CFR 1303.12(e)(3)
  - Be aware of what is considered research versus manufacturing

Who Needs Quota? Following a Product From Start To Finish

- A Bulk manufacturer imports poppy straw for morphine extraction. They sell the extracted morphine to company “A” which converts the bulk morphine into beads and encapsulates them.
- Company “ A” sends the finished morphine capsules to their bottling and labeling company “B.”
- Company “B” bottles and labels the finished dosage units and sends them to a distributing company.

Who need Quotas - Poppy Straw to Packager



- PQ to receive imported CPS
- MQ to extract morphine

- PQ to procure morphine & mfg tablets

- PQ to receive tablets

CPS = Concentrated Poppy Straw
MFG = Manufacturer
PQ = Procurement Quota
MQ = Manufacturing Quota

Who Needs Quota Answers:

- Bulk manufacturer
  - Procurement quota (CPS) is required to transfer the imported material to their manufacturing registration.
  - Manufacturing Quota (morphine) is required to extract morphine from the poppy straw.
- Company A – dosage form manufacturer
  - Procurement Quota (morphine) is required to procure bulk morphine for dosage form manufacturing.
- Company B – relabeler/repackager manufacturer
  - Procurement Quota (morphine) is required to acquire the finished dosage units for packaging and product labeling.

Combat Methamphetamine Epidemic Act 2005 (CMEA)

Enacted on March 9, 2006

Pseudoephedrine, Ephedrine, and Phenylpropanolamine

- Additional legislative and regulatory controls on the manufacture, distribution, importation, and exportation of these List 1 chemicals
- Registration now required for each physical location (manufacturer, distributor, importer or exporter)

Quota Provisions of CMEA

- Interim Final Rule - July 10, 2007 (71 FR 56008)
- Bulk manufacturers who synthesize EPH, PSE and PPA must obtain a manufacturing quota (DEA-189).
- Manufacturers who purchase EPH, PSE and PPA must obtain a procurement quota (DEA-250).
  - Dosage form manufacturers, packagers, labelers, repackagers and relabelers
- Importers who import EPH, PSE and PPA (or products containing EPH, PSE, and PPA) must obtain an import quota (DEA-488).

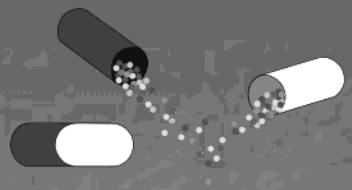
CMEA Quota Requirements

Pursuant to 21 CFR Part 1315

- Assessment of Annual Needs
  (21 CFR 1315.11 and 1315.13)
- Individual Manufacturing Quotas
  (21 CFR 1315.21 through 1315.27)
- Procurement Quotas
  (21 CFR 1315.30 and 1315.32)
- Import Quotas
  (21 CFR 1315.34 and 1315.36)



Import Quotas



- DEA registered importer
- Only applies to E, PE, PPA
- Established maximum amount which may be imported in a calendar year
- Quota adjustments may be requested at any time during the calendar year

Relationship Between Assessment of Annual Needs and Quotas



AAN = 164 kg

Frequently Asked List I Quota Questions

Can a DEA registered analytical lab import List I chemicals as a coincidental activity?

- **No.** Only DEA registered importers may import List I chemicals. Analytical labs may import *controlled substances* as a coincident activity only.

Frequently Asked List I Quota Questions
(Cont)

Does a manufacturer who consumes all of a list I chemical internally qualify as an "end user"?

- No. All DEA registered manufacturers who procure List I chemicals for a manufacturing activity must have quota, including those who do not distribute these list I chemicals.
- The absence of this information would prevent DEA from considering all relevant information required by law when establishing the assessment of annual needs.

Frequently Asked List I Quota Questions (Cont)

Can an importer of list I chemicals accept returns?

- No. Returns to an Importer are not allowed under the current statute and regulations. However, if the material is “not usable” and returned to the importer then this will be allowable as an “incomplete transaction”

Frequently Asked List I Quota Questions (Cont)

I am an importer and have a new customer can I supply the List I chemical to them?

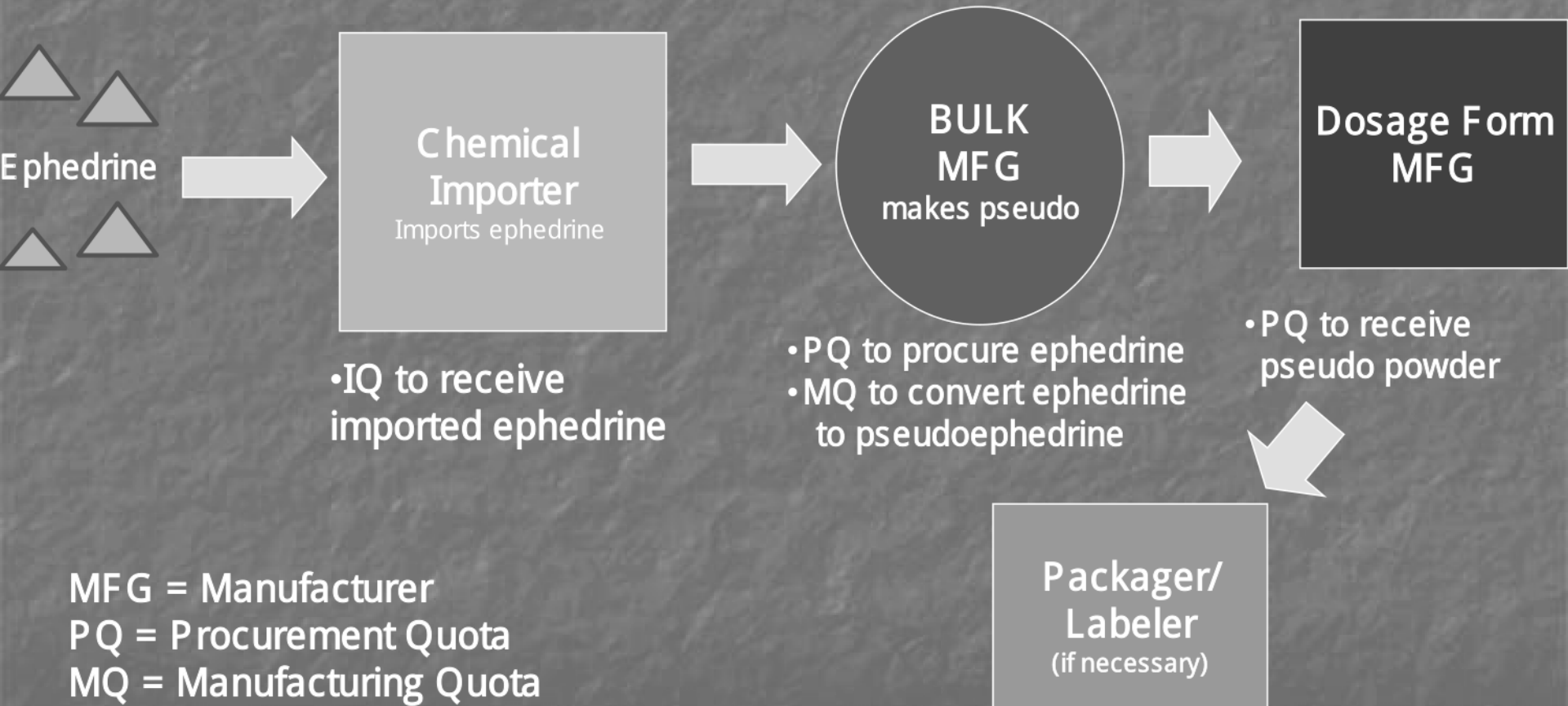
- You may import to the extent of your firms import quota and may supply API to your customers who can supply certification that they have quota to receive this material. You may request an adjustment to your firm's import quota at anytime.

Page 1524

Who Needs Quota? Following a Product From Start To Finish

- A Bulk manufacturer imports bulk ephedrine for conversion into pseudoephedrine. They sell the pseudoephedrine to Company “A” which converts the bulk pseudoephedrine into dosage forms.

Who need Quotas - import ephedrine to pseudo



MFG = Manufacturer
PQ = Procurement Quota
MQ = Manufacturing Quota

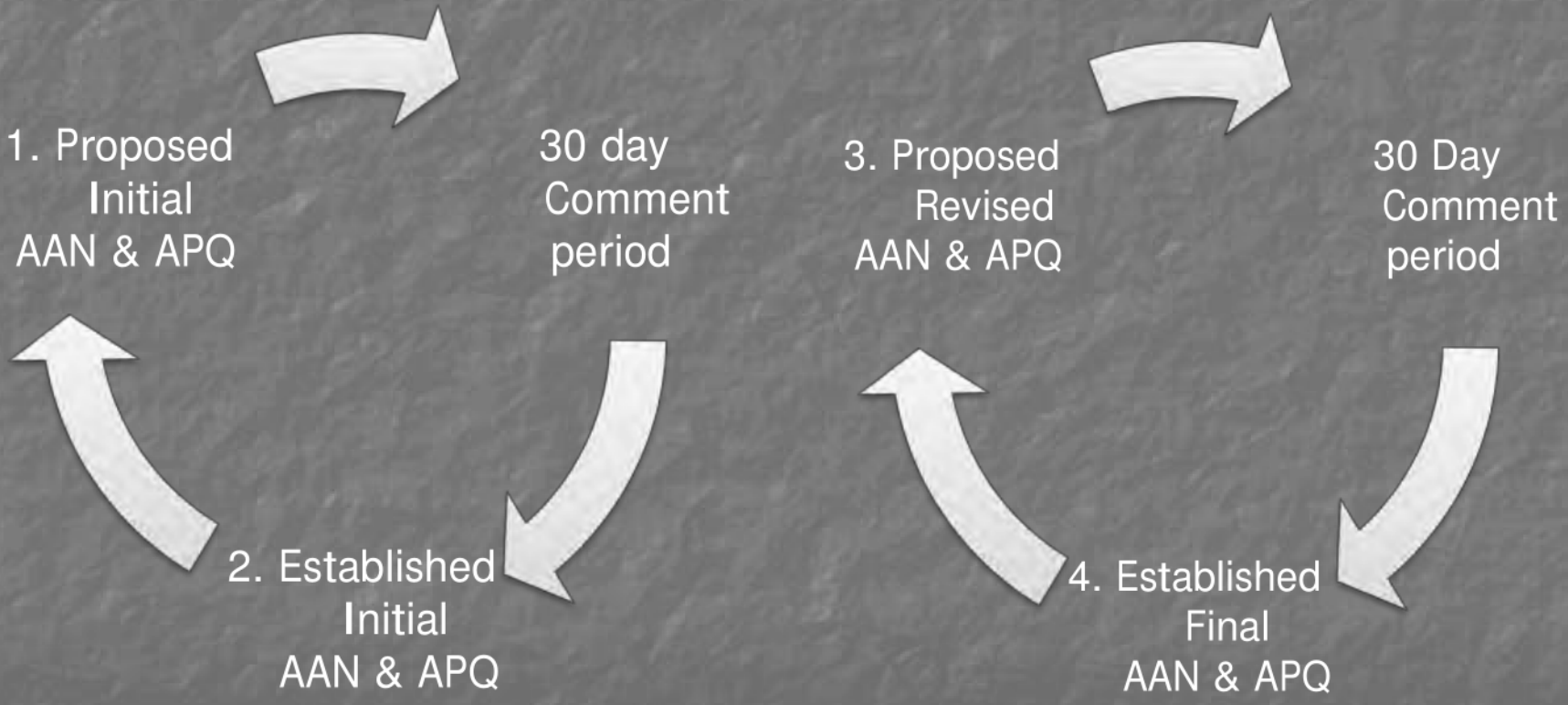
Who Needs Quota Answers:

- Importer
  - Import quota (ephedrine) is required to import the ephedrine into the U.S. under an importer registration.
- Bulk manufacturer
  - Procurement quota (ephedrine) is required to transfer the ephedrine from their importer registration to their manufacturing registration.
  - Manufacturing Quota (pseudoephedrine) is required to manufacture pseudoephedrine from the ephedrine.

Who Needs Quota Answers:
(cont)

- Company A – dosage form manufacturer
  - Procurement Quota (pseudoephedrine) is required to procure bulk pseudoephedrine for dosage form manufacturing
- Company B – repackager / relabeler
  - Procurement Quota (pseudoephedrine) is required to procure bulk dosage form for packaging/ labeling activities

Federal Registers Cycle



Overview of Procedure for Setting the Aggregate Production Quota

- To develop the APQ for the United States, DEA considers:
  - Applications for manufacturing and procurement quotas from DEA registered manufacturers
  - FDA Estimates
  - Other Considerations



Data Used to Establish Quotas: Company Data Includes

- Inventory
- Dispositions
- Acquisitions
- Other factors such as yields, product development needs, etc.



Data Used to Establish Quotas: FDA Information Includes

- New, discontinued, and recalled drug products
- New indications for previously approved dosage forms
- New dosage forms

Other Considerations



- Abuse Data
- Consumption Data
- Trafficking Data
- Investigational Studies
- Diversion Data



Overview of Procedure for Setting the Assessment of Annual Needs

- To develop the assessment of annual needs for the United States, DEA considers:
  - Applications for import, manufacturing and procurement quotas from DEA registered manufacturers and importers.
  - FDA Information
  - Trends in the national rate of disposals (sales/utilization).
  - Actual and estimated inventories.
  - Projected demand for the list I chemicals PE, E, PPA
  - Other factors

Quota Types Summary

PROCUREMENT

- DEA Form 250
- Dosage form manufacturers
- Packagers
- Labelers
- Repackager
- Relabelers

MANUFACTURING

- DEA Form189
- Bulk Manufacturers

IMPORT

- DEA 488 & Form A
- Importers of List I chemicals

Contact

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Drug Enforcement Administration

Year-End Reporting and Quota Management System

Quotas
User Manual

Version 1.1
April 11, 2011



Office of Diversion Control
Diversion Technology Section

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1.0 Introduction

The Drug Enforcement Administration (DEA) is the US competent body charged with the management of controlled substances and chemicals for scientific, medical, and industrial applications while preventing diversion of these same substances and chemicals. To manage this complex system, DEA requires that manufacturers of Schedule I and II controlled substances and the importers and manufacturers of ephedrine, pseudoephedrine, and phenylpropanolamine (CMEA List I chemicals) apply for quotas to control the quantity of material produced or procured per calendar year for US requirements. These individual import and procurement requests are aggregated to determine bulk manufacturer requirements, aggregate production quotas (APQ), annual assessment of needs (AAN), and generate reports to the United Nations regarding the consumption and manufacturing of Schedule I and II controlled substances and CMEA List I chemicals.

These specific individual importers and manufacturers apply for yearly importation and manufacturing quota allowances based on historical sales data and forecasted trends in their market. This information is transmitted to DEA through quota application forms DEA 189, DEA 250, and DEA 488. The individual manufacturing quota form - DEA 189 is for use by individual manufacturers that extract or synthesize a schedule I or II substance from plant material or other controlled substances. The procurement quota form - DEA 250 is required for dosage form manufacturers, compound pharmacies, labelers/relabelers, and packagers/repackagers. The importation form - DEA 488 is for use by the CMEA List I chemical importers.

1.1 Login



Figure 1: Login

Enter the following:

- **DEA Number**: the unique identifying number issued to each registrant upon enrolling with the DEA.
- **Username**: the user account name, provided by ODE.
- **Password**: the unique identifying set of characters comprised of alphanumerical and special characters used to access an account, initially provided by ODE.

To clear the fields, click the Reset button.

Click the Next button on this page to proceed to the Login Confirmation screen. An error will be displayed if any of the entered information is incorrect.

On the Login Confirmation screen, click the Next button to continue. The Back button will return users to the Login screen.

1.2 Changing the Password

To change the current password, check the **Change Password** checkbox on the Login screen before clicking the Next button.



Figure 2: Change Password

New passwords must be between 4 – 10 characters in length and contain at least one of the following:

- One (1) uppercase letter
- One (1) lowercase letter
- One (1) number

Enter the current password into the field provided. The new password must be entered twice to ensure accuracy.

When the fields have been filled, click the Next button. Quotas passwords will not expire.

2.0 Quota Application

2.1 Manufacturers and Types of Quota

Manufacturers can apply for three (3) different types of quota. The table below specifies the distinction between manufacturers, quotas, and controlled substances/CMEA List I chemicals.

Type of Account	Type of Quota	Substance/Chemical
Manufacturer	Procurement	Substance
Bulk Manufacturer	Procurement, Manufacturer	Substance
Chemical Manufacturer	Procurement, Manufacturer	Chemical
List I Chemical Importer	Import	Chemical

2.2 Quota Application

After confirming the account login, Quotas will load the Main Selection Menu. An initial quota may be requested or an already submitted quota request may be amended.

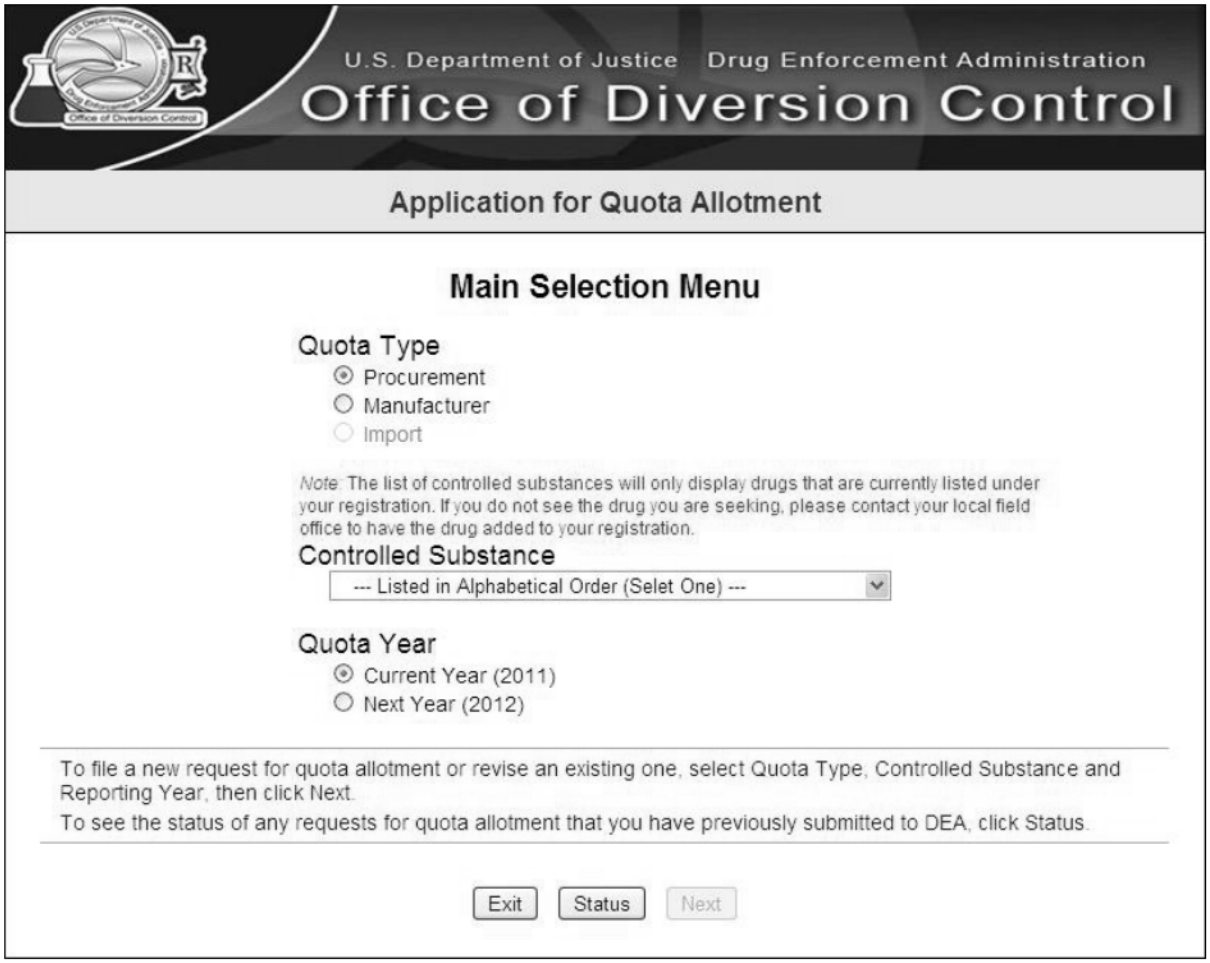


Figure 3: Main Selection Menu

The following information must be selected before the application process may continue.

- **Quota Type**: the type of quota being requested.
- **Controlled Substance**: the controlled substance for which a quota is being requested. List I chemical manufacturers and importers will only see the chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. No substance or chemical will be listed in the drop-down menu if it hasn't first been registered to the requesting manufacturer.
- **Quota Year**: the year during which the quota will be applied.

After all selections have been made, click the Next button. Following this page, the current or future year-end inventory, acquisitions, and dispositions are estimated and the quota amount is requested.

Note that the following screen will only be displayed if a request for the selected substance or chemical has already been submitted.

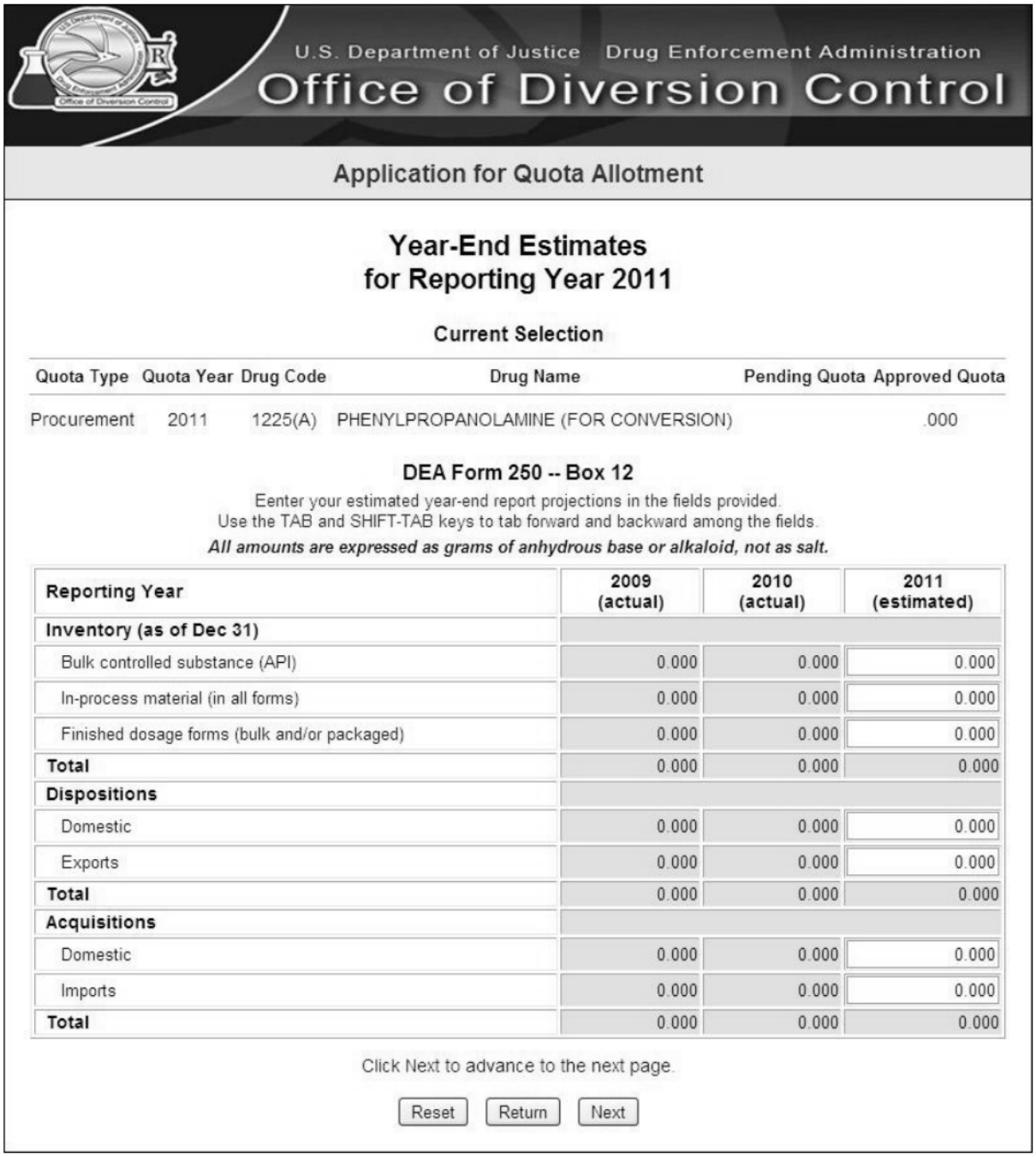


Figure 4: Quota Amendment Notice

Click the Next button to proceed to the Year-End Estimates screen.

Note that the fields, as displayed on the following page, will already contain values if this is an amendment to an already submitted quota.

Enter the estimated amounts of the controlled substance or listed chemical expected to be held in inventory, disposed/sold to other entities, and acquired from other entities by the end of the selected year (Figure 5, next page). At least one field must contain a value other than zero (0) before the quota application process may proceed.



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Year-End Estimates for Reporting Year 2011

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225(A)	PHENYLPROPANOLAMINE (FOR CONVERSION)		.000

DEA Form 250 -- Box 12

Eenter your estimated year-end report projections in the fields provided.
Use the TAB and SHIFT-TAB keys to tab forward and backward among the fields.

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.

Reporting Year	2009 (actual)	2010 (actual)	2011 (estimated)
Inventory (as of Dec 31)			
Bulk controlled substance (API)	0.000	0.000	0.000
In-process material (in all forms)	0.000	0.000	0.000
Finished dosage forms (bulk and/or packaged)	0.000	0.000	0.000
Total	0.000	0.000	0.000
Dispositions			
Domestic	0.000	0.000	0.000
Exports	0.000	0.000	0.000
Total	0.000	0.000	0.000
Acquisitions			
Domestic	0.000	0.000	0.000
Imports	0.000	0.000	0.000
Total	0.000	0.000	0.000

Click Next to advance to the next page.

Reset Return Next

Figure 5: Year-End Estimates

All entered values must be expressed as grams of anhydrous base or alkaloid, not as salt.

- **Bulk controlled substance (API [Active Pharmaceutical Ingredient])**: the measure of bulk (non-packaged) substances or chemicals held in inventory.
- **In-process material (in all forms)**: the measure of substances or chemicals in process for conversion.
- **Finished dosage forms (bulk and/or packaged)**: the measure of substances or chemicals to have completed processing.

- **Domestic**: the measure of substances or chemicals to have either been disposed or acquired within the United States.
- **Exports/Imports**: the measure of substances or chemicals to have either been disposed or acquired internationally.

*Note that a fourth column will be displayed if the **Next Year** option is selected on the Main Selection Menu screen (see* Figure 3). *The current year column will be unavailable for editing.*

Click the Next button to proceed to the **Quota Request** screen.

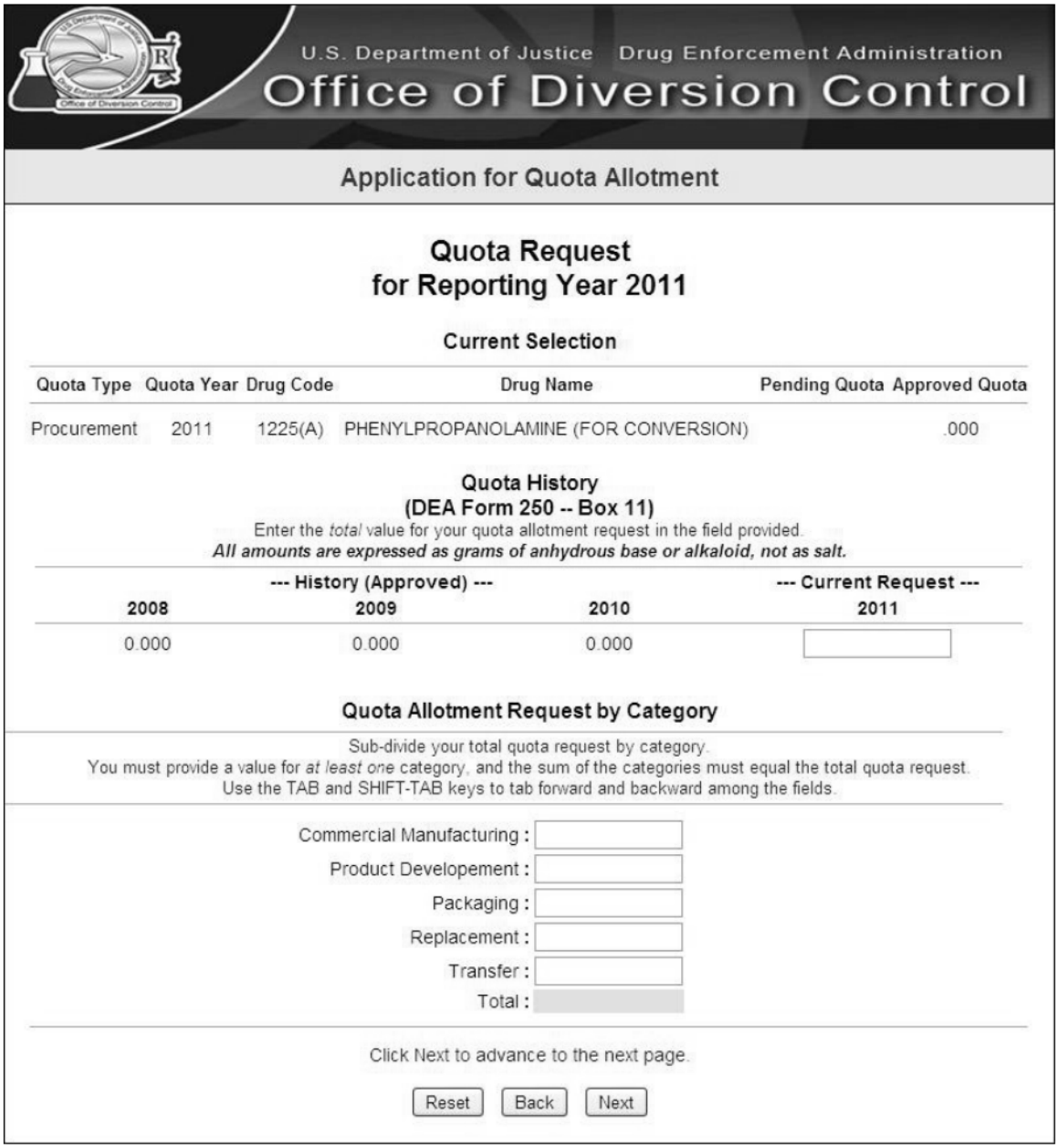


Figure 6: Quota Request

Sub-divide the total quota request by category. If quota will not be used toward a category, enter zero (0) into the relevant field. Click the Reset button to clear the fields.

The total value of the sub-category quota requests must equal the value entered in the Current Request field.

List I chemical importers will see the **Product Type** section rather than the **Quota Allotment Request by Category** section. In that case, select the type of List I chemical product being imported.

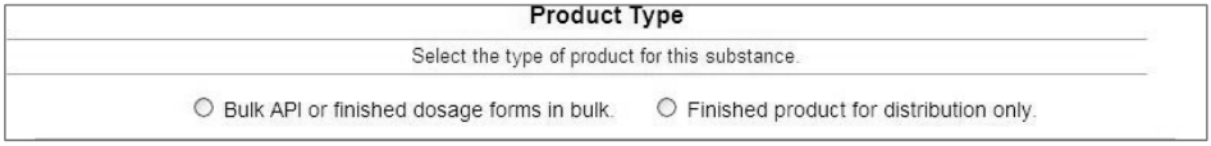


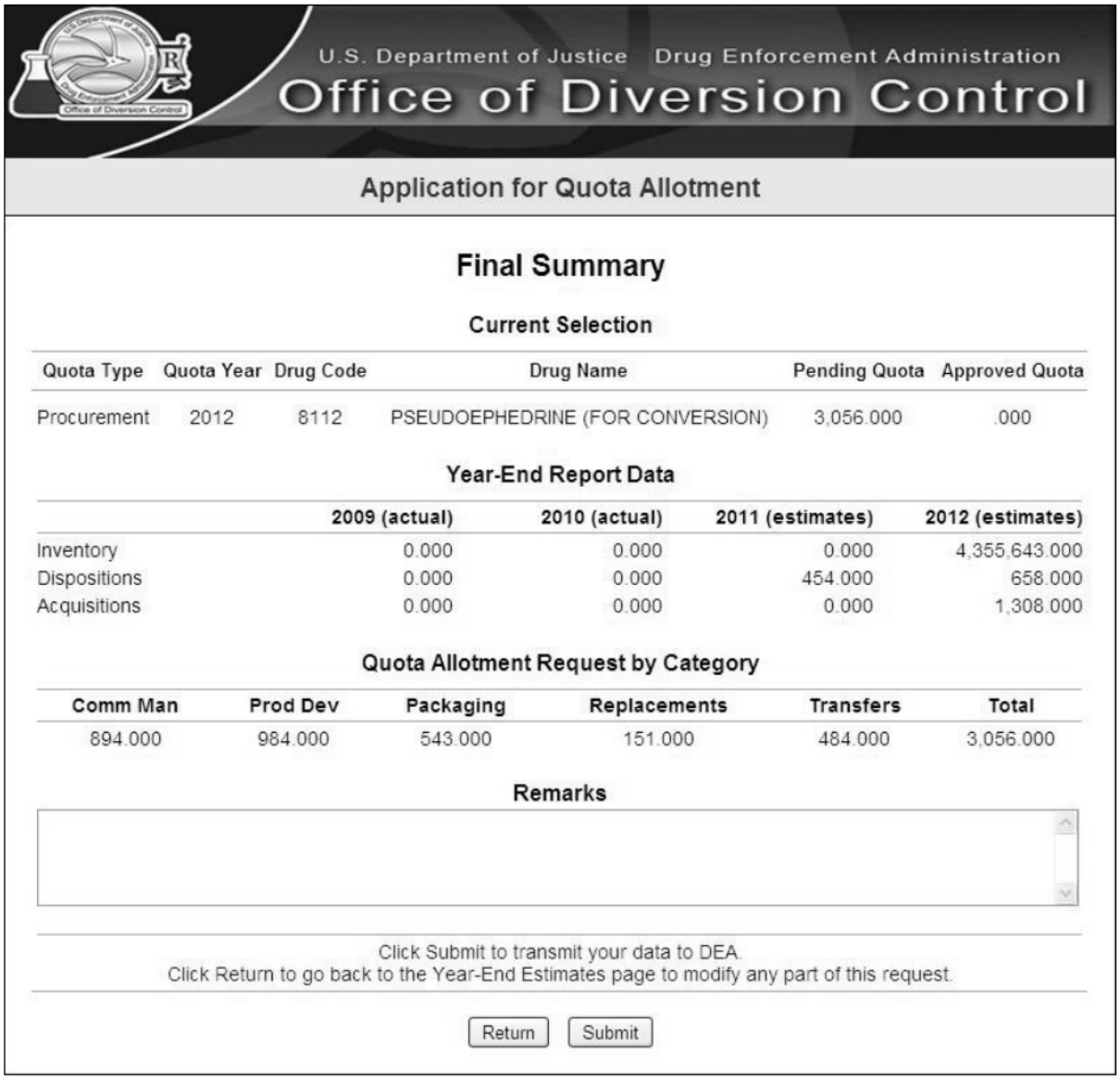
Figure 7: Import Product Type

After the desired fields have been filled and selection been made, click the Next button. The **Report Selection Menu** will be displayed.



Figure 8: Report Selection Menu

Refer to section 3.0 Quota Sub-Category Forms for information about the Quota sub-category forms. When finished, click the Next button.


U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control

Application for Quota Allotment

Final Summary

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2012	8112	PSEUDOEPHEDRINE (FOR CONVERSION)	3,056.000	.000

Year-End Report Data

	2009 (actual)	2010 (actual)	2011 (estimates)	2012 (estimates)
Inventory	0.000	0.000	0.000	4,355,643.000
Dispositions	0.000	0.000	454.000	658.000
Acquisitions	0.000	0.000	0.000	1,308.000

Quota Allotment Request by Category

Comm Man	Prod Dev	Packaging	Replacements	Transfers	Total
894.000	984.000	543.000	151.000	484.000	3,056.000

Remarks

Click Submit to transmit your data to DEA.
Click Return to go back to the Year-End Estimates page to modify any part of this request.

Return Submit

Figure 9: Final Summary

Review the summary of the quota request. Any additional remarks should be placed in the **Remarks** field.

If a mistake was made, click the Return button to return to the **Main Selection Menu**.

Click the Submit button to complete the Quota request. A reference number will be assigned to the quota request (Figure 10, following page). Reference this number in any emails to ODQ concerning this quota request.

A PDF copy of the Quota request application may be saved to a local computer for printing. Click the Print button to create the PDF copy.



Figure 10: Summary Confirmation

2.3 Check Application Status

To check the current status of a pending quota application, click the Status button from the **Main Selection Menu**.

The following information is available (Figure 11, subsequent page):

- **Quota Type**: the type of quota for which the application has been submitted (procurement, manufacturer, import).
- **Quota Year**: they year for which the quota will be applied.
- **Date Submitted**: the date on which the request was submitted.
- **Drug Code**: the code given to the controlled substance or listed chemical for which a quota was requested.
- **Drug Name**: the name of the controlled substance or listed chemical for which a quota was requested.
- **Quota**: the quota amount requested for the applicable year.



Figure 11: Quota Request Status

- **Date Approved**: the date on which the quota request was approved. Pending indicates that the request is still awaiting final determination by ODQ. Note: Approval date does **not** indicate the quota amount requested is the amount granted. DEA will still send a letter (by email and post) indicating the amount of quota granted for the request.
- **Request ID**: every quota request is assigned a unique six (6)-digit number. This number should be referenced with inquiries concerning the quota request. Click on the Request ID to display and/or print the details of that specific request.

Clicking the Print button will create a PDF copy of the status page information suitable for printing.

To return to the **Main Selection Menu**, click the Back button.

3.0 Quota Sub-Category Forms

3.1 Commercial Manufacturing (Converted Substances)

The **Converted Substances** sub-category form is only available for substances and List I chemicals specifically marked for conversion. Filing the **Converted Substances** sub-category form is an optional activity for every type of manufacturer.

Select a drug from the drop down menu (Figure 12, next page).

Any selections will be added to the **Basic Class to be Manufactured** table. If User Choice is selected, the name of the drug must be manually entered into the **Drug Name** column.

Fill in the estimated year and percentage yield fields and click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 8).

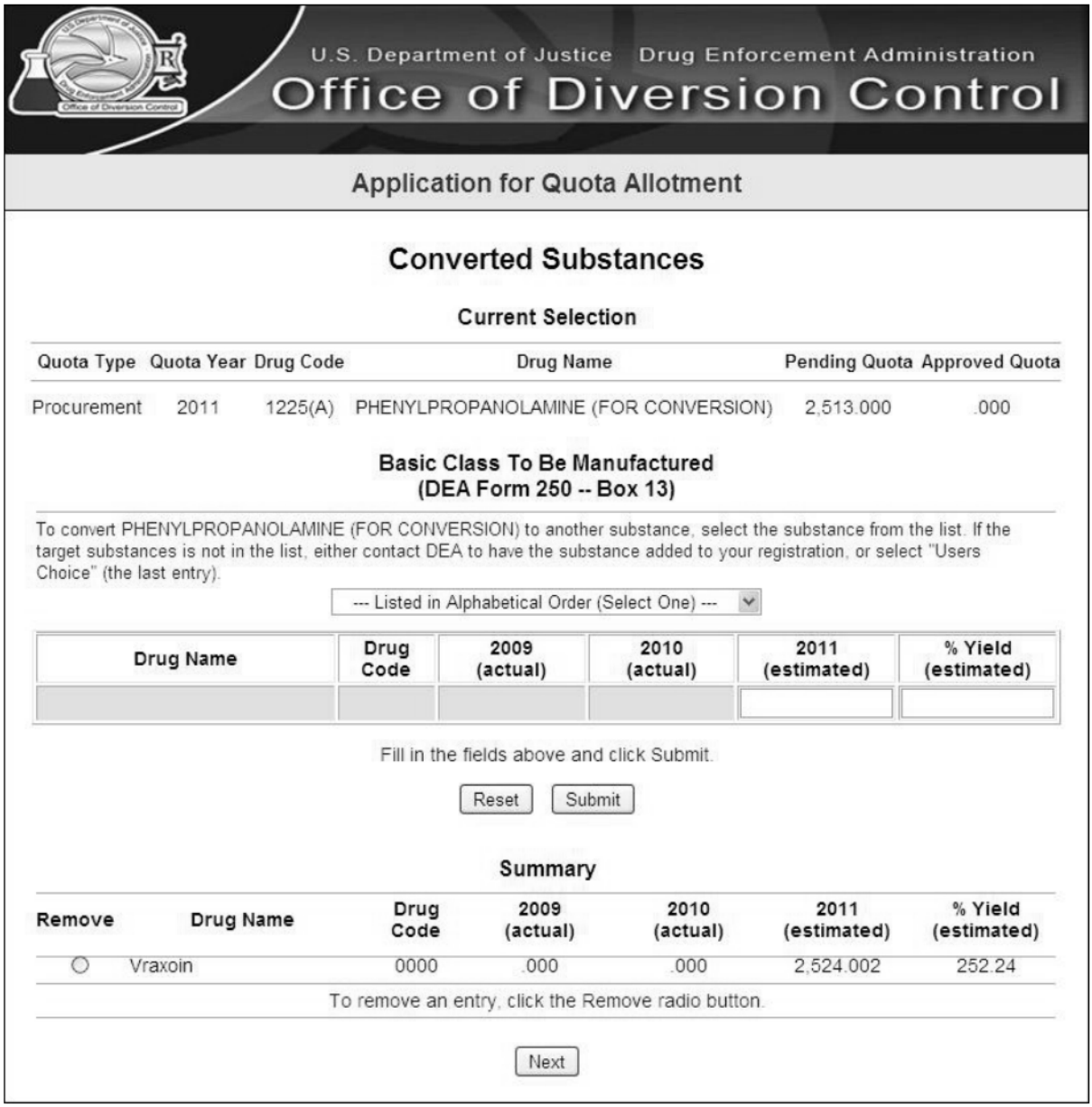


Figure 12: Converted Substances

3.2 Commercial Manufacturing (Dosage Form)

The **Commercial Manufacturing** sub-category form is only available for procurement manufacturers and importers. Filing the **Commercial Manufacturing** sub-category form is optional.

Complete the following fields (Figure 13, following page):

- **Name**: the name of the manufactured dosage form.
- **Mkt Auth**: the authority with which the indicated dosage form is marketed.
- **Used <2 years prior>**: the amount used two (2) years prior to the current year.
- **Used <1 years prior>**: the amount used one (1) year prior to the current year.
- **Est. <quota year>**: the estimated amount to be used during the requested year.

Click the Submit button. The information will be added to the **Summary** table. To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 8).

Page 155 Vol. 1



Figure 13: Commercial Manufacturing

3.3 Product Development

The **Product Development** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Product Development** sub-category form is mandatory if the registrant placed a numerical value in the quota allotment by category (see Figure 6, page 6).

Complete the following fields (Figure 14, subsequent page):

- **Name**: the name of the substance required for product development.
- **Strength**: the strength of the dosage required for product development.
- **Units/Batch**: the number of units allotted per batch required for product development.
- **# Batches**: the number of batches of the substance required for product development.
- **Purpose**: the purpose of the substance's use in product development.
- **Qty**: the total quantity expected to produce through product development.
- **Completion Time**: the time required to complete product development.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to complete the sub-form and return to the **Report Selection Menu** (see Figure 8).



Figure 14: Product Development

3.4 Packaging

The **Packaging** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Packaging** sub-category form is mandatory if the registrant placed a numerical value in the quota allotment by category (see Figure 6, page 6).

Complete the following fields (Figure 15, following page):

- **Name**: the name of the package into which the substance will be segmented.
- **Strength**: the strength of the packaged segments.
- **Units/Pkg**: the number of units allotted per package.
- **# Pkgs**: the number of segments the package will comprise.
- **Purpose**: the purpose of segmenting the substance into packages.
- **Qty**: the quantity of total packages required.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to complete the sub-form and return to the **Report Selection Menu** (see Figure 8).



Figure 15: Packaging

3.5 Replacement

The **Replacement** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Replacement** sub-category form is mandatory if a numerical value was typed in the quota allotment section (see Figure 6, page 7).

Enter the following information (Figure 16, subsequent page):

- **Destruction Date**: the date the original substance was destroyed. Click this field to display a calendar from which the date of destruction may be chosen.
- **Explanation**: as well as the reason for its destruction of the original substance or chemical.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to complete the sub-form and return to the **Report Selection Menu** (see Figure 8).



Figure 16: Replacement

3.6 Transfer

The **Transfer** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Transfer** sub-category form is mandatory if a numerical value was typed in to the quota allotment (see Figure 6, page 7).

Enter the DEA number of the manufacturer to whom the substance was transferred, as well as the reason for the transfer.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.



Figure 17: Transfer

Click the Next button to return to the **Report Selection Menu** (see Figure 8).

3.7 Worksheet A

The **Worksheet A** sub-report form is only available for List I chemical importers. Filing the **Worksheet A** sub-report form is mandatory unless the form is submitted via email with the reference number of this request displayed in the subject line.

Enter the following information (Figure 18, next page):

- **DEA Number (if applicable)**: the registration number assigned by the DEA.
- **Name of Company**: the name of the company or manufacturer that the user account represents.
- **Address**: the mailing address of the company or manufacturer listed above.
- **Phone**: the telephone number where the corporate user or administrator may be reached.
- **Fax**: the fax number where the corporate user or administrator may be reached.
- **Email**: the email address where the corporate user or administrator may be reached.
- **Contact Person**: the name of the designated representative of the company or manufacturer.
- **Quantity to be Sold (as grams of anhydrous base)**: the estimated quantity of chemicals expected to be sold during the requested year.
- **Provide documentation for Quantity to be sold (purchase order, supply agreements, etc.)**: list details supporting the Quantity to be Sold estimate.
- **Intended Use**: select one of the three options provided. If "Other" is selected, provide an explanation for the intended use of the chemical.

When all fields have been completed, click the Submit button. Quotas will save the sub-report form and display a summary of the completed worksheet.

A worksheet may be removed from the **Summary** page by selecting the "Remove" radio button.

Click Next to return to return to the Report Selection Menu (see Figure 8, page 8).



Figure 18: Worksheet A

Drug Enforcement Administration

Year-End Reporting and Quota Management System

Quotas
User Manual

Version 1.5
January 10, 2017



DIVERSION CONTROL DIVISION
TECHNOLOGY SECTION

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1.0 Introduction

1.1 Overview

The Drug Enforcement Administration (DEA) is the United States (US) competent body charged with the management of controlled substances and chemicals for scientific, medical, research, and industrial applications while preventing diversion of these same substances and chemicals. To manage this complex system, DEA requires that manufacturers of Schedule I and II controlled substances and the importers and manufacturers of ephedrine, pseudoephedrine, and phenylpropanolamine (Combat Methamphetamine Epidemic Act [CMEA] List I chemicals) apply for quotas to control the quantity of material produced or procured per calendar year for US requirements. These individual import and procurement requests are aggregated to determine bulk manufacturer requirements, aggregate production quotas (APQ), annual assessment of needs (AAN), and generate reports to the United Nations regarding the consumption and manufacturing of Schedule I and II controlled substances and CMEA List I chemicals.

These specific individual importers and manufacturers apply for yearly importation and manufacturing quota allowances based on historical sales data and forecasted trends in their market. This information is transmitted to DEA through quota application forms DEA 189, DEA 250, and DEA 488. The individual manufacturing quota form DEA 189 is for use by individual manufacturers that extract or synthesize a Schedule I or II substance from plant material or other controlled substances. The procurement quota form DEA 250 is required for dosage form manufacturers, compound pharmacies, labelers/re-labelers, and packagers/re-packagers. The importation form DEA 488 is for use by the CMEA List I chemical importers.

1.2 Basic Navigation

Use the buttons at the bottom of the page to navigate the Quotas application. Button functionality is as follows:

Next : continue to the next page in sequence.

Back : return to the previous page.

Reset : clear any fields, drop down menus, and radio buttons with enterable data.

Return : similar to the Back button. This usually appears when beginning a new form or sub-form.

Exit : exit the Quotas application.

Do *not* use the browser's navigation buttons.

1.3 Login



Figure 1: Login

Enter the following:

- **DEA Number**: the unique identifying number issued to each registrant upon enrolling with the DEA.
- **Username**: the user account name used to differentiate between one user account and another, provided by the corporate administrator.
- **Password**: the unique identifying set of characters comprised of alphanumerical and special characters used to access an account, initially provided by the corporate administrator.

To clear the fields, click the Reset button.

Click the Next button on this page to proceed. An error will be displayed if any of the entered information is incorrect.

On the Login Confirmation screen (not pictured), click the Next button to continue. The Return button will return users to the Login screen.

1.4 Changing the Password

To change the current password, check the **Change Password** checkbox on the Login screen before clicking the Next button.



Figure 2: Change Password

New passwords must be between 4 – 10 characters in length and contain at least one of the following:

- One (1) uppercase letter
- One (1) lowercase letter
- One (1) number

Enter the current password into the field provided. The new password must be entered twice to ensure accuracy.

When the fields have been filled, click the Next button. Quotas passwords will not expire.

To return to the previous screen without making any changes, click the Back button.

To clear any entered text from the Password fields, click the Reset button.

2.0 Quota Application

2.1 Manufacturers and Types of Quota

Manufacturers can apply for three (3) different types of quota based on the business activities permitted by their DEA registration(s). The table below specifies the distinction between manufacturers, quotas, and controlled substances/CMEA List I chemicals.

Type of Account	Type of Quota	Substance/Chemical
Manufacturer	Procurement	Substance
Bulk Manufacturer	Procurement, Manufacturer	Substance
Chemical Manufacturer	Procurement, Manufacturer	Chemical
List I Chemical Importer	Import	Chemical

2.2 Quota Application

After confirming the account login, Quotas will load the **Main Selection Menu**. An initial quota may be requested or an already granted quota may be revised. From this page, users may check the status of existing quota requests (see Section 2.3) or file a new or amendment request.

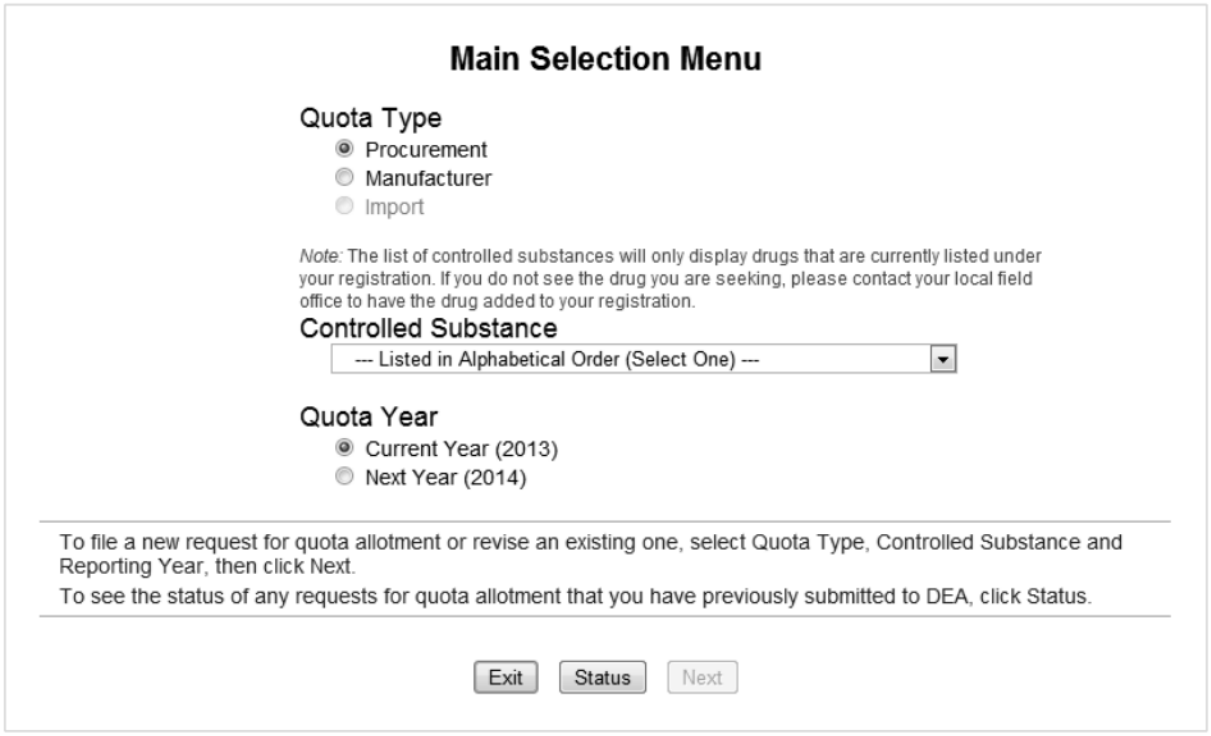


Figure 3: Main Selection Menu

The following information must be selected before the application process may continue.

- **Quota Type**: the type of quota being requested.
- **Controlled Substance**: the controlled substance for which a quota is being requested. List I chemical manufacturers and importers will only see the chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. No substance or chemical will be listed in the drop-down menu if it hasn't first been registered to the requesting manufacturer.
- **Quota Year**: the year during which the quota will be applied.

After all selections have been made, click the Next button. Following this page, the current or future year-end inventory, acquisitions, and dispositions are estimated and the quota amount is requested.

2.2.1 Current Selection

Once through the Main Selection Menu, every subsequent page in the Quota application process will display the following information.

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2014	9120	DIHYDROCODEINE		.000

Figure 4: Current Selection

2.2.2 Quota Revision

Note that the screen below will only be displayed if a request for the selected substance or chemical has already been submitted.

Quota Request Amendment

Notice

You have previously filed a quota allotment request for the substance noted below. The request was filed on Oct 26, 2012 in the amount of 100.000 grams. The Reference Number is 113654.

In the pages that follow, your original data values for the request will be displayed. You may freely remove, append or amend this data. Once you complete this amended request, it will be filed with its own reference number and will become the new statement of record for the requested quota allotment for this substance.

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2013	9150	HYDROMORPHONE	100.000	.000

Back Next

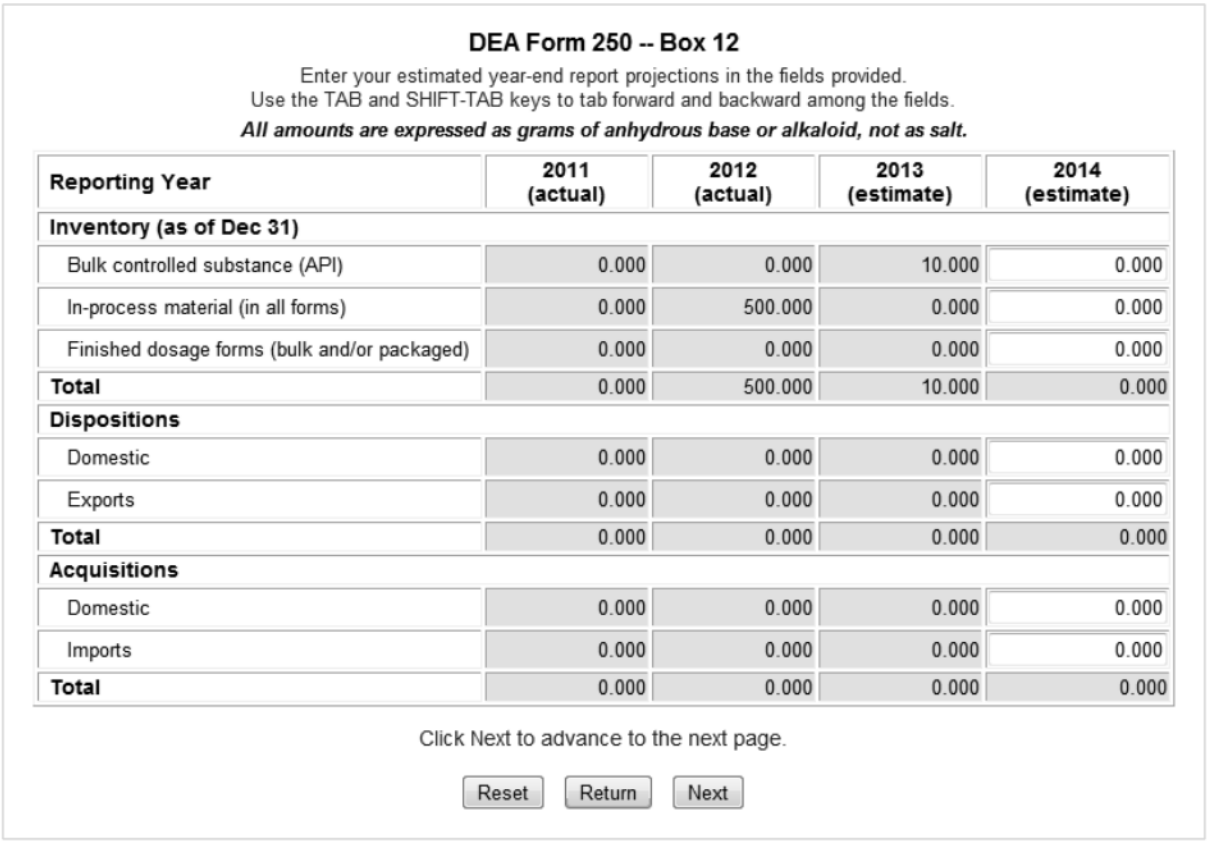
Figure 5: Quota Amendment Notice

Click the Next button to proceed to the Year-End Estimates screen.

2.2.3 Year-End Estimates for Report Year

Note that the fields, as displayed in the image below, will already contain values if this is an amendment to an already submitted quota.

Enter the estimated amounts of the controlled substance or listed chemical expected to be held in inventory, disposed/sold to other entities, and acquired from other entities by the end of the selected year. At least one field must contain a value other than zero (0) before the quota application process may proceed.



DEA Form 250 -- Box 12

Enter your estimated year-end report projections in the fields provided.
Use the TAB and SHIFT-TAB keys to tab forward and backward among the fields.

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.

Reporting Year	2011 (actual)	2012 (actual)	2013 (estimate)	2014 (estimate)
Inventory (as of Dec 31)				
Bulk controlled substance (API)	0.000	0.000	10.000	0.000
In-process material (in all forms)	0.000	500.000	0.000	0.000
Finished dosage forms (bulk and/or packaged)	0.000	0.000	0.000	0.000
Total	0.000	500.000	10.000	0.000
Dispositions				
Domestic	0.000	0.000	0.000	0.000
Exports	0.000	0.000	0.000	0.000
Total	0.000	0.000	0.000	0.000
Acquisitions				
Domestic	0.000	0.000	0.000	0.000
Imports	0.000	0.000	0.000	0.000
Total	0.000	0.000	0.000	0.000

Click Next to advance to the next page.

Reset Return Next

Figure 6: Year-End Estimates

All entered values must be expressed as grams of anhydrous base or alkaloid, not as salt.

- **Bulk controlled substance (API [Active Pharmaceutical Ingredient])**: the quantity of bulk (non-packaged) substances or chemicals held in inventory.
- **In-process material (in all forms)**: the quantity of substances or chemicals in process for conversion, formulation, blending, tableting, encapsulation, etc.
- **Finished dosage forms (bulk and/or packaged)**: the quantity of substances or chemicals to have completed processing.
- **Domestic**: the quantity of substances or chemicals to have either been disposed or acquired within the United States.
- **Exports/Imports**: the quantity of substances or chemicals to have either been disposed or acquired internationally.

*Note that a fourth column will be displayed only if the **Next Year** option is selected on the **Main Selection Menu** screen (see* Figure 3*). The current year column will be unavailable for editing.*

Note that any values entered for an amended quota request will overwrite any values previously requested. New submissions for revising quota requests are not added to or subtracted from existing quota values.

Click the Next button to proceed to the **Quota Request** screen.

2.2.4 Quota Request

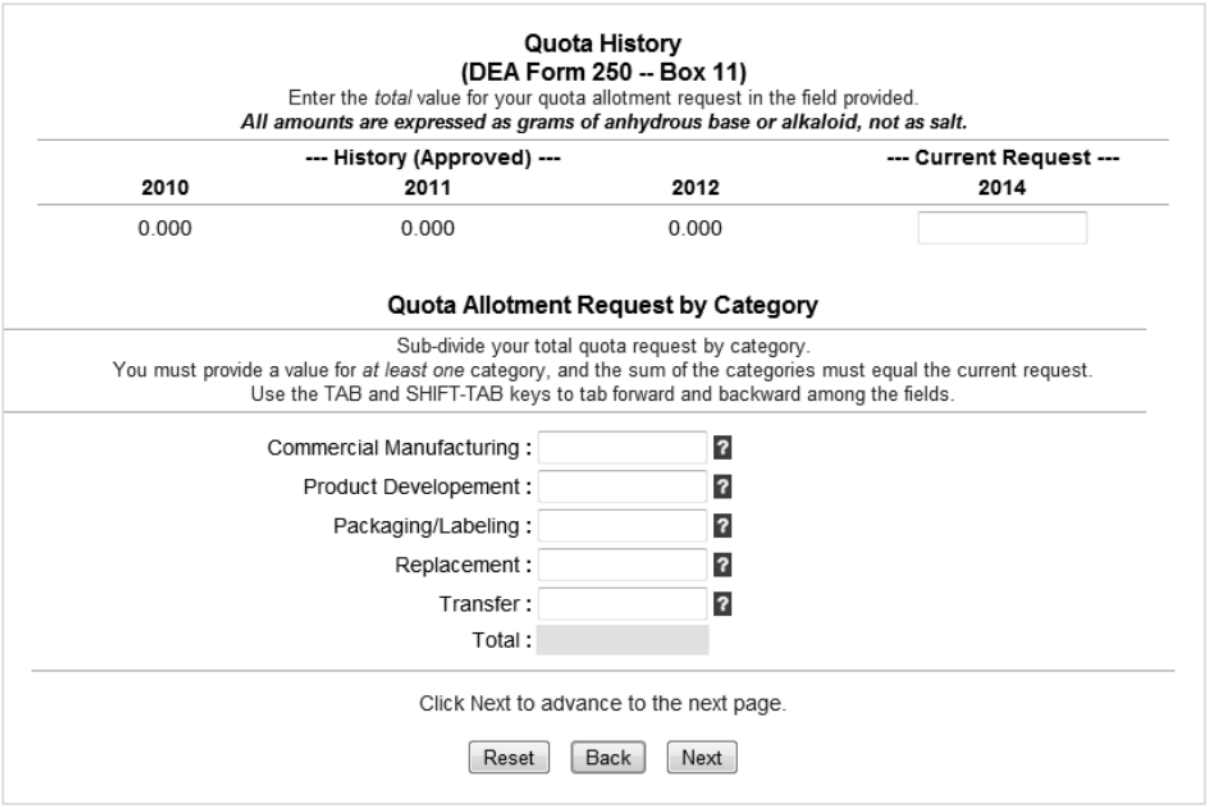


Figure 7: Quota Request

Enter the total value of the Quota reqest in the Total Requested for calendar year field.

separate the total of the current request into the fields of the **Quota Allotment Request by Category**. All fields must be filled; if no quota will be used in a particualr category, enter (0) for that field. Click the Reset button to clear the fields.

The total value of the **Quota Allotment Request by Category fields** must equal the value entered in the Current Request field. Hover the pointer over a ? icon to display a tooltip with specific information about the request categories.

List I chemical importers will see the **Product Type** section rather than the **Quota Allotment Request by Category** section. List I chemical importers must select the type of List I chemical product being imported.

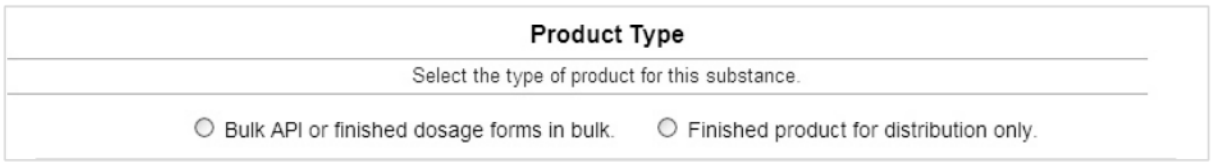


Figure 8: Import Product Type

After the fields have been filled and selection been made, click the Next button.

The following message shall appear for quota revision requests where the new value is lower than that already approved by DEA.

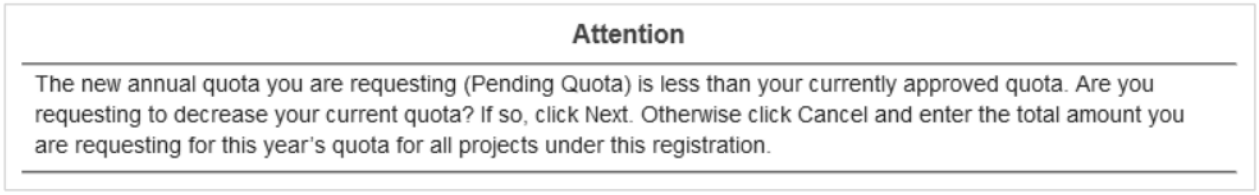


Figure 9: Attention

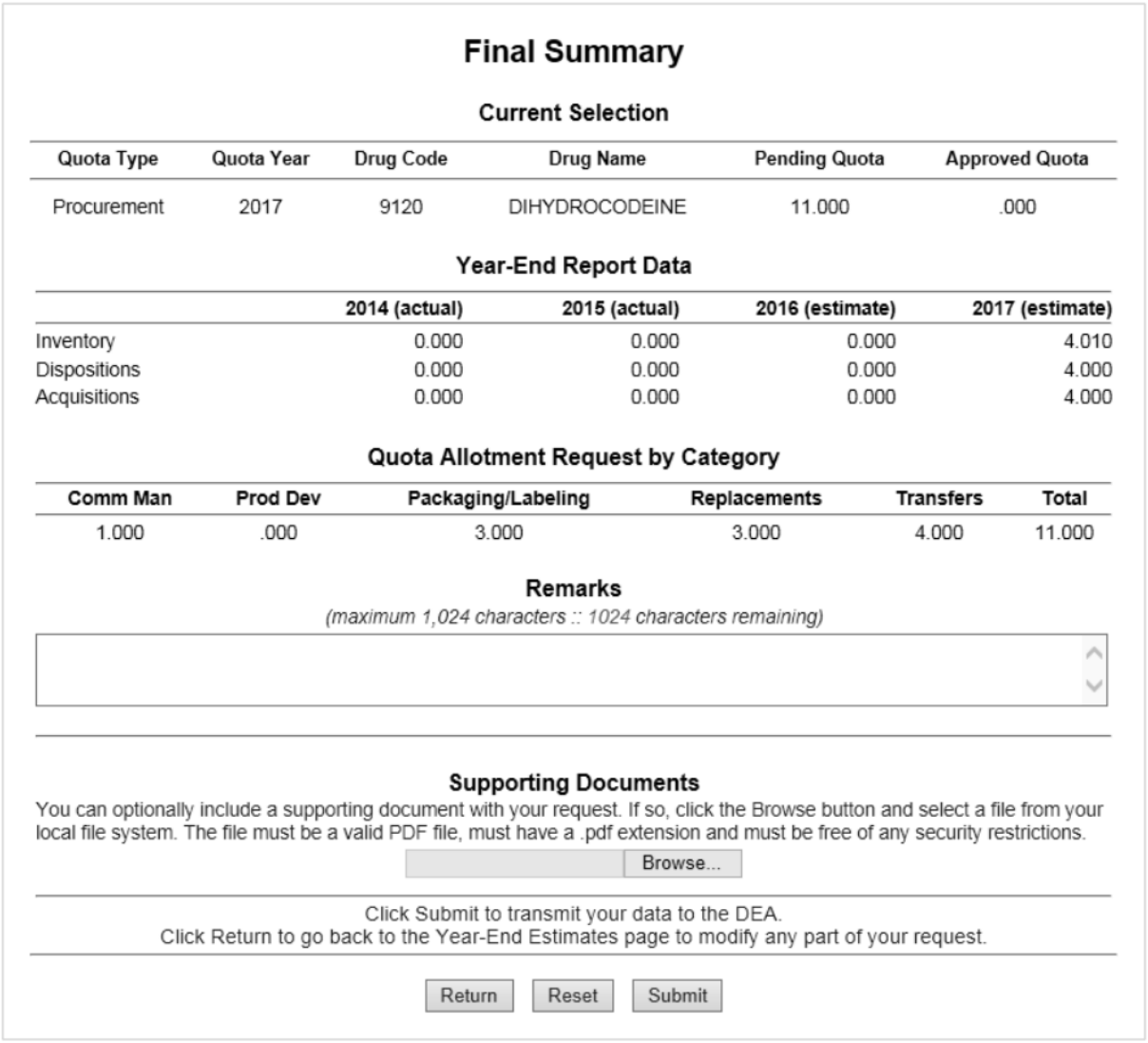
Click the Next button to display the **Sub-Report Selection Menu**.



Figure 10: Sub-Report Selection Menu

Refer to Section 3.0 for information about the Quota sub-category forms. When finished, click the Next button.

2.2.5 Final Summary



Final Summary

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2017	9120	DIHYDROCODEINE	11.000	.000

Year-End Report Data

	2014 (actual)	2015 (actual)	2016 (estimate)	2017 (estimate)
Inventory	0.000	0.000	0.000	4.010
Dispositions	0.000	0.000	0.000	4.000
Acquisitions	0.000	0.000	0.000	4.000

Quota Allotment Request by Category

Comm Man	Prod Dev	Packaging/Labeling	Replacements	Transfers	Total
1.000	.000	3.000	3.000	4.000	11.000

Remarks

(maximum 1,024 characters :: 1024 characters remaining)

Supporting Documents

You can optionally include a supporting document with your request. If so, click the Browse button and select a file from your local file system. The file must be a valid PDF file, must have a .pdf extension and must be free of any security restrictions.

Browse...

Click Submit to transmit your data to the DEA.
Click Return to go back to the Year-End Estimates page to modify any part of your request.

Return Reset Submit

Figure 11: Final Summary

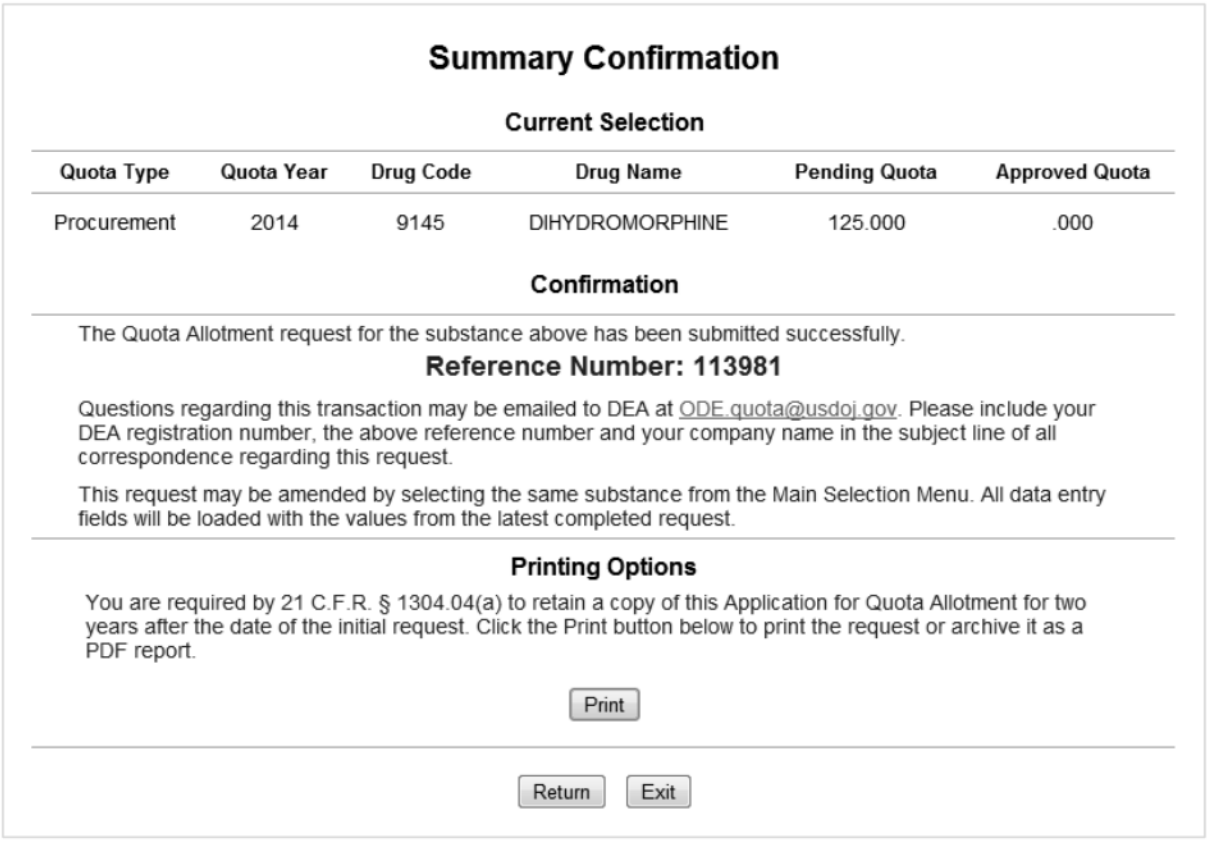
Review the summary of the quota request. Any additional remarks should be placed in the **Remarks** field.

Optionally, a Portable Document Format (PDF) file supporting the Quota request may be uploaded. Click the Browse... button to choose the file. *Note that PDF files may not take the place of a submitted quota request.*

If a mistake was made, click the Return button to return to the **Main Selection Menu**.

Click the Submit button to complete the Quota request.

A reference number will be assigned to the quota request. Reference this number in any emails to the UN Reporting and Quota Section (DRQ) concerning this quota request.



Summary Confirmation

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2014	9145	DIHYDROMORPHINE	125.000	.000

Confirmation

The Quota Allotment request for the substance above has been submitted successfully.

Reference Number: 113981

Questions regarding this transaction may be emailed to DEA at ODE.quota@usdoj.gov. Please include your DEA registration number, the above reference number and your company name in the subject line of all correspondence regarding this request.

This request may be amended by selecting the same substance from the Main Selection Menu. All data entry fields will be loaded with the values from the latest completed request.

Printing Options

You are required by 21 C.F.R. § 1304.04(a) to retain a copy of this Application for Quota Allotment for two years after the date of the initial request. Click the Print button below to print the request or archive it as a PDF report.

Print

Return Exit

Figure 12: Summary Confirmation

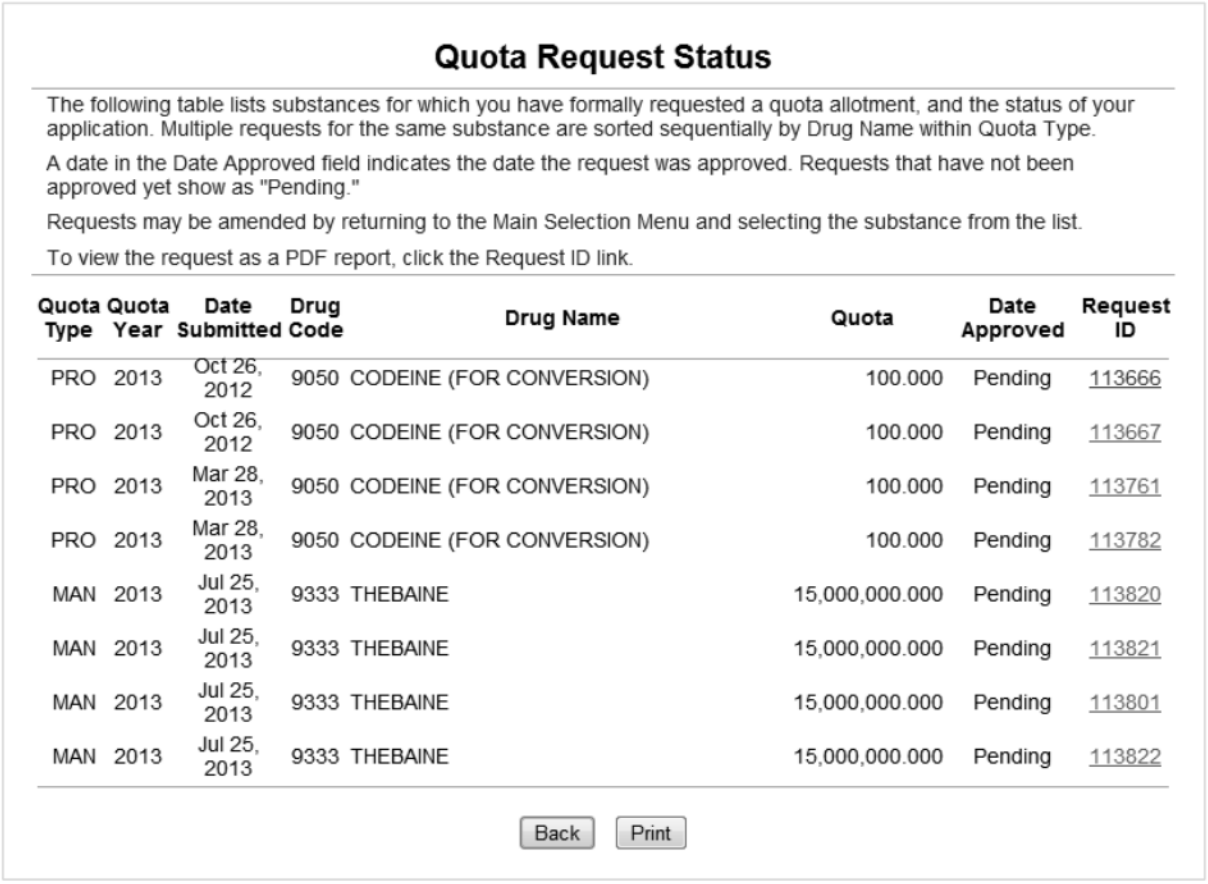
A PDF copy of the Quota request application may be saved to a local computer for printing. Click the Print button to create the PDF copy.

Click the Return button to return to the **Main Selection Menu** (Figure 3) to submit another Quota request.

Click the Exit button to return to the Office of Diversion Control website and exit the application.

2.3 Checking the Application Status

To check the current status of a pending quota application, click the Status button from the **Main Selection Menu**.



Quota Request Status

The following table lists substances for which you have formally requested a quota allotment, and the status of your application. Multiple requests for the same substance are sorted sequentially by Drug Name within Quota Type.

A date in the Date Approved field indicates the date the request was approved. Requests that have not been approved yet show as "Pending."

Requests may be amended by returning to the Main Selection Menu and selecting the substance from the list.

To view the request as a PDF report, click the Request ID link.

Quota Type	Quota Year	Date Submitted	Drug Code	Drug Name	Quota	Date Approved	Request ID
PRO	2013	Oct 26, 2012	9050	CODEINE (FOR CONVERSION)	100.000	Pending	113666
PRO	2013	Oct 26, 2012	9050	CODEINE (FOR CONVERSION)	100.000	Pending	113667
PRO	2013	Mar 28, 2013	9050	CODEINE (FOR CONVERSION)	100.000	Pending	113761
PRO	2013	Mar 28, 2013	9050	CODEINE (FOR CONVERSION)	100.000	Pending	113782
MAN	2013	Jul 25, 2013	9333	THEBAINE	15,000,000.000	Pending	113820
MAN	2013	Jul 25, 2013	9333	THEBAINE	15,000,000.000	Pending	113821
MAN	2013	Jul 25, 2013	9333	THEBAINE	15,000,000.000	Pending	113801
MAN	2013	Jul 25, 2013	9333	THEBAINE	15,000,000.000	Pending	113822

Back Print

Figure 13: Quota Request Status

The following information is available:

- **Quota Type**: the type of quota for which the application has been submitted (procurement, manufacturer, import).
- **Quota Year**: they year for which the quota will be applied.
- **Date Submitted**: the date on which the request was submitted.
- **Drug Code**: the code given to the controlled substance or listed chemical for which a quota was requested.
- **Drug Name**: the name of the controlled substance or listed chemical for which a quota was requested.
- **Quota**: the quota amount requested for the applicable year.
- **Date Approved**: the date on which the quota request was approved. Note: Approval date does **not** indicate the quota amount requested is the amount granted. DEA will still send a letter (by email and post) indicating the amount of quota granted for the request.
    - Pending indicates that the request is still awaiting final determination by DRQ.

  - Withdrawn indicates that the request has been withdrawn either by registrant's written request to DRQ or that DRQ has combined the application with the registrant's additional pending request for the same drug code. Withdrawn requests may be resubmitted.
- **Request ID**: every quota request is assigned a unique six (6)-digit number. This number should be referenced with inquiries concerning the quota request. Click on the Request ID to display and/or print the details of that specific request.

Clicking the Print button will create a PDF copy of the status page information suitable for printing. A letter addressed to the registrant from the Deputy Assistant Administrator of DC will be displayed on the final page of the summary.

To return to the **Main Selection Menu**, click the Back button.

3.0 Quota Sub-Category Forms

3.1 Commercial Manufacturing (Converted Substances)

The **Converted Substances** sub-category form is only available for substances and List I chemicals specifically marked for conversion. Filing the **Converted Substances** sub-category form is an optional activity for bulk manufacturers.

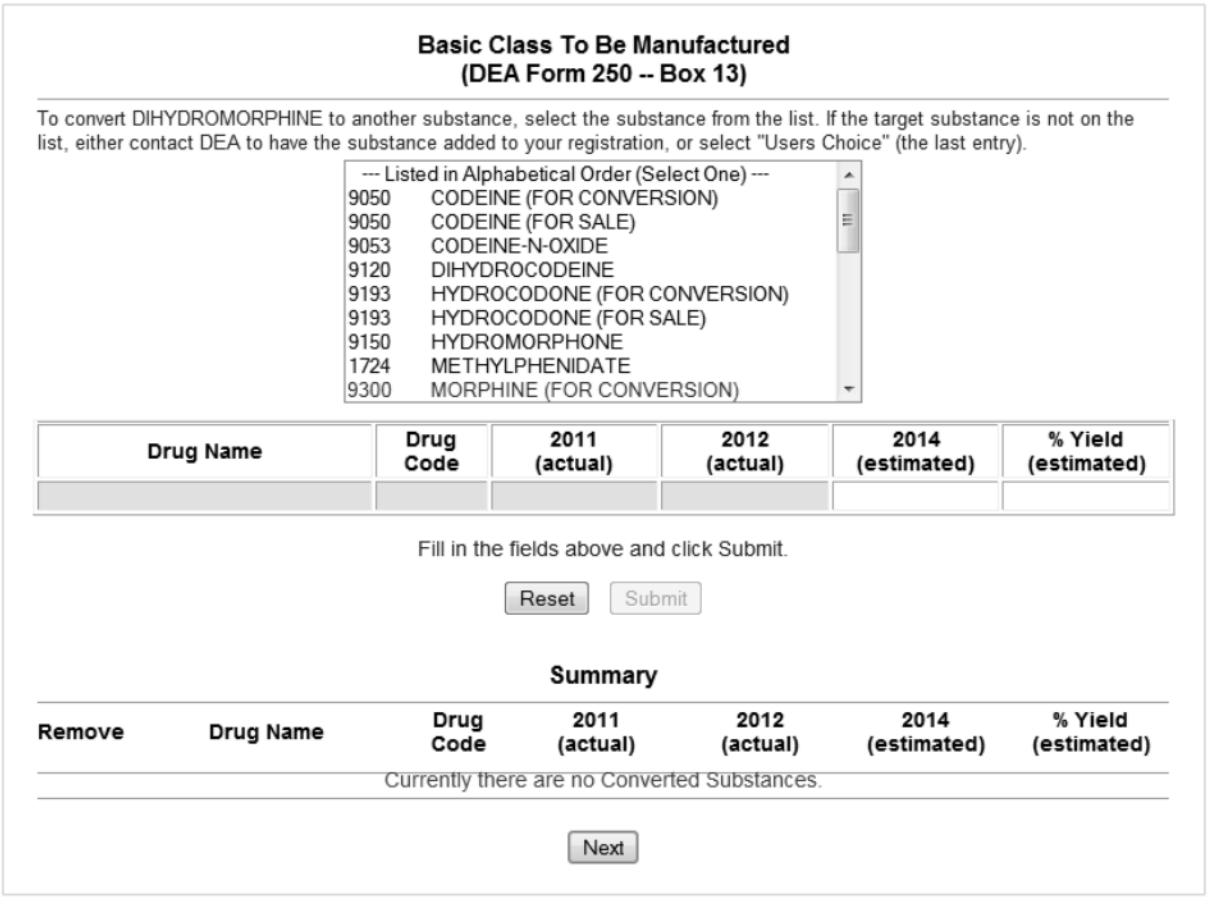


Figure 14: Converted Substances

Select a drug from the drop down menu.

Note that substances will only be listed if they can be products of the selected base substance.

Any selections will be added to the **Basic Class to be Manufactured** table. If User Choice is selected, the name of the drug must be manually entered into the **Drug Name** column.

Fill in the estimated year and percentage yield fields and click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.2 Commercial Manufacturing (Dosage Form)

The **Commercial Manufacturing** sub-category form is only available for procurement manufacturers and importers. Filing the **Commercial Manufacturing** sub-category form is optional.

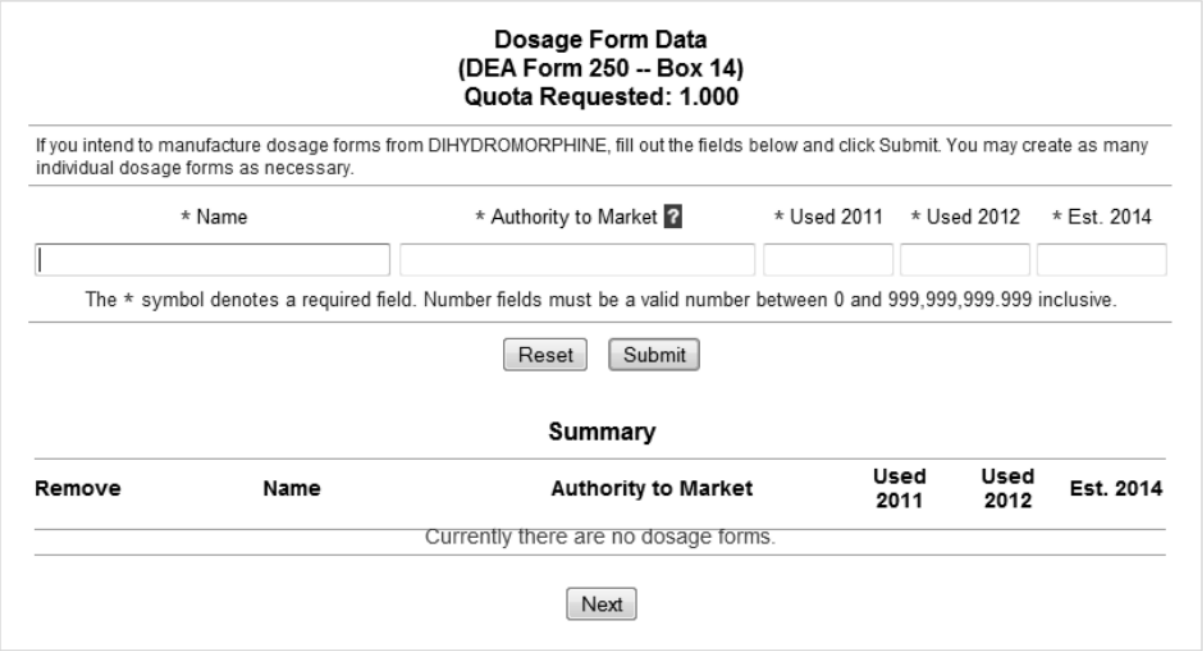


Figure 15: Commercial Manufacturing

Complete the following fields:

- **Name**: the name of the manufactured dosage form.
- **Authority to Market**: the authority with which the indicated dosage form is marketed. Click on a ? icon to display a popup with specific information about the request categories.
- **Used <2 years prior>**: the quantity used two (2) years prior to the current year.
- **Used <1 years prior>**: the quantity used one (1) year prior to the current year.
- **Est. <quota year>**: the estimated quantity to be used during the requested year.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.3 Product Development

The **Product Development** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Product Development** sub-category form is mandatory if the registrant placed a numerical value in the quota allotment by category (see Figure 7, page 6).



Figure 16: Product Development

Complete the following fields:

- **Name**: the name of the substance required for product development.
- **Strength**: the strength of the dosage required for product development. Click on a ? icon to display a tooltip with specific information about the request categories.
- **Units/Batch**: the number of units allotted per batch required for product development.
- **# Batches**: the number of batches of the substance required for product development.
- **Purpose**: the purpose of the substance's use in product development. Click on a ? icon to display a tooltip with specific information about the request categories.
- **Qty**: the total quantity expected to be utilized through product development. Click on a icon ? display a tooltip with specific information about the request categories.
- **Completion Time**: the time required to complete product development.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.4 Packaging/Labeling

The **Packaging** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Packaging** sub-category form is mandatory if the registrant placed a numerical value in the quota allotment by category (see Figure 7, page 6).

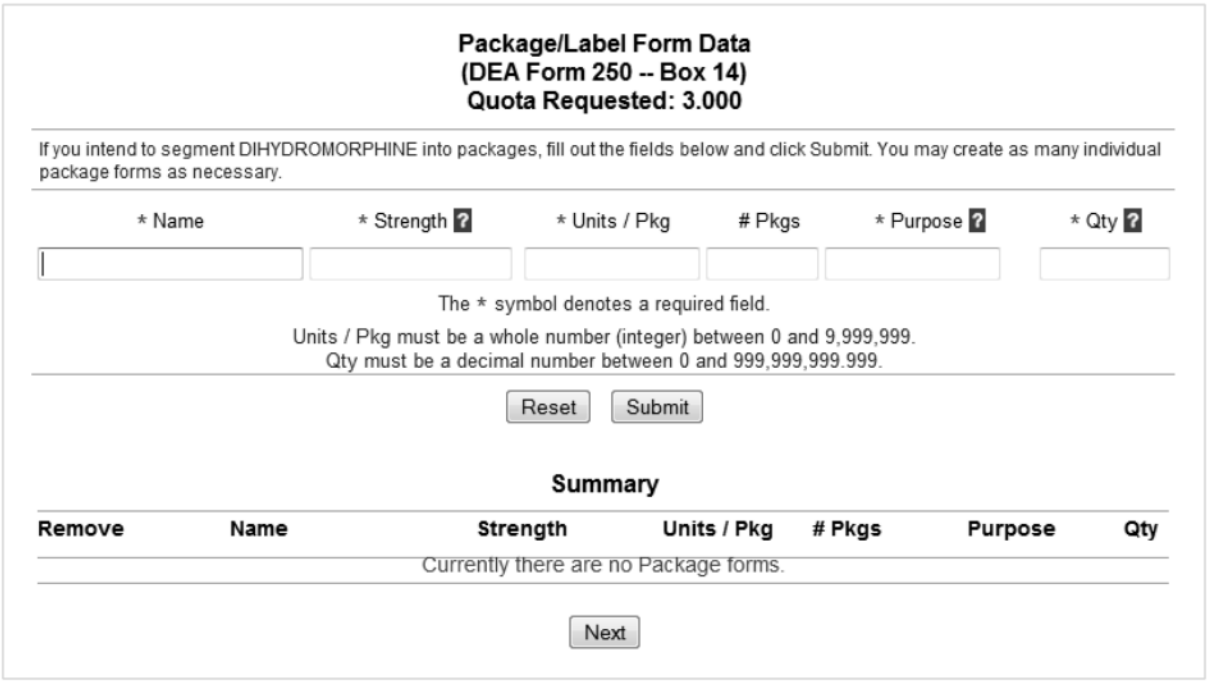


Figure 17: Packaging

Complete the following fields:

- **Name**: the name of the package into which the substance will be segmented.
- **Strength**: the strength of the packaged segments. Click on a ? icon to display a tooltip with specific information about the request categories.
- **Units/Pkg**: the number of units allotted per package.
- **# Pkgs**: the number of segments the package will comprise.
- **Purpose**: the purpose of segmenting the substance into packages. Click on a ? icon to display a tooltip with specific information about the request categories.
- **Qty**: the quantity of total packages required. Click on a ? icon to display a tooltip with specific information about the request categories.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.5 Replacement

The **Replacement** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Replacement** sub-category form is mandatory if a numerical value was typed in the quota allotment section (see Figure 7, page 11).

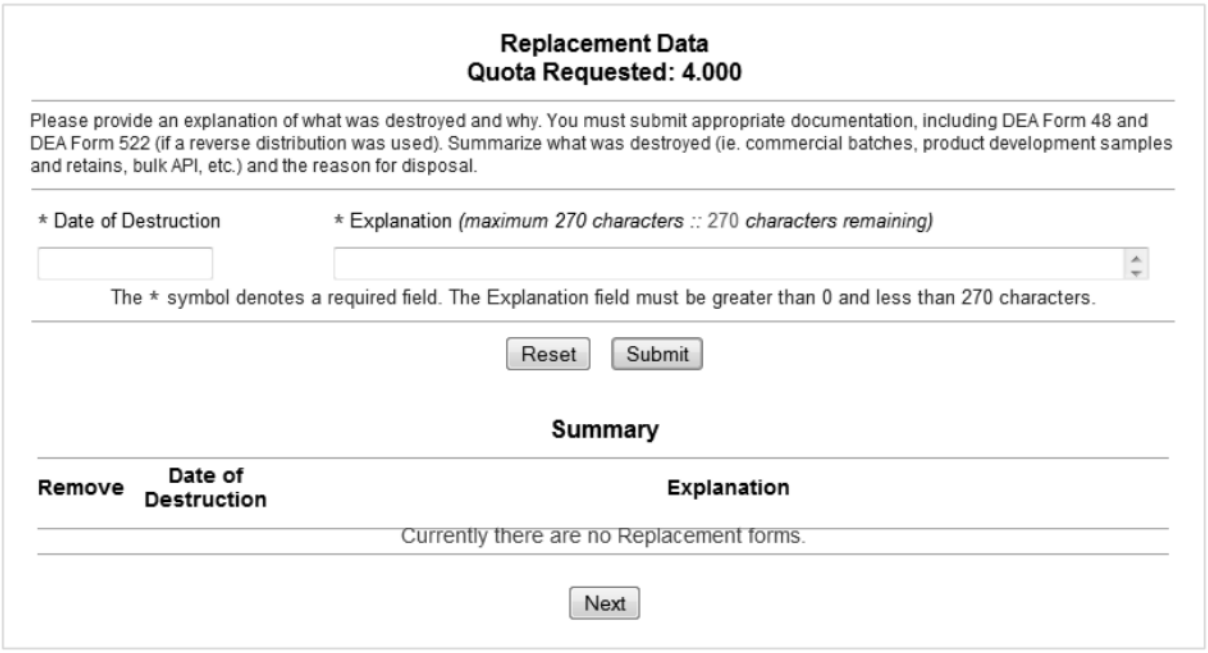


Figure 18: Replacement

Enter the following information:

- **Destruction Date**: the date the original substance was or will be destroyed. Click this field to display a calendar from which the date of destruction may be chosen.
- **Explanation**: the reason for the destruction of the original substance or chemical.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.6 Transfer

The **Transfer** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Transfer** sub-category form is mandatory if a numerical value was typed in to the quota allotment (see Figure 7, page 11).

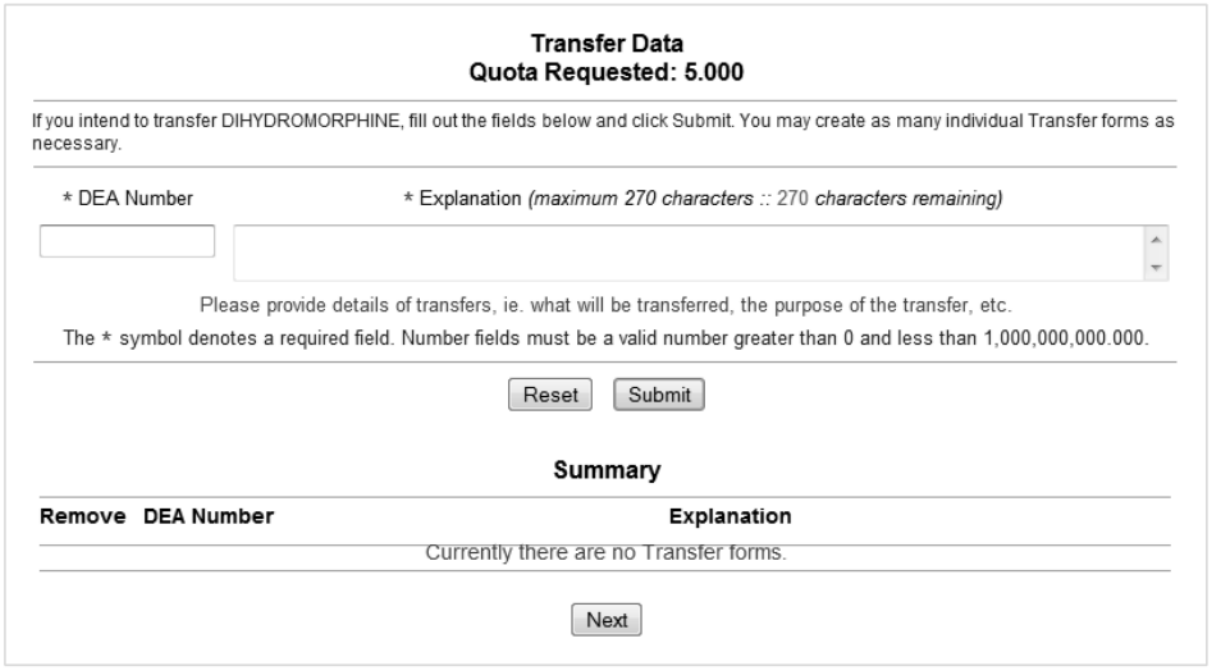


Figure 19: Transfer

Enter the DEA number of the manufacturer to whom the substance was transferred, as well as the reason for the transfer.

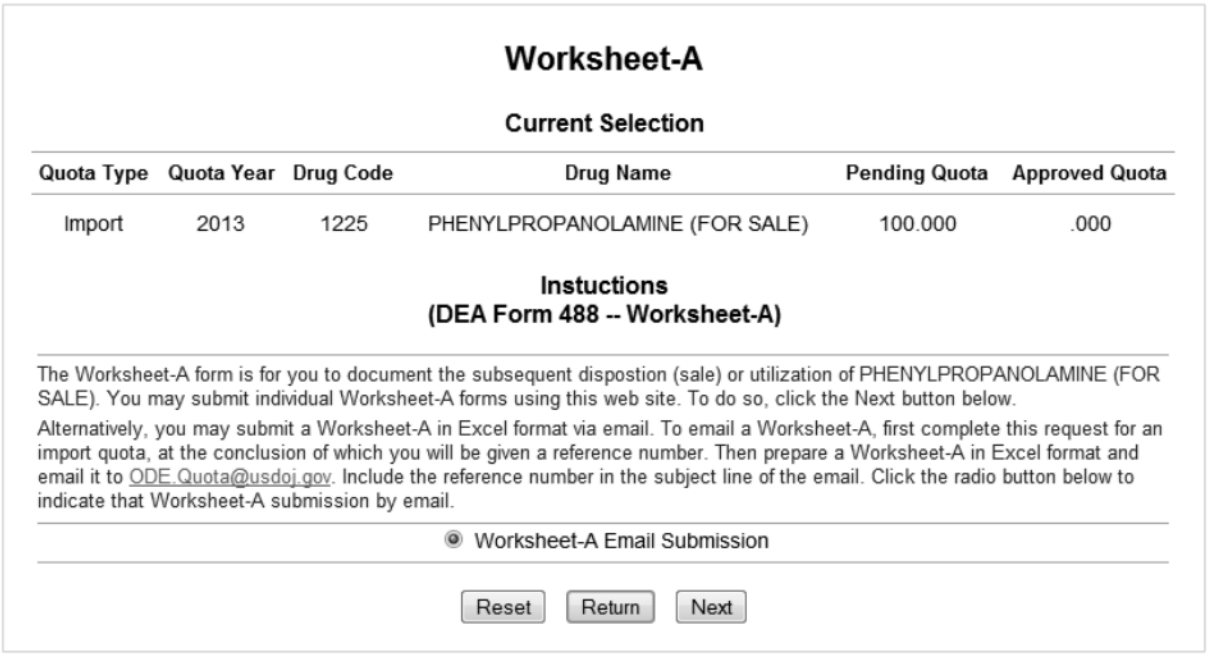
Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.7 Worksheet A

The **Worksheet A** sub-report form is only available for List I chemical importers. Filing the **Worksheet A** sub-report form is mandatory unless the form is submitted via email with the reference number of this request displayed in the subject line.



Worksheet-A

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Import	2013	1225	PHENYLPROPANOLAMINE (FOR SALE)	100.000	.000

Instuctions
(DEA Form 488 -- Worksheet-A)

The Worksheet-A form is for you to document the subsequent dispostion (sale) or utilization of PHENYLPROPANOLAMINE (FOR SALE). You may submit individual Worksheet-A forms using this web site. To do so, click the Next button below.

Alternatively, you may submit a Worksheet-A in Excel format via email. To email a Worksheet-A, first complete this request for an import quota, at the conclusion of which you will be given a reference number. Then prepare a Worksheet-A in Excel format and email it to ODE.Quota@usdoj.gov. Include the reference number in the subject line of the email. Click the radio button below to indicate that Worksheet-A submission by email.

◉ Worksheet-A Email Submission

Reset Return Next

Figure 20: Worksheet-A Introduction

Click the Next button.

If the Worksheet-A Email Submission radio button has been selected, Quotas will return to the **Report Selection Menu** (Figure 10). Otherwise, Quotas will display **Worksheet-A** (Figure 21, next page).

If **Worksheet-A** appears, enter the following information:

- **DEA Number (if applicable)**: the registration number assigned by the DEA.
- **Name of Company**: the name of the company or manufacturer purchasing drugs from the importer.
- **Address**: the mailing address of the company or manufacturer listed above.
- **Phone**: the telephone number where the corporate user or administrator may be reached.
- **Fax**: the fax number where the corporate user or administrator may be reached.
- **Email**: the email address where the corporate user or administrator may be reached.
- **Contact Person**: the name of the designated representative of the company or manufacturer.
- **Quantity to be Sold (as grams of anhydrous base)**: the estimated quantity of chemicals expected to be sold to the listed company during the requested year.
- **Provide documentation for Quantity to be sold (purchase order, supply agreements, etc.)**: list details supporting the Quantity to be Sold estimate.

- **Intended Use**: select one of the three options provided. If "Other" is selected, provide an explanation for the intended use of the chemical.

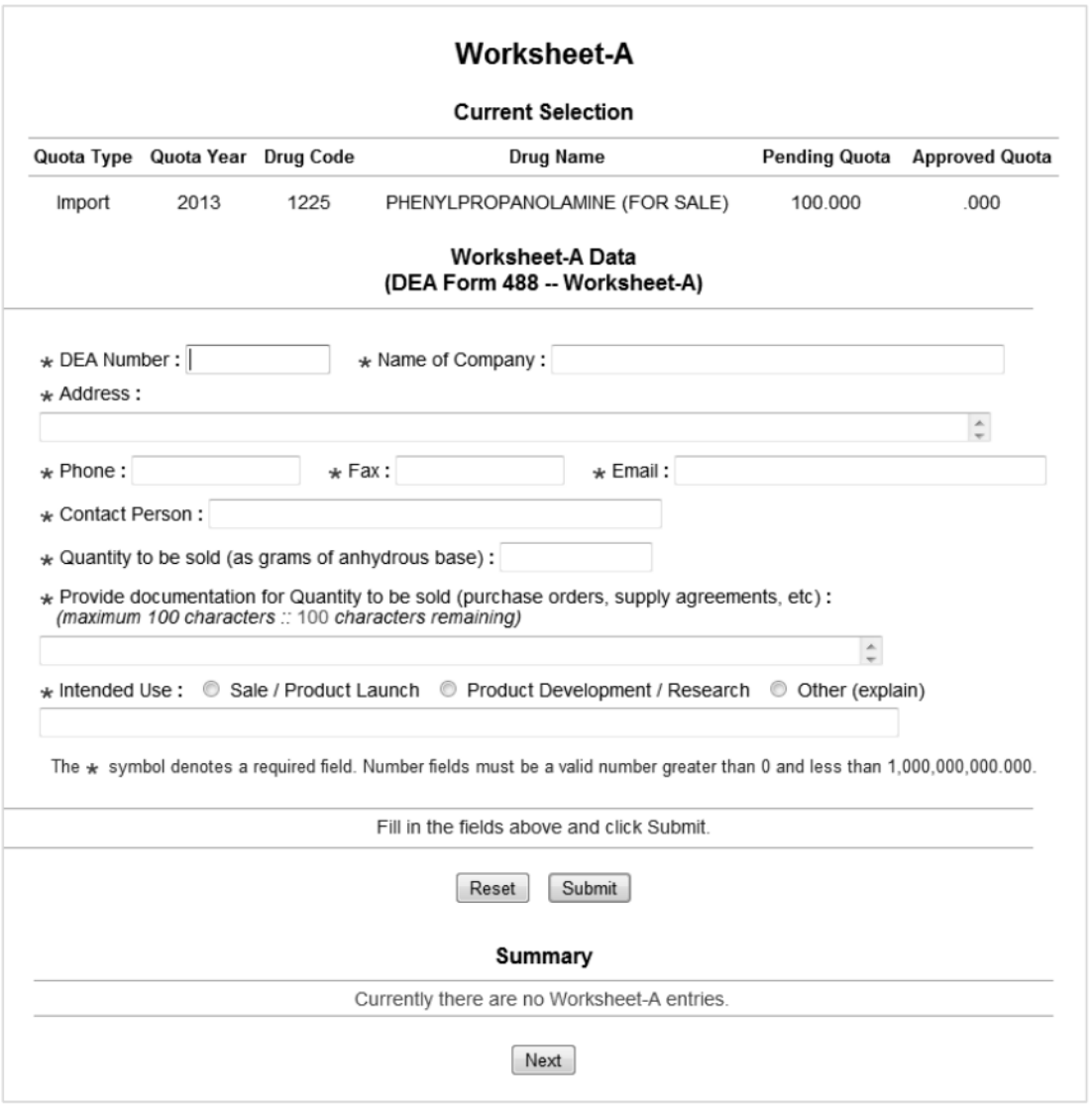


Figure 21: Worksheet A

When all fields have been completed, click the Submit button. Quotas will save the sub-report form and display a summary of the completed worksheet.

A worksheet may be removed from the **Summary** page by selecting the "Remove" radio button.

Click Next to return to return to the **Report Selection Menu** (see Figure 10, page 12).

Appendices

A.0 Glossary

Term	Definition
Acquisition	Acquiring any Schedule I or II controlled substance or CMEA List I chemical by means that include domestic procurements, acquisitions, and transfers; imports, returns by customers for salvage, rework, etc.; and those acquired from manufacture or conversion during the course of a calendar year.
Aggregate Production Quota	The total quantity of a basic class of controlled substances listed in Schedule I or II necessary to be manufactured during the calendar year to provide for the estimated medical, scientific, research, and industrial needs of the US , for lawful export requirements, and the establishment and maintenance of reserve stock.
Annual Assessment of Needs	Total quantity of ephedrine, pseudoephedrine, and phenylpropanolamine, including products containing such, necessary to be manufactured and/ or imported during the calendar year to provide for the estimated medical, scientific, research, and industrial needs of the US, for lawful export requirements, and for the establishment and maintenance of reserve stocks.
Authority to Market	Approval number from the Food and Drug Administration demonstrating the ability to lawfully market specified dosage form(s) in the US .
Bulk Controlled Substances	Any controlled substance manufactured in bulk quantities.
Bulk Manufacturer	Manufacturers of Schedules I and II controlled substances whose production methods include extraction from plant material, propagation, or synthesis from other controlled or non-controlled substances or chemicals
Chemical Manufacturer	Manufacturers of CMEA List I chemicals who product ephedrine, pseudoephedrine, or phenylpropanolamine (PPA) from controlled or non-controlled substances or chemicals
CMEA List I Chemicals	Ephedrine, pseudoephedrine, PPA
Commercial Manufacturing	Production, compounding, or processing of a controlled substance for retail sale
Controlled Substance	A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of the Controlled Substances Act (CSA). The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986. It is a substance determined potentially harmful for human consumption and therefore limited by the DEA. Controlled substances may or may not have beneficial properties.
DEA Number	A valid registration number assigned to the registrant by CSA.
Disposition	Removing from inventory any controlled substance by means that include domestic sales and transfers, conversion, exportation, returns, the manufacture of exempted or excluded products, losses, and authorized destruction during the

Term	Definition
	course of a calendar year.
Domestic	Any substance or chemical manufactured or produced within the United States.
Finished Dosage Forms	Substances or chemicals classified as having completed processing.
Import	Any bringing in or introduction of any article into either the jurisdiction of the United States or the customs territory of the united States, and from the jurisdiction of the United States into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States.
Importer	Every person who imports, or who acts as an import broker for importation of, controlled substances listed in a schedule and or/ listed chemicals.
Initial Quota Request	First quota request submitted for a calendar year
In-Process Material	Substances or chemicals classified as in process for conversion.
Inventory	All factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor.
Labeling	All labels and other written, printed, or graphic matter either placed upon any controlled substance or any of its commercial containers or wrappers of any controlled substance by any manufacturer of such substance or accompanying such controlled substance.
Listed Chemical	Any chemical specifically designated by the Administrator that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is important to the manufacture of a controlled substance; and any chemical other than that described above specifically designated by the Administrator that, in addition to the legitimate uses, is used in manufacturing a controlled substance in violation of the CSA.
Manufacturer	A person who manufacturers a drug or other substance, whether under registration as a manufacturer or under authority of registration as a researcher or chemical analyst.
Password	The unique identifying set of characters comprised of alphanumerical and special characters used to access an account. User passwords are provided by the corporate administrator.
Pending	A quota request that has been submitted, but has not yet been approved.
Procurement	The act of obtaining a controlled substance for the purpose of producing reference standards, exempt preparations, dosage forms or manufacturing another

Term	Definition
	controlled substance.
Product Development	Manufacturing of dosage forms for testing, FDA approval, clinical trials
Quota Revision Request	Any submitted request that occurs after the initial quota request for the calendar year has been submitted and/or granted.
Quota Type	Bulk manufacturing, procurement, or importation
Quota Year	Calendar year for which the requested and/or granted quota is valid
Reference Number	Unique identification number generated when a request is submitted
Strength	The dosage of controlled substance per unit
Substance Conversion	The process by which two (2) or more controlled substances and/or listed chemicals are combined to manufacture a different substance. The new substance may or may not be itself subject to control by the DEA.
Supporting Document	A document submitted in support of a quota application.
Username	The user account name used to differentiate between one user account and another, provided by the corporate administrator.

B.0 Acronyms

Acronym	Definition
AAN	Assessment of Annual Needs
API	Active Pharmaceutical Ingredient
APQ	Aggregate Production Quota
CMEA	Combat Methamphetamine Epidemic Act
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DRQ	UN Reporting and Quota Section
PDF	Portable Document Format
US	United States

MEMORANDUM OF UNDERSTANDING

Between the

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

And the

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

For the

SHARING OF INFORMATION

I. PREAMBLE

Pursuant to this Memorandum of Understanding ("MOU" or "Agreement"), the Center for Drug Evaluation and Research ("CDER"), as part of the Food and Drug Administration ("FDA") within the Department of Health and Human Services ("DHHS"), and the Drug Enforcement Administration ("DEA"), as part of the Department of Justice ("DOJ"), both United States Federal Government entities agree that CDER and the DEA Office of Diversion Control ("OD") may share information in areas of mutual concern, consistent with their distinct legislative mandates as defined by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, the Public Health Service Act, 42 U.S.C. §§ 201 *et seq.*, and the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* CDER and OD will hereinafter jointly be referred to as the "Federal Partners."

FDA and DEA are federal agencies within two different departments, DHHS and DOJ, with related statutory mandates and responsibilities.

FDA is a regulatory agency responsible for promoting and protecting the public health by ensuring the safety of drugs. FDA administers the Federal Food, Drug, and Cosmetic Act and relevant sections of the Controlled Substances Act. Among its responsibilities, FDA approves new drug applications ("NDAs") and abbreviated new drug applications ("ANDAs"), conducts inspections of manufacturing facilities, and monitors post-marketing data to identify and evaluate adverse events and mitigate and help prevent drug shortages. FDA also has responsibilities that specifically relate to controlled substances and require collaboration with DEA including the following: evaluating schedule I research protocols for scientific merit; providing scientific and medical evaluation and scheduling recommendations for drugs under consideration for control; and providing

information for DEA's calculation of estimates of U.S. medical and scientific stock needs for schedule I and II substances.

DEA is a federal agency responsible for enforcing the controlled substance laws and regulations of the United States. Among its responsibilities, DEA coordinates and cooperates with federal, state, and local law enforcement officials on mutual drug enforcement efforts and investigates and prepares for the prosecution of major violators of controlled substance laws. Among its regulatory roles, DEA is responsible for domestic drug and chemical control, setting and implementing quotas for schedule I and II substances and certain listed chemicals, issuing DEA registrations to handle controlled substances, and preventing the diversion of controlled substances from the legitimate market. Under 21 U.S.C. § 873(a), the Attorney General is directed to cooperate with "local, State, tribal, and Federal agencies concerning traffic in controlled substances and in suppressing the abuse of controlled substances," including through the exchange of information between government officials. This responsibility has been delegated to the Administrator of DEA in 28 C.F.R. § 0.100(b). Additionally, 28 C.F.R. § 0.103(a)(1) authorizes the Administrator of DEA "[t]o release information obtained by DEA and DEA investigative reports to Federal . . . officials engaged in the enforcement of laws related to controlled substances." Accordingly, DEA has clear regulatory authority to share information with FDA and other Federal entities, although DEA understands that nothing in this regulatory authority should be construed to contravene DEA's agreement in this MOU section IV.A that it will not disclose information provided to it by CDER.

II. PURPOSE AND GOALS

As described above, the FDA and DEA missions are related in a variety of ways. This MOU is intended to create a mechanism to facilitate timely sharing of information, and to build upon and establish additional collaborative efforts between the Federal Partners.

III. SUBSTANCE OF MOU

A. Procedure Governing Information Exchanges

In an effort to achieve the goals described above, the undersigned agree to the following procedure for exchanging information:

1. **Periodic Meetings:** The Federal Partners will meet periodically for the purpose of discussing information exchanges between the Federal Partners. These meetings will be attended by at least one Authorized Official (as defined in section III.A.2 below) representing each Federal Partner. For the first year after the approval of this MOU, as described in section IX below, the meetings will be held quarterly, and thereafter on a biannual basis. Consistent with the waiver and amendment provision of this MOU in section VIII below, the frequency of these meetings may be increased or decreased.

2. **Authorized Officials:** The Director of CDER or his or her designee shall designate one or more Authorized Officials for CDER. The Deputy Assistant Administrator, OD,

shall appoint one or more Authorized Officials for OD. The Authorized Officials shall be authorized to discuss and approve the procedures for information exchanges pursuant to this MOU, including the approval of Workplans, as discussed in section III.A.3 below. Each Federal Partner will provide a list of its Authorized Officials to the other Federal Partner and will update such list whenever Authorized Officials change.

3. Workplans of Organizational Components within FDA/CDER and DEA/OD: Any exchange of information between the Federal Partners or their organizational components, except as authorized by sections VI and VII below, shall be consistent with a written, approved workplan that describes specific information exchanges and procedures for implementing such exchanges ("Workplan"). The Federal Partners may approve Workplans at the periodic meetings referred to in section III.A.1 by agreement of an Authorized Official of each Federal Partner or by another method mutually agreed to by an Authorized Official of each Federal Partner. All Workplans must comply with applicable law as well as the terms and conditions of this MOU. Once a Workplan is approved by an Authorized Official of Each Federal Partner, as documented by their signatures on the original Workplan, the Federal Partners may begin sharing information pursuant to that Workplan immediately.

4. Persons Authorized to Exchange Information: Workplans will include the designation of one or more Authorized Contact Persons who will serve as primary points of contact for information exchanges between the Federal Partners. The names of all Authorized Contact Persons, along with their contact information, must be identified in the Workplan or as an Addendum to it and the names and contact information must be kept up-to-date at all times.

5. Timely Sharing of Information: Information exchanged pursuant to this MOU (including under accepted Workplans) will be exchanged in a timely manner, considering agency priorities and resources. Any instances of undue delay may be reported to an Authorized Official of each Federal Partner.

However, the undersigned acknowledge that each Federal Partner may be limited in its ability to share information or expertise in response to a particular request for several reasons, for example: agency priorities, resources, and statutory or regulatory prohibitions. In the event that an Authorized Contact Person within one of the Federal Partners determines that he/she cannot share certain information sought by the other Federal Partner, the Authorized Contact Person may refer the issue to Authorized Officials of CDER and OD, if necessary. If the Authorized Officials are unable to reach an understanding, then the matter may be escalated to the Director of CDER and the Deputy Assistant Administrator, OD.

6. Methods of Sharing Information: The Federal Partners may share information in the following ways: in writing (including in electronic form and e-mail) and verbally (whether in in-person meetings or by telephone, video-conferencing or other electronic means).

a. Exchanges of Information in Written Form

When an Authorized Contact Person requests information, documents, or data in written form, the request should be made in writing, which may include an informal email. The following language should be included in the request:

> "Information that is shared under this request will be under the 2015 CDER-DEA Memorandum of Understanding for the Sharing of Information. We agree not to further disclose any shared information in any manner without your written permission or, if such disclosure is required by law, without advance notice to the originating agency."

With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

The response to such request should also be in writing, but it, too, can be an informal e-mail that acknowledges transmission of information in response to the request. The following language should be included in the response:

> "This communication acknowledges that information is being shared pursuant to the 2015 CDER-DEA Memorandum of Understanding for the Sharing of Information. The shared information may not be further disclosed in any manner without our express written consent or, if such disclosure is required by law, without advance notice to the originating agency."

With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.

b. Exchanges of Information in Meetings and other Verbal Communications

The Federal Partners may exchange information at meetings of the Federal Partners (whether in person or by telephone, videoconference or other electronic means). Approved Workplans will address such situations.

Meeting notices, announcements, and any agendas for such meetings will include the following language:

> "Information shared during this meeting will be pursuant to the 2015 CDER-DEA Memorandum of Understanding for the Sharing of Information. Such information may not be further disclosed or shared in any manner without the express written consent of the originating agency or, if such disclosure is required by law, without advance notice to the originating agency."

Any verbal exchanges of the Federal Partners made pursuant to the MOU will be prefaced by the language above.

7. Tracking of Information Exchanges: The Federal Partners will allow for tracking of information exchanges between them. To this end, the CDER Authorized Official will

ensure that CDER's Executive Operations Staff ("CDER EXECSEC") (or its successor, designee, or other FDA office designated by CDER's Director) is made aware of all written requests for information received from DEA and all written information provided to DEA by any of FDA's organizational components pursuant to this MOU (including under approved Workplans). CDER EXECSEC's tracking may include the establishment of a mailbox or electronic notification system. Workplans must provide a procedure for verbal exchanges to be documented by CDER.

DEA will establish a specific mailbox for DEA to track information exchanges between the Federal Partners.

8. Prohibited Exchange of Information Between the Federal Partners: All information exchanges between the Federal Partners must be made in accordance with applicable laws, regulations, and policies, this MOU and, except in the circumstances discussed in sections VI and VII below, in accordance with a Workplan. Any information exchanges that are not made in accordance with applicable laws, regulations, and policies, this MOU and any relevant Workplan are not permitted and are considered prohibited exchanges. Any information exchanged in such prohibited exchanges must still be safeguarded and protected as discussed in section IV.A of this MOU.

Each Federal Partner has an affirmative obligation to notify affected personnel of their responsibilities and obligations under this MOU and any related Workplan in order to prevent prohibited exchanges.

9. Mitigation of Prohibited Exchanges & Disclosures: The undersigned agree that confidential and other non-public information (directly or indirectly (*i.e.*, through verbal or written communication, conduct or any other means)) that is not disclosed in accordance with applicable laws, regulations, policy, this MOU, and any relevant Workplan (whether disclosed directly or indirectly (i.e., through verbal or written communication, conduct, or any other means)) may be detrimental to agency activities and may interfere with the Federal Partners' ability to protect personal privacy, confidential and/or trade secret information. Accordingly, if a Federal Partner becomes aware of a prohibited exchange or disclosure, whether made to the other Federal Partner or to a third-party, it will immediately notify an Authorized Official of the other Federal Partner, providing the content of the prohibited exchange or disclosure, the identity of the person by whom it was made, the identity of the person to whom it was made, and the date on which it occurred. The Federal Partners will work with one another to develop and implement a plan to remedy the prohibited exchange or disclosure, taking into consideration the Federal Partners' responsibility to preserve documents and records in accordance with applicable law or legal process.

10. This MOU supersedes in its entirety the Memorandum of Understanding Between the Drug Enforcement Administration and the Food and Drug Administration dated July 1, 1974.

B. Substance of Information to be Exchanged Under this Agreement

The undersigned agree that information exchanges between the Federal Partners are important to their ability to successfully carry out their statutory and regulatory responsibilities. Toward that end, this MOU is intended to provide a means for establishing and defining procedures by which information is to be exchanged between the Federal Partners and to enhance the Federal Partners' collaboration. Each Workplan will detail the specific information that may be exchanged.

IV. GENERAL PROVISIONS

A. Safeguarding & Limiting Access to Shared Information

The undersigned recognize that information exchanged that contains any of the following types of information must be protected from unauthorized use and disclosure:

(1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA);

(2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA;

(3) information compiled for law enforcement purposes, such as information that would be protected from public disclosure pursuant to Exemption 7 of the FOIA; or

(4) information that is otherwise protected from public disclosure by federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 USC 1905), the Privacy Act (5 USC 552a), other Freedom of Information Act exemptions not mentioned above (5 USC 552(b)), the Federal Food, Drug, and Cosmetic Act (21 USC 301 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191).

Pursuant to Federal Food, Drug, and Cosmetic Act section 301(j) (21 USC 331(j)), FDA will not reveal to DEA any method or process which is entitled to protection as a trade secret.

The Federal Partners will ensure that information shared under this MOU shall be used and disclosed solely in accordance with applicable laws, regulations, and policies. Access to the information shared under this MOU shall be restricted to authorized employees and contractors of the Federal Partners who require access to perform their official duties in accordance with the uses of information as authorized by this MOU and any related Workplan. Such personnel shall be advised of (1) the necessity to safeguard and limit access to the information, and (2) the administrative, civil, and criminal penalties for noncompliance contained in applicable federal laws. Contractors of the Federal Partners who will receive access to the information shared under this MOU will

sign the non-disclosure agreement included in Appendix A. Each Federal Partner will maintain on file non-disclosure agreements signed by its contractors.

If either Federal Partner receives a FOIA request for information provided by the other Federal Partner pursuant to this MOU or a related Workplan, the Federal Partner receiving the FOIA request will refer the request to the Federal Partner that provided the information to respond directly to the requestor. The Federal Partner that refers the request will notify the requestor that a referral has been made to the other Federal Partner and that a response will issue directly from the other Federal Partner. In such cases where the Federal Partner has incorporated another Federal Partner's information in a responsive record, the Federal Partner should consult with the Federal Partner whose information appears in the responsive records.

Nothing in this MOU shall be construed to prevent a disclosure required by law or legal process. Notwithstanding this provision, should information shared pursuant to this MOU (including under approved Workplans) be subpoenaed or otherwise ordered through a legal process, the Federal Partner to whom the subpoena or order is directed will notify an Authorized Official of the other Federal Partner immediately to provide an opportunity to seek to intervene and block the disclosure.

Termination of this MOU or any related Workplans does not relieve either of the Federal Partners of their obligation to safeguard, protect, and limit access to the shared information established under section IV of this MOU or any related Workplan.

B. Effect on Existing Statutes and Regulations

Each Federal Partner will take actions under this collaboration that are consistent with existing laws, regulations, and policies, and nothing in the MOU shall be construed as changing the current requirements under the statutes and regulations administered and enforced by the Federal Partners including but not limited to: Titles 21 and 42 of the United States Code, the Public Health Service Act, and the Federal Food, Drug, and Cosmetic Act. Further, nothing contained in this MOU constitutes a mandate or a requirement that is additional to the mandates or requirements imposed on the Federal Partners by federal statutes, regulations, and policies.

V. RESOURCE OBLIGATIONS

This MOU represents the broad outline of the intent that the Federal Partners will enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to them. It does not create binding, enforceable obligations against any party. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect the ability of the Federal Partners to enter into other agreements or arrangements related to this MOU. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the Federal Partners operate.

VI. EMERGENCY CIRCUMSTANCES

In certain emergency circumstances, as that term is understood and agreed upon by the Director of CDER and the Deputy Assistant Administrator, OD, information can be exchanged between the Federal Partners without the need for a Workplan governing the information exchange if the exchange is mutually agreed upon by the Director of CDER and the Deputy Assistant Administrator, OD. However, even in such emergency circumstances, the General Provisions under section IV and the limitations on information sharing in section III.A.6 remain applicable.

VII. EXCHANGES PRIOR TO THE DEVELOPMENT OF WORKPLANS

The undersigned acknowledge that after the execution of this MOU it may take some time to develop the Workplans required pursuant to section III.A.3. While the Federal Partners agree to work expeditiously toward the completion of those Workplans, the undersigned also agree that, until such Workplans are established, information exchanges that are necessary and appropriate to the respective missions of the Federal Partners may take place pursuant to 21 CFR 20.85 and 21 U.S.C. § 873(a).

VIII. WAIVER AND AMENDMENT

The requirements of this MOU including, but not limited to, the number and frequency of meetings required by section III.A.1 and the obligation to safeguard and protect the information required by section IV, may be waived or amended by the mutual written agreement of the Director of CDER and the DEA Administrator, but neither Federal Partner can waive requirements or restrictions imposed by Federal law. The requirements of any related Workplans may be waived or amended by the mutual written agreement of the Director of CDER and the Deputy Assistant Administrator, OD, or by Authorized Officials, pursuant to the same limitations. The Federal Partners' failure to enforce or abide by any requirement of this MOU (or any requirement of any Workplan approved hereunder), whether once or repeatedly, is not to be construed as a waiver of the requirement and cannot be deemed to alter or amend the MOU (or any Workplan approved hereunder).

IX. TERM, TERMINATION AND MODIFICATION

This agreement, when accepted by the undersigned, will have an effective period of performance from the date of the latest signature until three years from that date and may be modified or terminated by mutual written consent by both parties or may be terminated by either party upon a thirty day advance written notice to the other.

Approved for the
Drug Enforcement Administration

Michele Leonhart

By: Michele M. Leonhart
Administrator
Drug Enforcement Administration

Michele M. Leonhart
Print Name

2/27/15
Date

Approved for the
Food and Drug Administration

By: Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Janet Woodcock
Print Name

3/24/15
Date

APPENDIX A
Non-Disclosure Agreement for Contractors

Access to information shared under to the Memorandum of Understanding ("MOU" or "Agreement"), the Center for Drug Evaluation and Research ("CDER"), as part of the Food and Drug Administration ("FDA") within the Department of Health and Human Services ("DHHS"), and the Drug Enforcement Administration ("DEA"), as part of the Department of Justice ("DOJ"), dated [**insert date**], is required to perform my official duties under the contractual agreement with my employer, in accordance with the uses of information as authorized by the MOU and any related Workplan. I am an authorized contractor of FDA or DEA.

I recognize that information exchanged that contains any of the following types of information must be protected from unauthorized use and disclosure:

(1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA);
(2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA;
(3) information compiled for law enforcement purposes, such as information that would be protected from public disclosure pursuant to Exemption 7 of the FOIA; or
(4) information that is otherwise protected from public disclosure by federal statutes and their implementing regulations (e.g., Trade Secrets Act (18 USC 1905), the Privacy Act (5 USC 552a), other Freedom of Information Act exemptions not mentioned above (5 USC 552(b)), the Federal Food, Drug, and Cosmetic Act (21 USC 301 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191).

I have been advised of (1) the necessity to safeguard and limit access to the information, and (2) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws.

I, on this _____ day of _____, 20__, hereby agree that I shall not further release, publish, or disclose information shared under this MOU without the express written consent of the originating agency or, if such disclosure is required by law, without advance notice to the originating agency. I shall protect such information in accordance with applicable laws and regulations governing the confidentiality of non-public information.

Signature: _____ Date: _____
Type or Print Name _____