(b)(4)

(b)(4)

CONFIDENTIAL

MAY 19 RECD

May 16, 2014

~~MAY 19 RECD~~
JB

Ms. Christine A. Sannerud, Ph.D.
Drug Enforcement Administration
Drug & Chemical Evaluation (ODE)
8701 Morrissette Drive
Springfield, VA 22152

Subject: (b)(4);(b)(7)(E) requests Reclassification of Codeine (for conversion) Inventory

Dear Dr. Sannerud:

(b)(4) manufacturing registration (b)(4);(b)(7)(E) requests the DEA allow us to reclassify 694,518 grams as base of Codeine (for conversion) to Codeine (for sale).

We produce a material at the (b)(4) site called codeine alkaloid technical (CAT). The problem we have is the CAT produced at (b)(4) cannot be used in the production of Codeine Phosphate due to our DMF filings, so all CAT production for codeine phosphate is produced in the (b)(4) site. Our customer (b)(4) (manufacturing registration number (b)(4);(b)(7)(E) has expressed an interest in purchasing Codeine Phosphate for a grandfathered codeine antitussive application, meaning we can use the CAT produced for (b)(4) site.

Between (b)(4) we have a large inventory of material. In 2012 we were producing CAT for conversion into Hydrocodone Bitartrate, and we planned on selling tons of this material to (b)(4) as per our contract. (b)(4) backed off on ordering Hydrocodone Bitartrate, leaving us with a large inventory. Because we are not producing any Hydrocodone Bitartrate this year (or next year), we would like to take two batches of CAT in inventory at (b)(4) (b)(4) that is in the quota classification as Codeine (for conversion), and call it Codeine (for sale). Once the DEA grants the permission, the reclassified CAT will undergo a purification process and be converted into Codeine Phosphate.

We request the DEA consider the information presented and allow (b)(4) to reclassify up to 694,518 grams of CAT produced as Codeine (for conversion) to Codeine (for sale). This will allow us to avoid production of Codeine (for sale) starting material and reduce our inventory of the recently slow moving Codeine (for conversion) material.

Thank you for your consideration in this matter. Should you have any questions, please contact me at (b)(6)

(b)(4) considers this commercial information privileged and confidential. We believe the release of this information will likely cause (b)(4) substantial competitive harm.

Very truly yours,

(b)(6)

DEA Materials Control Manager

(b)(4)

Substance	2011	2012	% Change	2013	% Change	2014*	% Change
Amphetamine (D,L)	**9,703.48**	**10,938.95**	**12.73%**	**10,928.20**	**-0.10%**	**11,921.39**	**9.09%**
Amphetamine (D)	**10,597.70**	**11,725.30**	**10.64%**	**11,597.10**	**-1.09%**	**12,584.00**	**8.51%**
Cocaine	48.53	44.03	-9.28%	39.63	-9.99%	37.17	-6.21%
Codeine	26,170.71	22,758.28	-13.04%	21,716.68	-4.58%	22,238.38	2.40%
Dihydrocodeine	107.21	75.02	-30.03%	36.22	-51.72%	6.76	-81.33%
Diphenoxylate	462.60	413.01	-10.72%	406.20	-1.65%	382.07	-5.94%
Dronabinol	110.82	106.13	-4.24%	110.92	4.52%	115.78	4.38%
Ephedrine	1,535.52	1,973.12	28.50%	2,083.14	5.58%	2,203.60	5.78%
Fentanyl	539.85	575.07	6.53%	548.23	-4.67%	544.38	-0.70%
Hydrocodone	**64,933.52**	**63,163.25**	**-2.73%**	**61,575.69**	**-2.51%**	**59,479.05**	**-3.40%**
Hydromorphone	1,675.27	1,912.39	14.15%	1,926.07	0.72%	1,857.15	-3.58%
Levorphanol	0.32	1.54	378.02%	2.33	51.13%	2.53	8.41%
Lisdexamfetamine	**12,336.18**	**14,001.29**	**13.50%**	**13,653.65**	**-2.48%**	**14,525.01**	**6.38%**
Meperidine	2,303.07	1,885.59	-18.13%	1,537.31	-18.47%	1,364.13	-11.27%
Methadone	7,639.42	6,776.34	-11.30%	5,804.38	-14.34%	5,531.24	-4.71%
Methamphetamine	13.86	14.40	3.87%	13.09	-9.11%	12.48	-4.65%
Methylphenidate	**19,212.63**	**19,534.84**	**1.68%**	**17,949.13**	**-8.12%**	**18,613.58**	**3.70%**
Morphine	30,435.83	28,705.35	-5.69%	26,266.30	-8.50%	25,445.23	-3.13%
Nalbuphine	61.42	63.60	3.55%	42.02	-33.93%	39.88	-5.08%
Naloxone	391.27	430.32	9.98%	478.98	11.31%	497.20	3.80%
Naltrexone	4.56	0.00	-99.98%	0.00	-100.00%	0.00	0.00%
Opium	84.96	81.02	-4.63%	77.44	-4.42%	77.41	-0.03%
Oxycodone	**70,885.82**	**66,702.94**	**-5.90%**	**60,308.91**	**-9.59%**	**59,796.79**	**-0.85%**
Oxymorphone	**2,655.74**	**1,958.25**	**-26.26%**	**1,865.58**	**-4.73%**	**1,951.68**	**4.62%**
Pentazocine	839.71	698.43	-16.82%	563.20	-19.36%	411.38	-26.96%
Pentobarbital	79.12	46.62	-41.07%	24.25	-47.99%	29.66	22.34%
Pseudoephedrine	104,476.73	93,931.68	-10.09%	93,125.29	-0.86%	100,386.58	7.80%
Remifentanil	1.05	1.11	5.83%	1.16	5.09%	1.20	3.53%
Secobarbital	20.78	15.67	-24.59%	11.98	-23.55%	10.48	-12.52%
Sufentanil	0.05	0.05	-2.53%	0.05	-7.93%	0.04	-24.36%

*Estimates based on Jan-Mar 2014 Data

Basic Class: 9737-0
Total PQ Requested: 194.000

2015 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc
(b)(4);(b)(7)(E)		2.000	2.000	0.000	5,836.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500
		12,320.000	14,080.000	5,836.000	5,836.000	1.000	194.000	8,937.000	11,000.000	13,200.000	0.000	8,836.000	17,262.750
MQ Totals:		12,322.000	14,082.000										

2014 Final Initial APQ:	14,100.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	14,100.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	14,100.000
2015 Proposed Initial APQ:	14,100.000
with 25% buffer:	17,625.000

Basic Class: 9602-0

2015 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc
(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
MQ Totals:		2.000	2.000										

2014 Final Initial APQ:	2.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	2.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	2.000

Basic Class: 9743-0

Total PQ Requested: 5.000

2015 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	2014 DEA Projected Inventory	Adj Avail Calc
(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
		5.000	5.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	0.000	4.000	4.000	3.750
MQ Totals:		10.000	10.000											

2014 Final Initial APQ:	15.000
2014 Final Revised APQ:	0.000
FDA Est: [2014 Initial APQ * 1 + FDA Est]:	15.000
IMS Est: [2014 Initial APQ * 1 + IMS Est]:	15.000

Basic Class: 9050-A
Total PQ Requested: 4,230,005.000

2015 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Num	2015 Requested MQ	MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	2014 DEA Projected Inventory	Adj Avail Calc
(b)(4);(b)(7)(E)		5.000	0.000	0.000	36,250,765.000	0.000	0.000	0.000	0.000	5.000	0.000	1.000	-5.000	0.000
		30,000,000.000	24,506,599.000	29,406,047.000	36,250,765.000	0.811	3,431,313.128	7,534,825.000	0.000	30,216,718.000	0.000	9,756,452.000	1,624,709.000	24,031,070.250
MQ Totals:		30,000,005.000	24,506,599.000											

2014 Final Initial APQ: 55,000,000.000
2014 Final Revised APQ: 0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est): 55,000,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est): 55,000,000.000

Note: [redacted] in letter dated May 16, 2014, stated that they have more API on hand than expected because [redacted] cancelled their purchase of hydrocodone

2015 Proposed Initial APQ: 40,000,000.000
with 25% buffer: 50,000,000.000

(b)(4)

(b)(4)

Basic Class: 9050-S

Total PO Requested: 24,230,293.940

2015 Initial APQ Worksheets

FDA Est:

INS Est:

Company	DEA Num	2015 Requested MQ	MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	2014 DEA Projected Inventory	Adj Avail Calc
(b)(4);(b)(7)(E)		5.000	5.000	0.000	26,011,178.528	0.000	0.000	1.600	0.000	5.000	0.000	1.600	1.600	5.100
		100.000	100.000	1.039	26,011,178.528	0.000	0.968	43.893	0.000	25.000	0.000	104.093	117.893	107.920
		628,000.000	0.000	0.000	26,011,178.528	0.000	0.000	0.000	0.000	558,670.000	0.000	0.000	-558,670.000	0.000
		722,000.000	148,000.000	106,667.000	26,011,178.528	0.004	99,363.824	456,397.000	0.000	296,000.000	0.000	234,397.000	308,397.000	453,797.750
		11,600,000.000	13,145,613.000	12,022,449.000	26,011,178.528	0.462	91,199,318.510	5,121,283.000	150,220.000	10,903,400.000	0.000	5,602,152.000	7,283,276.000	13,737,672.000
		24,701,000.000	17,231,565.000	13,170,419.000	26,011,178.528	0.506	12,268,691.453	5,127,800.000	0.000	18,717,000.000	0.000	8,596,000.000	3,642,365.000	16,768,523.750
		1,000.000	1,000.000	1.338	26,011,178.528	0.000	1.239	0.000	0.000	1,000.000	0.000	0.000	0.000	750.000
		4,935,000.000	2,554,914.000	711,641.000	26,011,178.528	0.027	662,917.699	0.000	0.000	3,476,000.000	0.000	147,330.000	-822,086.000	1,916,165.500
MQ Totals:		42,287,105.000	33,081,197.000											

2014 Final Initial APQ:	36,900,000.000
2014 Final Revised APQ:	0.000
FDA Est (2014 Initial APQ * 1 + FDA Est):	36,900,000.000
INS Est (2014 Initial APQ * 1 + INS Est):	36,900,000.000
2015 Proposed Initial APQ:	36,900,000.000
with 25% buffer:	46,125,000.000

Basic Class: 9273-0

2015 Initial APQ Worksheets

Total PQ Requested: 90.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	2014 DEA Projected Inv	Adj Avail Calc
(b)(4);(b)(7)(E)		5.000	5.000	0.000	1,572,158.567	0.000	0.000	0.000	0.000	4.000	0.000	0.000	1.000	3.750
		10.000	10.000	0.567	1,572,158.567	0.000	0.000	6.088	0.000	1.000	0.000	84.286	15.056	12.085
MQ Totals:		15.000	15.000											

2014 Final Initial APQ:	15.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	15.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	15.000
2015 Proposed Initial APQ:	15.000
with 25% buffer:	18.750

Basic Class: 9120-9

2015 Initial APQ Worksheets

Total PQ Requested: 8,113.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	7,988,764	0.000	0.000	0.000	0.000	5.000	0.000	1.000	3.750	1.250
		5.000	5.000	0.764	7,988,764	0.000	0.872	14.945	0.000	3.000	0.000	15.945	14.959	17.817
		60,000.000	60,000.000	7,987.000	7,988,764	1.000	9,110.988	202,423.000	0.000	50,250.000	0.000	164,963.000	211,817.250	241,283.968
		1,000.000	250.000	0.200	7,988,764	0.000	0.228	136.960	0.000	1,000.000	0.000	0.000	290.220	575.825
MQ Totals:		61,010.000	60,260.000											241,878.879

2014 Final Initial APQ:	60,600.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	60,600.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	60,600.000
2015 Proposed Initial APQ:	61,100.000
with 25% buffer:	101,375.000

Basic Class: 0120-0

Total PQ Requested: 9,113.000

2016 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc
(b)(4);(b)(7)(E)		5.000	5.000	0.000	7,988.764	0.000	0.000	0.000	0.000	5.000	0.000	1.000	3.750
		5.000	5.000	0.764	7,988.764	0.000	0.872	14.645	0.000	3.000	0.000	15.946	14.959
		80,000.000	80,000.000	7,987.000	7,988.764	1.000	9,110.968	202,423.000	0.000	50,250.000	0.000	164,963.000	211,817.250
		1,000.000	250.000	0.209	7,988.764	0.000	0.228	136.960	0.000	1,000.000	0.000	0.000	290.220
MQ Totals:		81,010.000	80,260.000										

2014 Final Initial APQ:	80,600.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	80,600.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	80,600.000

2015 Proposed Initial APQ:	81,100.000
with 25% buffer:	101,375.000

Basic Class:

2015 Initial APQ Worksheets

Total PQ Requested: 1,000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Aval Calc
(b)(4);(b)(7)(E)		2,000	2,000	0.000	702,222.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500
		27,900.000	0.000	465.000	702,222.000	0.001	0.001	13,489.000	0.000	27,900.000	0.000	13,455.000	10,118.750
		620,000.000	580,000.000	701,757.000	702,222.000	0.999	0.999	285,969.000	18,400.000	570,400.000	0.000	334,783.000	649,476.750
MQ Totals:		647,902.000	580,002.000										

2014 Final Initial APQ:	600,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	600,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	600,000.000

2015 Proposed Initial APQ: 1,070,000.000 based on 2014 pending revised APQ and (b)(4) initial low request value in 2014

with 25% buffer: 1,337,500.000

Basic Class: 9180-0

2015 Initial APQ Worksheets

Total PQ Requested: 5.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc
(b)(4);(b)(7)(E)		2.000	2.000	0.206	0.206	1.000	5.000	0.744	0.000	0.800	0.000	1.944	2.058
MQ Totals:		2.000	2.000										

2014 Final Initial APQ:	2.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	2.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	2.000

Basic Class: [illegible]

2015 Initial APQ Worksheets

Total PQ Requested: 1,002,276,255

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc
(b)(4);(b)(7)(E)		5.000	5.000	0.000	998,926.931	0.000	0.000	0.101	0.000	4.000	0.000	1.000	3.626
		200,000.000	151,000.000	36,960.000	998,926.931	0.037	37,083.924	53,892.000	0.000	200,000.000	0.000	50,000.000	153,669.000
		2.000	2.000	0.538	998,926.931	0.000	0.543	1.010	0.000	0.500	0.000	1.711	2.256
		13,330.000	14,151.000	9,082.000	998,926.931	0.009	9,112.451	103.000	0.000	13,330.000	0.000	1,000.000	10,690.500
		475,000.000	461,271.000	245,042.000	998,926.931	0.245	245,863.607	230,549.000	0.000	445,120.000	0.000	266,183.000	518,865.000
		670,000.000	610,000.000	645,039.000	998,926.931	0.646	647,201.765	298,686.000	122,050.000	850,527.000	0.000	388,205.000	831,514.500
		33,000.000	18,000.000	4,460.000	998,926.931	0.004	4,474.954	17,597.000	0.000	33,000.000	0.000	13,000.000	25,197.750
		13,500.000	6,500.000	0.000	998,926.931	0.000	0.000	0.000	0.000	6,500.000	0.000	7,214.900	4,950.000
MQ Totals:		1,604,837.000	1,459,029.000										

2014 Final Initial APQ:	1,687,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	1,687,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	1,687,000.000
2015 Proposed Initial APQ:	1,687,000.000
with 25% buffer:	2,108,750.000

Basic Class: 9193-A
Total PQ Requested: 5.000

2015 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	4.000	0.000	1.000	0.000	4.000
		101,000.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	81,000.000	0.000	10,000.000	0.000	81,000.000
MQ Totals:		101,005.000	0.000											81,004.000

2014 Final Initial APQ:	0.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	0.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	0.000
2015 Proposed Initial APQ:	110,000.000
with 25% buffer	137,500.000

Basic Class: 9193-B

Total PQ Requested: 92,877,262.749

2015 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	45,068,169.355	0.000	0.000	0.051	0.000	4.000	0.000	1.000	3.758	0.399
		200,000.000	99,400.000	0.000	45,068,169.355	0.000	0.000	0.000	0.000	200,000.000	0.000	60,000.000	74,550.000	125,450.000
		20.000	20.000	3.375	45,068,169.355	0.000	7.367	74.093	0.000	5.000	0.000	69.094	70.570	95.450
		388,000.000	175,079.000	39,742.000	45,068,169.355	0.001	81,901.001	12,258.000	0.000	386,000.000	0.000	5,000.000	140,502.750	344,809.001
		29,000,000.000	13,274,159.000	22,852,826.000	45,068,169.355	0.507	47,095,499.004	7,741,874.000	12,200.000	23,464,731.000	0.000	8,102,029.000	20,261,302.750	26,000,000.000
		3,602,000.000	1,885,910.000	148,721.000	45,068,169.355	0.003	306,486.809	2,031,879.000	0.000	3,100,000.000	0.000	1,983,000.000	2,536,410.000	36,706.011
		25,002,000.000	22,658,367.000	18,079,428.830	45,068,169.355	0.401	37,250,155.898	3,655,635.900	0.000	29,002,000.000	0.000	5,566,000.000	19,960,302.175	29,002,000.000
		10,000,000.000	2,184,719.000	605,442.000	45,068,169.355	0.013	1,247,705.343	2,209,940.000	0.000	8,456,000.000	0.000	6,600,000.000	3,295,894.250	4,167,152.429
		11,600,000.000	6,981,532.000	103,852.000	45,068,169.355	0.002	214,018.997	3,845,502.000	0.000	9,150,000.000	0.000	1,203,500.000	8,120,275.500	8,120,275.500
MQ Totals:		80,790,025.000	53,559,191.000											67,796,489.600

2014 Final Initial APQ: 79,700,000.000

2014 Final Revised APQ: 0.000

FDA Est (2014 Initial APQ * 1 + FDA Est): 79,700,000.000

IMS Est (2014 Initial APQ * 1 + IMS Est): 79,700,000.000

Basic Class: 9150-0

Total PQ Requested: 5,247,008,428

2015 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5,000	5,000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	4,000	0.000	1,000	3.750	5,000
		64,080.000	78,700.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	50,000.000	0.000	28,000.000	57,525.000	64,080.000
		30.000	30.000	2.921	3,574,775.079	0.000	4.287	49,447	0.000	14.000	0.000	63.848	59.586	30.000
		116,000.000	78,000.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	812,470.000	0.000	0.000	58,500.000	116,000.000
		625,176.000	535,996.000	679,938.334	3,574,775.079	0.190	998,004.655	209,218.035	5,900.000	568,344.000	0.000	130,000.000	558,912.026	568,344.000
		356,000.000	445,000.000	334,715.000	3,574,775.079	0.094	491,290.329	251,602.000	0.000	356,000.000	0.000	251,600.000	322,451.500	356,000.000
		1,180,000.000	1,179,510.000	997,252.000	3,574,775.079	0.279	1,463,753.533	392,659.000	1,760.000	837,820.000	0.000	535,939.000	1,179,501.750	1,180,000.000
		2,060,000.000	1,674,810.000	1,389,805.400	3,574,775.079	0.389	2,039,936.314	855,997.550	0.000	2,059,000.000	0.000	924,000.000	1,398,111.663	2,060,000.000
		200,000.000	97,711.000	44,542.000	3,574,775.079	0.012	65,378.169	31,189.000	0.000	133,500.000	0.000	64,000.000	96,575.000	110,759.461
MQ Totals:		4,701,293.000	4,095,072.000											4,455,299.461

2014 Final Initial APQ:	5,400,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	5,400,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	5,400,000.000
2015 Proposed Initial APQ:	5,000,000.000
with 25% buffer	6,250,000.000

Basic Class: 9226-0

2015 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(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
MQ Totals:		2.000	2.000											1.500

2014 Final Initial APQ:	4.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	4.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	4.000

Basic Class: 9648-0

2015 Initial APQ Worksheets

Total PQ Requested: 0.003

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(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	1.512	1.500	1.500
MQ Totals:		2.000	2.000											1.500

2014 Final Initial APQ:	3.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	3.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	3.000

Basic Class: 9219-0

2015 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.330	0.330	1.000	0.000	2.038	0.000	1.500	0.000	1.538	3.027	2.538
MQ Totals:		2.000	2.000											2.538

2014 Final Initial APQ:	156.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	156.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	156.000
2015 Proposed Initial APQ:	4.000
with 25% buffer:	5.000

Basic Class: 9220-0

2015 Initial APQ Worksheets

Total PQ Requested: 4,197.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	1,907.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500	2.000
		2,600.000	1,598.000	1,907.000	1,907.000	1.000	4,197.000	42.000	6.000	2,094.000	0.000	1,210.000	1,230.000	2,600.000
MQ Totals:		2,602.000	1,600.000											2,602.000

2014 Final Initial APQ:	1,600.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	1,600.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	1,600.000

2015 Proposed Initial APQ:	2,700.000
with 25% buffer:	3,375.000

Basic Class: [illegible]

2015 Initial APQ Worksheets

Total PQ Requested: 1,692,004.767

FDA Est:

IMS Est: -.113

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	2,500,073.540	0.000	0.000	0.000	0.000	4.000	0.000	1.000	3.750	0.250
		5.000	5.000	1.540	2,500,073.540	0.000	0.000	1.842	4.791	0.000	1.000	0.000	7.343	9.833
		130,500.000	0.000	0.000	2,500,073.540	0.000	0.000	0.000	0.000	104,400.000	0.000	52,200.000	0.000	104,400.000
		1,150,000.000	710,000.000	329,151.000	2,500,073.540	0.132	222,763.474	93,062.000	0.000	1,000,000.000	0.000	220,000.000	602,311.500	652,872.343
MQ Totals:		1,280,510.000	710,010.000											757,282.426

2014 Final Initial APQ:	5,000,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	5,000,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	4,436,500.000

Other considerations:

[ ] has not submitted request as of 5-1-14, left voicemail 5-27-14 requesting update of business plans in 2015

On 5-30 [ ] submitted 2015 applications, meperidine request = 4,000kg, will leave APQ set from 2014

(b)(4)

(b)(4)

Basic Class: 9232-0

2015 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		3.000	3.000	0.000	0.000	0.000	0.000	0.000	0.000	0.200	0.000	2.600	2.250	2.800
MQ Totals:		3.000	3.000											2.800

2014 Final Initial APQ:	5.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	5.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	5.000

Basic Class: 9233-0

2015 Initial APQ Worksheets

Total PQ Requested: 1.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4):(b)(7)(E)		5.000	7.000	0.579	0.579	1.000	1.000	7.031	0.000	1.000	0.000	11.531	10.523	14.031
MQ Totals:		5.000	7.000											14.031

2014 Final Initial APQ:	9.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	9.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	9.000

Basic Class: 9234-0

2015 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		3.000	3.000	0.000	0.000	0.000	0.000	0.000	0.000	0.200	0.000	2.800	2.250	2.800
MQ Totals:		3.000	3.000											2.800

2014 Final Initial APQ:	5.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	5.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	5.000

Basic Class: 9240-0

2015 Initial APQ Worksheets

Total PQ Requested: 5.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	0.000	0.000	0.000	0.000	0.000	4.000	0.000	1.000	3.750	0.250
		5.000	5.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	0.000	4.000	3.750	4.000
MQ Totals:		10.000	10.000											4.250

2014 Final Initial APQ:	15.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	15.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	15.000

Basic Class: 9250.0

2015 Initial APQ Worksheets

Total PQ Requested: 18,334,767.887

FDA Est:

IMS Est: -.047

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	0.000	0.000	19,975,758.454	0.000	0.000	0.000	0.000	5.000	0.000	0.000	0.000	5.000
		10.000	10.000	1.454	19,975,758.454	0.000	1.335	6.841	0.000	5.000	0.000	11.349	12.631	13.176
		526,000.000	339,395.000	65,918.000	19,975,758.454	0.003	60.501.126	10,087.000	0.000	461,500.000	0.000	44,500.000	262,111.500	292,493.157
		15,000,000.000	19,155,194.000	11,396,608.000	19,975,758.454	0.571	10,460,399.245	3,456,715.000	44,830.000	14,105,610.000	0.000	5,997,352.000	10,208,931.750	15,000,000.000
		4,640,000.000	4,532,275.000	3,226,429.000	19,975,758.454	0.162	2,961,383.994	546,478.000	0.000	3,346,400.000	0.000	821,150.000	3,609,064.750	3,102,445.742
MQ Totals:		20,166,015.000	15,026,874.000											18,394,857.075

2014 Final Initial APQ: 25,500,000.000
2014 Final Revised APQ: 0.000
FDA Est (2014 Initial APQ * 1 + FDA Est): 25,500,000.000
IMS Est (2014 Initial APQ * 1 + IMS Est): 24,298,950.000

Other considerations:

(b)(4) is closing its facilities at the end of 2014
2014 MQ 6,376,000.000
2013 MQ 6,321,000.000

the new supplier(s) for their customer (b)(4) is not apparent at this time
sales in 2013 for (b)(4)
ARCOS 5,816,000.000
IMS 3,100,000.000

2014 PQ 5,673,785.000
2013 PQ 5,617,134.000

ARCOS 2014 top distributors receiving pq

Rank No.	Drug Name	Distributor's DEA No	Distributor's Name	Distributor's City	Distributor's State	Distributor's Division	Distributor's Office	Total Grams
1	METHADONE(9250)	(b)(4);(b)(7)(E)			NY	NEW YORK	ALBANY	1,786,320.723
2	METHADONE(9250)				FL	MIAMI	TAMPA	530,005.035
3	METHADONE(9250)				OH	DETROIT	COLUMBUS	529,141.798

2,845,497.556

Methadone

Measure : Tot Kg (Absolute)

	Tot Kg CalYr/12/2011	Tot Kg CalYr/12/2012	Tot Kg CalYr/12/2013
(b)(4)	3,764.8	4,115.1	3,100.0
	3,856.7	2,542.8	2,399.3
	0.0	98.8	281.7
	10.9	13.1	15.3
	6.9	6.5	7.9
	0.1	0.1	0.1
	0.0	0.0	0.0

27/05/14

Basic Class: 9254-0

2015 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		10.000	10.000	0.000	22,287,908.000	0.000	0.000	0.000	0.000	7.500	5.000
		1,148,000.000	822,975.000	194,755.000	22,287,908.000	0.009	0.000	66,287.000	0.000	666,946.500	1,025,700.000
		16,200,000.000	11,928,645.000	10,780,265.000	22,287,908.000	0.484	0.000	2,170,972.000	0.000	10,574,712.750	16,200,000.000
		4,960,000.000	5,070,739.000	4,002,598.000	22,287,908.000	0.180	0.000	1,258,126.000	0.000	4,746,648.750	4,960,000.000
MQ Totals:		22,308,010.000	17,822,369.000								22,185,705.000

2014 Final Initial APQ: 31,100,000.000
2014 Final Revised APQ: 0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est): 31,100,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est): 31,100,000.000

2015 Proposed Initial APQ: 27,500,000.000
% buffer: 34,375,000.000

(b)(4)

Other considerations:
(b)(4) has not requested MQ for 2014 or 2015
in 2013 (b)(4) MQ was 9,000kg was zero
not clear who has picked up (b)(4) customers, so add 50% of their 2013 quota to proposed APQ

Basic Class: 8300-A

2015 Initial APQ Worksheets

Total PQ Requested: 1,069,755.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	0.000	0.000	47,603,753.601	0.000	0.000	0.000	0.000	5.000	0.000	0.000	0.000	5.000
		749,000.000	0.000	0.000	47,603,753.601	0.000	0.000	0.000	0.000	749,000.000	0.000	0.000	0.000	749,000.000
		4,800,000.000	5,350,000.000	3,335,263.000	47,603,753.601	0.070	74,636.697	24,303.000	3,640,000.000	3,640,000.000	0.000	6,944,301.000	4,030,727.250	3,738,492.871
		37,000,000.000	44,000,000.000	36,564,556.000	47,603,753.601	0.765	818,243.621	12,904,916.000	0.000	37,123,902.000	0.000	9,983,296.000	42,678,682.500	20,599,251.621
		22,001,000.000	19,430,762.000	7,817,794.000	47,603,753.601	0.165	176,289.702	2,451,207.000	0.000	20,263,000.000	0.000	4,168,000.000	9,681,476.750	10,209,083.628
		2,000.000	2,675.000	160.000	47,603,753.601	0.000	3.560	69.210	0.000	2,000.000	0.000	0.000	2,206.158	947.790
		4,500,000.000	1,960,000.000	0.000	47,603,753.601	0.000	0.000	0.000	0.000	4,500,000.000	0.000	0.000	1,470,000.000	3,030,000.000
MQ Totals:		69,052,005.000	61,743,437.000											38,324,780.910

2014 Final Initial APQ:	73,000,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	73,000,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	73,000,000.000

Basic Class: 9300-B

Total PQ Requested: 42,841,348.397

2015 Initial APQ Worksheets

FDA Est:

IMS Est: -.031

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	35,757,656.635	0.000	0.000	0.026	0.000	4.000	0.000	1.000	3.778	0.224
		100.000	100.000	2.165	35,757,656.635	0.000	0.000	130.576	0.000	20.000	0.000	208.576	872.934	213.206
		216,000.000	0.000	0.000	35,757,656.635	0.000	0.000	0.000	0.000	216,000.000	0.000	0.000	0.000	216,000.000
		4,700,000.000	4,778,867.000	3,271,287.000	35,757,656.635	0.091	3,919,338.102	71,327.000	0.000	4,700,000.000	0.000	71,326.000	3,636,393.500	5,942,945.377
		13,800,000.000	14,244,008.000	12,819,884.000	35,757,656.631	0.361	15,468,568.031	5,199,456.000	839,250.000	13,299,750.000	0.000	6,502,250.000	14,582,596.500	17,592,397.039
		1,000.000	1,000.000	0.360	35,757,656.635	0.000	0.431	0.000	0.000	1,000.000	0.000	0.000	750.000	250.539
		28,002,000.000	19,333,576.000	15,047,146.000	35,757,656.635	0.449	19,226,130.492	6,729,629.000	0.000	21,183,000.000	0.000	5,553,000.000	19,547,553.750	23,965,652.185
		7,000,000.000	4,200,000.000	0.000	35,757,656.635	0.000	0.000	0.000	0.000	7,000,000.000	0.000	8,200,000.000	3,150,000.000	3,850,000.000
		450,000.000	0.000	0.000	35,757,656.635	0.000	0.000	0.000	0.000	450,000.000	0.000	0.000	0.000	450,000.000
MQ Totals:		54,169,105.000	42,558,564.000											52,037,456.502

2014 Final Initial APQ:	50,000,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	50,000,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	48,435,000.000

Basic Class: 9630-0

Total PQ Requested: 1,130,005.000

2015 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		53,450.000	35,000.000	21,054.000	386,654.000	0.054	61,530.786	14,352.000	0.000	38,000.000	0.000	19,000.000	37,814.000	74,311.485
		450,000.000	430,000.000	365,600.000	386,654.000	0.946	1,068,474.212	173,187.000	0.000	440,000.000	0.000	203,914.000	452,390.250	1,278,905.765
		40,000.000	0.000	0.000	386,654.000	0.000	0.000	0.000	0.000	40,000.000	0.000	0.000	0.000	40,000.000
MQ Totals:		543,450.000	465,000.000											1,394,217.250

2014 Final Initial APQ:	500,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	500,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	500,000.000
2015 Proposed Initial APQ:	550,000.000
with 25% buffer:	687,500.000

Basic Class: 9639-0

Total PQ Requested: 68,124.000

2015 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		56,000.000	58,271.000	51,164.000	51,164.000	1.000	68,124.000	93.000	0.000	17,000.000	0.000	19,000.000	43,773.000	58,358.750
MQ Totals:		56,000.000	58,271.000											58,358.750

2014 Final Initial APQ:	90,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	90,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	90,000.000

Basic Class: 9330-0
Total PQ Requested: 3,251,005.000

Worksheets

FDA Est:
IMS Est:

Company	DEA Num	MQ	MQ	2013 Sales	Sales	% of 2013 Sales	Share of 2015 Total PQ	Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	2014 DEA Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	13,621,761.460	0.000	0.000	0.000	0.000	5.000	0.000	0.000	0.000	3.750	5.000
		1,200,000.000	1,100,000.000	839,490.000	13,621,761.460	0.047	152,622.346	3,167.000	0.000	1,200,000.000	0.000	0.000	-90,833.000	827,375.250	1,200,000.000
		1,131,000.000	1,674,318.000	178,502.000	13,621,761.460	0.013	42,601.751	253,484.000	0.000	1,131,000.000	0.000	0.000	796,802.000	1,445,851.500	1,127,000.000
		19,000,000.000	10,732,298.000	10,148,533.000	13,621,761.460	0.745	2,424,597.858	68,282.000	0.000	18,777,778.000	0.000	316,178.000	-7,976,198.000	6,101,185.000	19,000,000.000
		5,151,000.000	3,263,650.000	2,565,244.460	13,621,761.460	0.188	612,227.915	151,100.000	0.000	2,692,000.000	0.000	1,339,000.000	542,750.000	2,578,062.500	3,970,000.000
		1,000,000.000	612,500.000	0.000	13,621,761.460	0.000	0.000	324,264.000	0.000	1,000,000.000	0.000	1,400,000.000	-63,236.000	702,573.000	1,000,000.000
		1,000,000.000	430,000.000	0.000	13,621,761.460	0.000	0.000	0.000	0.000	1,403,000.000	0.000	23,000.000	-973,000.000	322,500.000	1,000,000.000
MQ Totals:		28,482,005.000	17,832,771.000												27,297,005.000

2014 Final Initial APQ:	18,200,000.000
2014 Final Revised APQ:	0.000
Est):	18,200,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	18,200,000.000
2015 Proposed Initial APQ:	27,300,000.000
with 25% buffer:	34,125,000.000

ORIPAVINE

BASIC CLASS:	2015 Initial Quota Worksheets	Oripavine	9330												
Company:	(b)(4)														
Request:	1200.0			1131.0			19000.0			5151.0			1000.0			1000.0		
Current Year MQ:	1100.0			1674.0 (buprenorphine pd)			10732.0			3284.0			612.5			430.0		
Year end inventory	3.2			253.5			1579.8			1007.0			324.0 (PQ inventory)			327.0		
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	amt needed	substance MQ	yield
hydromorphone				257.778	116.000	0.45				2893.258	2060.000	0.712				428.571	300.000	0.700
oripavine				500.000 (fo	(b)(4)					1.000 (ref stds)								
oripavine/buprenorphine derivativ	1200.000 (fo	(b)(4)											1000.000	500.000	0.500			
oxymorphone (sale)				368.889	166.000	0.450										1666.667	700.000	0.420
oxymorphone (conv)							21948.052	16900.000	0.770									
losses										1071.000								
total needed	1200.000			1126.667			21948.052			3965.258			1000.000			2095.238		
INITIAL MQs																		
est need	1771.833			1573.349			28538.303			4770.573			1079.125			2399.531		
MQ:																		
Total Initial MQs:	1200.000			1127.000			19000.000			3970.000			1000.000			1000.000		

Total MQs:	27297.000	+ others	0.005	=	27297.005	

FURTHER CALCULATIONS

Proposed Initial APQ 27300

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 119726	Date Submitted: 01-MAY-14
Name of Basic Class or List 1 Chemical (only 1 per DEA-189): ORIPAVINE	Schedule/List Number: 2
Name and Address of Registrant: (b)(4)	Drug Code: 9330-0
	Quota Year: 2015
	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			
	2013	2014	2015	Quota Requested
	1,000,000.0	1,100,000.0	0.0	1,200,000.0
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...	3,167.0	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
	3,167.0	0.0	0.0	0.0
Disposition(Sale)/Utilization				
a.Domestic.....	640,094.0	0.0	1,200,000.0	1,200,000.0
b Exports.....	0.0	0.0	0.0	0.0
	640,094.0	0.0	1,200,000.0	1,200,000.0
Acquisition/Production				
a.Domestic Sources.....	731,568.0	0.0	1,200,000.0	1,200,000.0
	731,568.0	0.0	1,200,000.0	1,200,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2012	2013	2015	

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

Oripavine mfg quota is requested to convert oripavine to a Buprenorphine Intermediate for (b)(4) As there is no specific drug code the the Intermediate quota is being requested for oripavine as we have been instructed in the past. 1200 kg reflects modest growth for the product over 2014.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 118650		Date Submitted	26-MAR-14
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	2015
		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			
	2013	2014	2015	Quota Requested
	1,467,039.0	1,674,318.0	0.0	1,131,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31		26		
a.Bulk Controlled Substance/List 1 Chemical...	253,484.0	253,484.0	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
	253,484.0	0.0	0.0	0.0
Disposition(Sale)/Utilization				
a.Domestic.....	154,943.0	0.0	1,131,000.0	1,131,000.0
b Exports.....	0.0	0.0	0.0	0.0
	154,943.0	0.0	1,131,000.0	1,131,000.0
Acquisition/Production				
a.Domestic Sources.....	154,690.0	0.0	1,131,000.0	1,131,000.0
	154,690.0	0.0	1,131,000.0	1,131,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2012	2013	2015	
HYDROMORPHONE 209.218 (kg)	9150-0	0	0	116,000	45.00
OXYMORPHONE (FOR SALE) 1.672 (kg)	9652-B	35,053	17,237	166,000	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

Remarks

Quota is for supply of 500 Kg to (b)(4);(b)(7)(E) (b)(4); 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. 119506		Date Submitted	29-APR-14
Name of Basic Class or List I Chemical (only 1 per DEA-189)			
ORIPAVINE		Schedule/List Number	2
Name and Address of Registrant		Drug Code	9330-0
(b)(4);(b)(7)(E)		Quota Year	2015
		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 2013	2014	2015	Quota Requested
	10,400,000.0	10,732,298.0	0.0	19,000,000.0
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...	69,282.0	0.0	316,179.0	316,179.0
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
	69,282.0	0.0	316,179.0	316,179.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	18,777,778.0	18,777,778.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	18,777,778.0	18,777,778.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	19,000,000.0	19,000,000.0
	0.0	0.0	19,000,000.0	19,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% Yield
OXYMORPHONE (FOR CONVERSION)	9652-A	1,530,345	7,854,778	18,777,778	77.00
		1,579,762(INV)		16,900,000	

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. 119630		Date Submitted	01-MAY-14
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	2015
		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 2013	2014	2015	Quota Requested
	3,126,000.0	3,283,650.0	0.0	5,151,000.0

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	1,339,000.0	1,339,000.0
b.In-Process Material.....	151,100.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
Disposition(Sale)/Utilization	151,100.0	0.0	1,339,000.0	1,339,000.0
a.Domestic.....	4,676,705	0.0	2,892,000.0	2,892,000.0
b Exports.....	0.075	0.0	0.0	0.0
	4,676.78	0.0	2,892,000.0	2,892,000.0
Acquisition/Production				
a.Domestic Sources.....	2,003,510.0	0.0	5,151,000.0	5,151,000.0
	2,003,510.0	0.0	5,151,000.0	5,151,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% Yield
HYDROMORPHONE	9150-0	1,140,220	1,965,400.34	2,060,000	71.20

855.998(mV)

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

2,892,000 grams for conversion to hydromorphone, loss on production estimated at 1,071,000 grams 1,000 grams for oripavine reference standards/conversion to hydromorphone for reference standards

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 119606		Date Submitted	30-APR-14
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	2015
		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			
	2013	2014	2015	Quota Requested
	700,000.0	612,500.0	0.0	1,000,000.0

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...	324,264.0	0.0	1,400,000.0	1,400,000.0
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
	324,264.0	0.0	1,400,000.0	1,400,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	-67.0	0.0	1,000,000.0	1,000,000.0
b Exports.....	0.0	0.0	0.0	0.0
	67.0	0.0	1,000,000.0	1,000,000.0
Acquisition/Production				
a.Domestic Sources.....	327,581.0	0.0	1,000,000.0	1,000,000.0
	327,581.0	0.0	1,000,000.0	1,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2012	2013	2015	
Buprenorphine base	0000-0	0	0	500,000	50.00
Buprenorphine HCl	0000-0	0	0	500,000	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

Multistep conversion of intermediate purchased from a CMO against procurement quota to Buprenorphine base and Buprenorphine HCl against manufacturing quota.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 118690 | Date Submitted: 27-MAR-14

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

Schedule/List Number: 2
Drug Code: 9330-0
Quota Year: 2015

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 2013	2014	2015	Quota Requested
	0.0	430,000.0	0.0	1,000,000.0

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...	0.0	0.0	23,000.0	23,000.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	295.888 0.0	23,000.0	23,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	1,403,000.0	1,403,000.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	1,403,000.0	1,403,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	1,000,000.0	1,000,000.0
	0.0	0.0	1,000,000.0	1,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% 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

300kg → 31,189(in.)

1,200kg 1295.888(in.)

Remarks

303,000g is planned for use in Hydromorphone and 1,100,000g is planned for use in Oxymorphone.

Basic Class: 9143-A

2016 Initial APQ Worksheets

Total PQ Requested: 5.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	0.000	0.000	5,624,322.000	0.000	0.000	0.000	0.000	4.000	0.000	1.000	0.000	4.000
		1,600,000.000	6,157,639.000	5,624,322.000	5,624,322.000	1.000	1.000	572,678.000	0.000	1,403,309.000	0.000	1,101,720.000	5,347,586.500	1,600,000.000
MQ Totals:		1,600,005.000	6,157,639.000											1,600,004.000

2014 Final Initial APQ:	7,400,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	7,400,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	7,400,000.000

2015 Proposed Initial APQ:	6,660,000.000
with 25% buffer:	8,250,000.000

Other considerations:
looked at historical APQ, requested MQ, granted MQ to determine avg

	APQ	Requested MQ	Granted MQ
2010	5,600,000.000	5,600,000.000	5,600,000.000
2011	5,200,000.000	5,120,000.000	5,120,000.000
2012	7,600,000.000	8,000,000.000	7,542,000.000
2013	8,200,000.000	9,800,000.000	5,840,045.000
2014	7,400,000.000	7,400,000.000	6,157,639.000
	6,800,000.000	7,184,000.000	6,051,936.800
			6,678,645.600

BASIC CLASS:	2014 Initial Quota Worksheets			Oxycodone (conversion)		9143-A
Company:	(b)(4)					
Request:	2000.0	(will change after APQ pub)				
Current Year MQ:	6157.6					
Year end inventory	942.9					
Calculations	amt needed	substance MQ	yield			
oxymorphone (sale)	2462.296	1403.509	0.570			
total needed	2462.296					
INITIAL MQs						
est need	3674.401					
MQ:						
Total Initial MQs:	3700.000			0.005		
Total MQs:	3700.005	+ others			=	3700.005

FURTHER CALCULATIONS

Proposed Initial APQ 6680 used historical avg

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 119514		Date Submitted	29-APR-14
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
OXYCODONE (FOR CONVERSION)		Schedule/List Number	0
Name and Address of Registrant		Drug Code	9143-A
(b)(4)		Quota Year	2015
		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			
	2013	2014	2015	Quota Requested
	5,840,045.0	6,157,639.0	0.0	1,600,000.0

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...	856,356.0	0.0	1,101,720.0	1,101,720.0
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
Disposition(Sale)/Utilization	972,879.0	0.0	1,101,720.0	1,101,720.0
a.Domestic.....	0.0	0.0	1,403,509.0	1,403,509.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	1,403,509.0	1,403,509.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	1,600,000.0	1,600,000.0
	0.0	0.0	1,600,000.0	1,600,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2012	2013	2015	
OXYMORPHONE (FOR SALE)	9652-B	5,836,613	5,937,600	1,403,509	57.00

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

Basic Class: 9143 B

2015 Initial APQ Worksheets

Total PQ Requested: 70,213,784.830

FDA Est: .

IMS Est: -.009

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		10.000	5.000	1.520	78,591,255.584	0.000	1.358	2.000	0.000	5.000	0.000	1.000	5.250	0.847
		60.000	60.000	9.824	78,591,255.584	0.000	8.777	810.808	0.000	20.000	0.000	830.808	853.105	859.563
		6,425,000.000	1,335,520.000	48,062.000	78,591,255.584	0.001	41,152.000	23,138.000	0.000	6,425,000.000	0.000	25,000.000	1,018,993.500	5,451,662.000
		2,700,000.000	1,365,000.000	292,405.000	78,591,255.584	0.004	261,235.956	786,049.000	0.000	2,750,000.000	0.000	796,721.000	1,615,536.750	1,293,743.944
		15,900,000.000	24,000,000.000	14,639,041.000	78,591,255.584	0.189	13,257,266.653	14,301,462.000	0.000	15,670,902.000	0.000	8,967,335.000	28,726,398.500	35,589,126.653
		69,902,000.000	64,131,406.000	45,700,030.000	78,591,255.584	0.581	40,828,814.447	23,161,550.000	0.000	58,901,000.000	0.000	16,782,000.000	65,469,717.000	48,676,563.559
		2,000.000	1,000.000	866,355.240	78,591,255.584	0.011	774,005.708	92,406.000	0.000	2,000.000	0.000	0.000	70,054.500	876,356.135
		11,336,000.000	24,000,000.000	16,656,866.000	78,591,255.584	0.212	14,881,321.554	11,182,045.000	4,800,000.000	10,800,000.000	0.000	8,537,000.000	25,388,513.750	9,019,606.943
		1,900,000.000	784,639.000	190,483.000	78,591,255.584	0.002	170,176.378	537,901.000	0.000	1,250,000.000	0.000	402,792.000	991,905.000	346,342.722
MQ Totals:		107,265,070.000	115,617,630.000											97,354,359.486

2014 Final Initial APQ:	119,500,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	119,500,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	118,484,250.000

2015 Proposed Initial APQ:	110,000,000.000
with 25% buffer:	137,500,000.000

Basic Class: 9652-A

2015 Initial APQ Worksheets

Total PQ Requested: 6,226,005.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	0.000	0.000	7,793,786.000	0.000	0.000	0.000	0.000	4.000	0.000	1.000	0.000	4.000
		16,900,000.000	11,300,000.000	6,300,568.000	7,793,786.000	0.808	5,033,159.477	1,578,752.000	0.000	16,832,103.000	0.000	8,737,633.000	9,659,821.500	13,066,790.347
		451,000.000	2,507,509.000	1,493,218.000	7,793,786.000	0.192	1,192,845.523	269,660.000	0.000	513,000.000	0.000	624,000.000	2,157,891.750	3,557,034.523
		1,000.000	0.000	0.000	7,793,786.000	0.000	0.000	0.000	0.000	1,000.000	0.000	0.000	0.000	1,000.000
MQ Totals:		17,352,005.000	13,807,509.000											16,626,828.869

2014 Final Initial APQ:	20,000,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	20,000,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	20,000,000.000
2015 Proposed Initial APQ:	17,500,000.000
with 25% buffer:	21,875,000.000

BASIC CLASS:	2015 Initial Quota Worksheets			Oxymorphone (conversion)			9652-A		
Company:	(b)(4)								
Request:	16900.0			451.0			1.0		
Current Year MQ:	11300.0			2607.5			0.0		
2013 Year end inventory	1579.0			269.7			0.0		
Calculations	amt needed	substance MQ	yield	amt needed	substance MQ	yield	amt needed	substance MQ	yield
noroxymorphone (conv)	16825.397	10600.000	0.630	451.000	(for (b)(4) nal-drugs)		1.000	ref stds	
noroxymorphone (sale)	10.646	6.707	0.630						
total needed	16836.043			451.000			1.000		
INITIAL MQs									
est need	22291.054			945.947			1.250		
MQ:									
Total Initial MQs:	16900.000			451.000			1.000		

Total MQs: 17352.000 + others = 17352.000

FURTHER CALCULATIONS

Established Initial APQ 17500

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 119507 | Date Submitted: 29-APR-14

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

Schedule/List Number: 0
Drug Code: 9652-A
Quota Year: 2015
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 2013	2014	2015	Quota Requested
	9,400,000.0	11,300,000.0	0.0	16,900,000.0
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...	1,579,762.0	0.0	737,633.0	737,633.0
b.In-Process Material.....	0.0	0.0	1,000,000.0	1,000,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	1,579,762.0	0.0	1,737,633.0	1,737,633.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	16,832,103.0	16,832,103.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	16,832,103.0	16,832,103.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	16,900,000.0	16,900,000.0
	0.0	0.0	16,900,000.0	16,900,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% Yield
NOROXYMORPHONE (FOR SALE)	9668-B	0	0	6,707	63.00
NOROXYMORPHONE (FOR CONVERSION)	9668-A	1,328,952	4,333,939	16,825,396	63.00

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

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 119708 | Date Submitted: 01-MAY-14

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: 0
Drug Code: 9652-A
Quota Year: 2015
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 2013	2014	2015	Quota Requested
	3,030,649.0	2,607,509.0	0.0	451,000.0
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...	269,680.0	0.0	624,000.0	624,000.0
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
	269,680.0	0.0	624,000.0	624,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	77,017.0	0.0	513,000.0	513,000.0
b Exports.....	1,416,201.0	0.0	0.0	0.0
	1,493,218.0	0.0	513,000.0	513,000.0
Acquisition/Production				
a.Domestic Sources.....	1,317,098.0	0.0	451,000.0	451,000.0
	1,317,098.0	0.0	451,000.0	451,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% 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 loss estimated at 2,000 grams 1,000 grams to support reference standard business

2014 Quota	Current	Final	Delta
PSC-AOA	5,232	6,100	868
Morphine for Conversion	13,720	15,500	1,780
Oxymorphone Conversion Commercial	2,608	2,095	-513
Oxymorphone Conversion Development	0	671	671
Oxymorphone Sale Commercial	881	975	94
Oxymorphone Sale Development	0	0	0

2014 OMM Inventory Calculations	With Current Quota	Additional Grant
2013 Ending Inventory	518	518
Non saleable material	7	7
2013 Available End. Inv.	511	511
2014 API Quota	881	975
2014 Development Quota (not included in inventory)		0
2014 Dispositions:		
Sales	592	592
Processing Losses	(464)	(535)
2014 Ending Inventory	115	161
Converted to % Yearend	24.6%	33.4%

	kgs, base
2013 Dispositions	335
2014 Est. Dispositions	592
Average	481
50% Inventory Allowance	240

2014 COMd Inventory Calculations	With Current Quota	Additional Grant
2013 Ending Inventory	272	272
Non saleable material	3	3
2013 Available End. Inv.	269	269
2014 API Quota	2,608	2,095
2014 Development Quota (not included in inventory)		671
2014 Dispositions		
Sales	1,588	1,588
Processing Losses	(13)	(10)
Non-saleable (Sent out to Rev Dist)	(77)	(77)
2014 Ending Inventory	1,199	689
Converted to % Yearend	79.8%	45.9%

	kgs, base
2013 Dispositions	1,416
2014 Est. Dispositions	1,588
Average	1,502
50% Inventory Allowance	751

	ACTUAL YEAR TO DATE				ESTIMATE ON REMAINING QUOTA			WITH INCREASE		
Description	CPS-AOA Input	Process Yield	MWC	Net output of step	CPS-AOA Input	MWC	Net output of step	Input to Step	MWC	Net output of step
CPS-AOA to Crude Oxymorphone for Conversion	0	69.4%	1.0133	0	3,708	1.0133	2,608	[illegible]	1.0133	[illegible]
CPS-AOA to Crude Oxymorphone for Sale	419	71.6%	1.0133	304	795	1.0133	577	130	1.0133	94
TOTAL CPS-AOA	419				4,503			[illegible]		

	ACTUAL YEAR TO DATE					ESTIMATE ON REMAINING QUOTA			WITH INCREASE		
Description	Input to Step	Process Yield	MWC	Net output of step	Loss by step	Input to Step	Output of Step	Loss by step	Input to Step	Output of Step	Loss by step
Oxymorphone For Conversion											
COM to COMd	0	99.5%	1.0000	0	0	2,608	2,594	13	[illegible]	[illegible]	3
Total					0			[illegible]			3
Oxymorphone For Sale											
COM to COMO	198	91.5%	1.1212	203	5	577	594	15	93	93	2
COMH to POM	205	65.0%	0.8920	118	1959	591	343	[illegible]	97	56	[illegible]
POM to OMH	580	73.2%	1.1212	476	[illegible]	343	281	[illegible]	56	46	[illegible]
OMH FG	0	98.2%	1.0000	0	0	281	276	[illegible]	46	45	[illegible]
Total					[illegible]			[illegible]			[illegible]

2015 Quota	Apr-15
PSC-AOA	5,119
Morphine for Conversion	22,000
Oxymorphone Conversion	450
Oxymorphone Conversion Development	0
Oxymorphone Sale	3,500
Oxymorphone Sale Development	0

2015 OMH Inventory Calculations	With Current Quota
2014 Ending Inventory	115
Development material	0
2014 Available End. Inv.	115
2015 API Quota	3,500
2015 Dispositions:	
Sales	1,277
Processing Losses	(1,951)
Validation Inventory	334
2015 Ending Inventory	287
Converted to % Yearend	41.4%

	kgs, base
2014 Est. Dispositions	592
2015 Est. Dispositions	1,277
Average	934
50% Inventory Allowance	467

2015 COMd Inventory Calculations	With Current Quota
2014 Ending Inventory	689
Non saleable material	0
2014 Available End. Inv.	689
2015 API Quota	450
2015 Dispositions	
Sales	513
Processing Losses	(2)
Validation Inventory	0
2015 Ending Inventory	624
Converted to % Yearend	49.4%

	kgs, base
2014 Est. Dispositions	1,588
2015 Est. Dispositions	513
Average	1,050
50% Inventory Allowance	525

	2015 Quota Calc				
Description	CPS-AOA Input	Process Yield	MWC	Net output of step	
CPS-AOA to Crude Oxymorphone for Conversion	640	69.4%	1.0133	450	
CPS-AOA to Crude Oxymorphone for Sale	4,827	71.6%	1.0133	3,500	
TOTAL CPS-AOA	5,467				

	2015 Quota Calc				
Description	Input to Step	Process Yield	MWC	Net output of step	Loss by step
Oxymorphone For Conversion					
COM to COMd	450	99.5%	1.0000	448	[illegible]
Total					[illegible]
Oxymorphone For Sale					
COM to COMO	3,500	91.5%	1.1212	3,580	90
COMH to POM	3,590	65.0%	0.8920	2,081	[illegible]
POM to OMH	2,081	73.2%	1.1212	1,708	[illegible]
OMH FG	1,708	98.2%	1.0000	1,676	[illegible]
Total					[illegible]

2014 CPS-Oxipovine Inventory Calculations	With Current Quota	Additional Grant
2013 Ending Inventory	758	758
Non-saleable material	0	0
2013 Available End. Inv.	758	758
2014 API Quota	5,252	6,100
2014 Dispositions:		
Morphine for Conversion	-	1,190
Oxymorphone for Conversion	3,041	3,041
Oxymorphone for Sale	3,345	1,315
2014 Ending Inventory	1,604	1,413
Converted to % Yearend	42%	37%

2015 CPS-Oxipovine Inventory Calculations	With Current Quota
2014 Ending Inventory	1,604
Non-saleable material	0
2014 Available End. Inv.	1,604
2015 API Quota	5,139
2015 Dispositions:	
Morphine for Conversion	-
Oxymorphone for Conversion	640
Oxymorphone for Sale	4,827
2015 Ending Inventory	1,276
Converted to % Yearend	26%

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 119780		Date Submitted	02-MAY-14
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
OXYMORPHONE (FOR CONVERSION)		Schedule/List Number	II
		Drug Code	9652-A
Name and Address of Registrant		Quota Year	2015
(b)(4)		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 2013	2014	2015	Quota Requested
	0.0	0.0	0.0	1,000.0

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				
a.Domestic.....	0.0	0.0	1,000.0	1,000.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	1,000.0	1,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	1,000.0	1,000.0
	0.0	0.0	1,000.0	1,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% 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

to support reference standards business

Basic Class: 9652-B

Total PG Requested: 3,346,441,070

2015 Initial APQ Worksheets

FDA Est:

IMS Est: .046

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	3,604,592.071	0.000	0.000	0.007	0.000	4.000	0.000	1.000	3.755	0.243
		60.000	60.000	4.211	3,604,592.071	0.000	0.000	215.668	0.000	10.000	0.000	258.268	208.901	269.777
		166,000.000	143,000.000	6,820.000	3,604,592.071	0.002	5,166.336	23,682.000	0.000	156,000.000	0.000	25,000.000	125,011.300	45,303.420
		715,000.000	611,638.000	413,633.000	3,604,592.071	0.115	364,009.739	211,218.000	0.000	623,000.000	0.000	295,541.000	617,142.000	433,065.673
		600,000.000	2,810,598.000	2,602,150.000	3,604,592.071	0.377	2,601,467.700	1,132,591.000	0.000	948,061.000	0.000	423,694.000	2,957,391.750	957,356.125
		3,000.000	3,000.000	41,930.860	3,604,592.071	0.012	38,927.887	34,990.290	0.000	3,000.000	0.000	0.000	28,482.718	14,419.568
		3,501,000.000	880,564.000	330,485.000	3,604,592.071	0.092	306,825.854	310,739.000	0.000	1,277,000.000	0.000	387,000.000	693,477.250	685,370.318
		1,420,000.000	219,000.000	7,559.000	3,604,592.071	0.002	7,017.645	295,828.000	0.000	616,250.000	0.000	275,630.000	379,371.000	171,694.056
MQ Totals:		6,305,065.000	4,658,865.000											2,311,479.181

2014 Final Initial APQ:	5,200,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	5,200,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	5,466,440.000

Basic Class: 9142-0

2016 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(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
MQ Totals:		2.000	2.000											1.500

2014 Final Initial APQ:	2.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	2.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	2.000

Basic Class: 9739-II

2016 Initial APQ Worksheets

Total PQ Requested: 2,317,176

FDA Est:

WIS Est: .035

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	0.683	0.000	0.000	0.000	0.000	1.000	0.000	4.000	3.750	4.000
		1,820.000	1,820.000	0.000	0.683	0.000	0.000	2,723.000	0.000	1,820.000	0.000	2,723.000	3,407.250	2,723.000
		1,000.000	1,165.000	0.000	0.683	0.000	0.000	0.000	0.000	500.000	0.000	1,000.000	873.750	665.000
MQ Totals:		2,825.000	2,990.000											3,392.000

2014 Final Initial APQ:	3,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	3,000.000
WIS Est: (2014 Initial APQ * 1 + WIS Est):	3,105.000

Basic Class: 9740-8

2015 Initial APQ Worksheets

Total PQ Requested: 774,604.350

FDA Est:

IMS Est: 4.244

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		1,000.000	1,000.000	404.700	2,931.700	0.138	106,926.533	837.400	0.000	500.000	0.000	200.000	1,378.050	1,000.000
		2.000	2.000	0.000	2,931.700	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500	2.000
		700.000	650.000	261.000	2,931.700	0.096	74,244.917	127.000	0.000	548.000	0.000	366.000	582.750	700.000
		2,500.000	2,216.000	2,248.000	2,931.700	0.766	593,430.900	2,226.000	1,603.000	2,774.000	0.000	1,799.000	3,331.500	2,500.000
MQ Totals:		4,202.000	3,868.000											4,202.000

2014 Final Initial APQ:	5,004.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	5,004.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	3,785.026

Basic Class: 9780-0

2015 Initial APQ Worksheets

Total PQ Requested: 14,527,431.000

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		256,000.000	256,000.000	215.000	10,372,408.760	0.000	301.125	68,486.000	0.000	256,000.000	0.000	0.000	244,564.500	68,787.128
		10.000	10.000	0.000	10,372,408.760	0.000	0.000	3.992	0.000	6.000	0.000	7.992	10.484	7.992
		345,000.000	345,000.000	0.000	10,372,408.760	0.000	0.000	0.000	0.000	345,000.000	0.000	0.000	258,750.000	86,250.000
		1,000.000	0.000	10,266,906.560	10,372,408.760	0.990	84,379,666.294	7,015,667.600	0.000	1,000.000	0.000	0.000	5,261,900.700	10,959,715.258
		8,500,000.000	1,702,721.000	840.000	10,372,408.760	0.000	1,175.491	20,267.000	0.000	7,300,000.000	0.000	1,221,000.000	1,292,241.906	6,064,162.883
MQ Totals:		9,104,010.000	2,303,731.000											17,118,923.245

2014 Final Initial APQ:	14,000,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	14,000,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	14,000,000.000

2015 Proposed Initial APQ:	10,000,000.000
with 25% buffer:	12,500,000.000

Basic Class: 9333-0

Total PQ Requested: 5,100,110.000

2015 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5,000	5,000	0.000	58,114,802.224	0.000	0.000	0.002	0.000	4.000	0.000	1.000	3.752	0.248
		855,000.000	870,000.000	221,845.000	58,114,802.224	0.004	19,466.945	65,416.000	0.000	655,000.000	0.000	0.000	703,812.000	158,420.182
		25.000	25.000	2.664	58,114,802.224	0.000	0.229	56.650	0.000	5.000	0.000	74.650	61.193	78.819
		9,869,000.000	2,171,000.000	44,927.000	58,114,802.224	0.001	3,942.759	48,305.000	0.000	9,868,000.000	0.000	50,000.000	1,564,478.750	6,297,373.448
		23,000,000.000	42,968,039.000	27,999,549.000	58,114,802.224	0.482	2,457,216.799	16,221,462.000	0.000	22,823,004.000	0.000	11,732,425.000	44,366,568.250	36,821,665.719
		1,000.000	2,000.000	54.620	58,114,802.224	0.000	3.036	45,977.500	0.000	1,000.000	0.000	0.000	35,308.125	46,050.536
		8,900,000.000	10,672,013.000	9,293,794.000	58,114,802.224	0.160	615,616.158	2,921,970.000	0.000	7,500,000.000	0.000	4,393,000.000	9,745,467.250	6,309,599.138
		18,200,000.000	19,068,050.000	11,794,700.000	58,114,802.224	0.203	1,035,093.730	10,542,900.000	0.000	18,200,000.000	0.000	7,000,000.000	22,413,962.500	12,747,043.730
MQ Totals:		60,925,030.000	75,150,132.000											66,360,259.842

2014 Final Initial APQ:	116,000,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	116,000,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	116,000,000.000

2015 Proposed Initial APQ:	100,000,000.000
with 25% buffer:	125,000,000.000

2015 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), who has redelegated to the Deputy Administrator.

- The attached Federal Register notice, prepared for your signature, proposes to establish calendar year 2015 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, GHB and tetrahydrocannabinols) in an effort to prevent potential drug shortage issues.

- The Federal Drug Administration (FDA) has not yet responded to DEA's annual letter, sent on February 18, 2014, which requests information on new, continuing, and discontinued drug products containing schedule II substances. Therefore, this information could not be considered in the analysis for the current proposed adjustments

- 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.

- The following points provide brief explanations for some of the proposed AAN & APQ values:

Schedule I substances

- The APQ for **betamethadol** is proposed as an increase from zero for 2014, based on one registrant application received as of May 21, 2014. Applications can be received throughout the year and those received during the comment period will be considered at that time.

- The APQ for **morphine-n-oxide** is proposed as an increase from 2014. The change is based on receiving requests from bulk manufacturers for this substance. The manufacturing of this substance will be used for analytical standards, reference, and research material.

- The APQ for **marihuana** is proposed as a decrease from 2014, but not zero ~~because~~ to accommodate a bulk manufacturer with a new synthesis route for manufacturing API for dronabinol.

- The APQ for **tetrahydrocannabinols** is proposed as an increase from 2014 to accommodate a new bulk manufacturer that will supply dosage form manufacturers conducting product development efforts to formulate FDA approved generics to dronabinol.

Schedule II substances

- The APQs for **amobarbital, dihydrocodeine, diphenoxylate, ecgonine, levorphanol,** and **opium (tincture)** are proposed as increases to accommodate changes in registrant requirements and domestic market demands.

- The APQs for **amphetamine (for conversion)** and **lisdexamfetamine** are proposed to accommodate increased registrants' requirements based on brand holder exporting to new markets overseas and changes in domestic market demands.

- The APQs for **oripavine** and **noroxymorphone (for sale)** are proposed as increases to accommodate the change in synthesis and growing domestic demand for nal-drugs, and specifically Narcan, by legislators, police, and paramedics in states with rising heroin deaths.

- The APQs for **amphetamine (for sale), codeine (for conversion), hydromorphone, methadone intermediate, methamphetamine, methylphenidate, nabilone, oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), phenylacetone, tapentadol,** and **thebaine** were proposed as decreases from 2014 based on registrant applications received as of May 21, 2014. Applications can be received throughout the year and those received during the comment period will be considered at that time.

List I Chemicals

- The AAN for **ephedrine (for conversion)** is proposed as a decrease from 2014 based on registrant applications received as of May 21, 2014. Applications can be received throughout the year and those received during the comment period will be considered at that time.

- The AAN for **phenylpropanolamine (for sale)** and **pseudoephedrine (for conversion)** were proposed based on registrant applications received as of May 21, 2014. Applications can be received throughout the year and those received during the comment period will be considered at that time.

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-393]

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 2015

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to establish the 2015 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 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 midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-393" on all electronic and written correspondence. The DEA 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. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments, in lieu of electronic comments, they 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: Erika Gehrmann, Office of Diversion Control, Drug Enforcement Administration, 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 and will 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 (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 the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the "For Further Information Contact" paragraph above.

Legal Authority

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and 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. This responsibility has been delegated to the Administrator of the DEA pursuant to 28 CFR 0.100(b). The Administrator, in turn, has redelegated that authority to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

Analysis for Proposed 2015 Aggregate Production Quotas and Assessment of

Annual Needs

The proposed year 2015 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 2015 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 necessary to provide for the medical, scientific, or other legitimate needs of the United States.

In determining the proposed 2015 aggregate production quotas and assessment of annual needs, the DEA has taken into account the criteria that the DEA is required to consider 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 DEA proposes the aggregate production quotas and assessment of annual needs for 2015 by considering: (1) total net disposal of the 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 such 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 in the United States, lawful export requirements, and reserve stocks, as the Deputy Administrator finds relevant. Other factors the DEA 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 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

The DEA 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 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 proposes to include in all schedule II aggregate production quotas, and certain schedule I aggregate production quotas (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 resulting 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 Deputy Administrator, therefore, proposes to establish the 2015 aggregate production quotas for the following 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 Established 2015 Quotas (g)
Schedule I	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	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-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)	15
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)	15
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)	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-Fluoro-N-methylcathinone (3-FMC)	15
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)	15
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-ethylcathinone (4-MEC)	15
4-Methyl-N-methylcathinone (mephedrone)	45

4-Methyl-alpha-pyrrolidinopropiophenone (4-MePPP)	15
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-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)	15
alpha-Pyrrolidinopentiophenone (α-PVP)	15
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	200
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000

Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	21,000
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-1H-indazole-3-carboxamide (AKB48)	15
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	15
N,N-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	15
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	18
Phenomorphan	2
Psilocybin	30
Psilocyn	30

Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	15
Tetrahydrocannabinols	497,500
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,625
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	21,875,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	240,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	46,125,000
Dextropropoxyphene	19
Dihydrocodeine	101,375
Diphenoxylate	1,337,500
Ecgonine	174,375
Ethylmorphine	3
Fentanyl	2,108,750
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	6,250,000
Isomethadone	5
levo-Alphacetylmethadol (LAAM)	4
Levomethorphan	5
Levorphanol	3,375
Lisdexamfetamine	29,750,000
Meperidine	6,250,000
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	83,750,000
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	22,750,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	137,500,000
Oxymorphone (for conversion)	21,875,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	3,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Deputy 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. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as necessary.

Comments

In accordance with 21 CFR 1303.11(c) and 1315.11(d), any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this notice, the Deputy Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.11(c) and 1515.11(e). In the event the Deputy Administrator decides to hold such a hearing, the Deputy Administrator will publish a notice of the hearing in the *Federal Register*. After consideration of any comments or objections, or after a hearing, if one is held, the Deputy Administrator will issue and publish in the *Federal Register* a final order establishing the 2015 aggregate production quota for each basic class of controlled substance and establishing the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.11(c) and 1315.11(f).

Dated:

Thomas M. Harrigan,
Deputy Administrator.

INTERNATIONAL TRADE COMMISSION

[USITC SE-14-023]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.
TIME AND DATE: July 11, 2014 at 11 a.m.
PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205-2000.
STATUS: Open to the public.
MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote in Inv. Nos. 701-TA-515-521 and 731-TA-1251-1257 (Preliminary)(Certain Steel Nails from India, Korea, Malaysia, Oman, Taiwan, Turkey, and Vietnam). The Commission is currently scheduled to complete and file its determinations on July 14, 2014; views of the Commission are currently scheduled to be completed and filed on July 21, 2014.
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission:
Issued: June 30, 2014.

William R. Bishop,
Supervisory Hearings and Information Officer.

[FR Doc. 2014-15679 Filed 6-30-14; 4:15 pm]
BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-393]

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 2015

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to establish the 2015 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 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 1, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-393" on all electronic and written correspondence. The DEA 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. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments, in lieu of electronic comments, they 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: Erika Gehrmann, Office of Diversion Control, Drug Enforcement Administration, 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 and will 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 (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 the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the **FOR FURTHER INFORMATION CONTACT** paragraph above.

Legal Authority

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and 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. This responsibility has been delegated to the Administrator of the DEA pursuant to 28 CFR 0.100(b). The Administrator, in turn, has redelegated that authority to the Deputy Administrator, pursuant to 28 CFR part 0 subpart R, App.

Analysis for Proposed 2015 Aggregate Production Quotas and Assessment of Annual Needs

The proposed year 2015 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 2015 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 necessary to provide for the medical, scientific, or other legitimate needs of the United States.

In determining the proposed 2015 aggregate production quotas and assessment of annual needs, the DEA has taken into account the criteria that the DEA is required to consider 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 DEA proposes the aggregate production quotas and assessment of annual needs for 2015 by considering: (1) Total net disposal of the 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 such 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 in the United States, lawful export requirements, and reserve stocks, as the Deputy Administrator finds relevant. Other factors the DEA 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 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

The DEA 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 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 proposes to include in all schedule II aggregate production quotas, and certain schedule I aggregate production quotas (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 resulting 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 Deputy Administrator, therefore, proposes to establish the 2015 aggregate production quotas for the following 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 established 2015 quotas (g)
Schedule I	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	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-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)	15
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)	15
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)	15

Basic class	Proposed established 2015 quotas (g)
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)	15
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)	15
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-ethylcathinone (4-MEC)	15
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-alpha-pyrrolidinopropiophenone (4-MePPP)	15
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-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)	15
alpha-Pyrrolidinopentiophenone (α-PVP)	15
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	200
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	21,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2

Basic class	Proposed established 2015 quotas (g)
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	15
N,N-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	15
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	18
Phenomorphan	2
Psilocybin	30
Psilocyn	30
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	15
Tetrahydrocannabinols	497,500
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,625
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	21,875,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	240,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	46,125,000
Dextropropoxyphene	19
Dihydrocodeine	101,375
Diphenoxylate	1,337,500
Ecgonine	174,375
Ethylmorphine	3
Fentanyl	2,108,750
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	6,250,000
Isomethadone	5
levo-Alphacetylmethadol (LAAM)	4
Levomethorphan	5
Levorphanol	3,375
Lisdexamfetamine	29,750,000
Meperidine	6,250,000
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	83,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000

Basic class	Proposed established 2015 quotas (g)
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	22,750,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	137,500,000
Oxymorphone (for conversion)	21,875,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	3,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Deputy 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. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as necessary.

Comments

In accordance with 21 CFR 1303.11(c) and 1315.11(d), any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this notice, the Deputy Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.11(c) and 1515.11(e). In the event the Deputy Administrator decides to hold such a hearing, the Deputy Administrator will publish a notice of the hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Deputy Administrator will issue and publish in the **Federal Register** a final order establishing the 2015 aggregate production quota for each basic class of controlled substance and establishing the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.11(c) and 1315.11(f).

Dated: June 26, 2014.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2014–15549 Filed 7–1–14; 8:45 am]

BILLING CODE 4410–09–P

OFFICE OF MANAGEMENT AND BUDGET

Draft 2014 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice of availability and request for comments.

SUMMARY: The Office of Management and Budget (OMB) requests comments on its Draft 2014 Report to Congress on the Benefits and Costs of Federal Regulations, available at: *http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/*. The Draft Report is divided into two parts. Part I contains two chapters. Chapter I examines the benefits and costs of major Federal regulations issued in fiscal year 2013 and summarizes the benefits and costs of major regulations issued between October 2003 and September 2013. It also discusses regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Chapter II offers recommendations for regulatory reform. Part II summarizes agency compliance with the Unfunded Mandates Reform Act.

OMB requests that comments be submitted electronically to OMB by September 2, 2014 through *www.regulations.gov*.

DATES: To ensure consideration of comments as OMB prepares this Draft Report for submission to Congress, comments must be in writing and received by September 2, 2014.

ADDRESSES: Submit comments by one of the following methods:

- *www.regulations.gov:* Direct comments to Docket ID OMB–2014–0002
- *Fax:* (202) 395–7285
- *Mail:* Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: Mabel Echols, NEOB, Room 10202, 725 17th Street NW., Washington, DC 20503. To ensure that your comments are received, we recommend that comments on this draft report be electronically submitted.

All comments and recommendations submitted in response to this notice will be made available to the public, including by posting them on OMB's Web site. For this reason, please do not

Drug	Company	Comment	Amount	Response	Proposed APQ	Established APQ	Change
25B-NBOMe	(b)(4)	increase APQ	5	APQ sufficient	15	15	-
25C-NBOMe		increase APQ	5	APQ sufficient	15	15	-
25I-NBOMe		increase APQ	5	APQ sufficient	15	15	-
3-FMC		increase APQ	5	APQ sufficient	15	15	-
4-FMC		increase APQ	5	APQ sufficient	15	15	-
4-MEC		increase APQ	5	APQ sufficient	15	15	-
4-MePPP		increase APQ	5	APQ sufficient	15	15	-
5-Fluoro-PB-22		increase APQ	5	APQ sufficient	15	15	-
AB-FUBINACA		increase APQ	5	APQ sufficient	15	15	-
ADB-PINACA		increase APQ	5	APQ sufficient	15	15	-
alpha-PBP		increase APQ	5	APQ sufficient	15	15	-
alpha-PVP		increase APQ	5	APQ sufficient	15	15	-
amphetamine (for sale)		increase APQ	1,807,600	APQ sufficient	30,000,000	30,000,000	-
ANPP		increase APQ	1,320,000	APQ sufficient	2,150,000	2,150,000	-
butylone		increase APQ	5	APQ sufficient	15	15	-
codeine (for sale)		increase APQ	25,501,000	justified, increase APQ	36,900,000	39,600,000	2,700,000
dihydrocodeine		increase APQ	180,000	justified, increase APQ	81,100	181,100	100,000
diphenoxylate		increase APQ	740,000	APQ sufficient	1,070,000	1,070,000	-
fentanyl		increase APQ	940,000	justified, increase APQ	1,687,000	1,720,000	33,000
hydrocodone (for sale)		increase APQ	32,302,000	APQ sufficient	79,700,000	79,700,000	-
hydromorphone		increase APQ	2,585,000	justified, increase APQ	5,000,000	5,600,000	600,000
levorphanol		increase APQ	5,600	justified, increase APQ	2,700	5,700	3,000
marihuana		increase APQ	100,000	justified, increase APQ	21,000	125,000	104,000
morphine (for conversion)		increase APQ	26,251,000	APQ sufficient	73,000,000	73,000,000	-
naphyrone		increase APQ	5	APQ sufficient	15	15	-
oripavine		increase APQ	6,231,000	justified, increase APQ	18,200,000	28,000,000	9,800,000
oxycodone (for conversion)		increase APQ	3,000,000	APQ sufficient	6,680,000	6,680,000	-
oxymorphone (for conversion)		increase APQ	6,151,000	justified, increase APQ	17,500,000	23,200,000	5,700,000
oxymorphone (for sale)		increase APQ	1,600,000	APQ sufficient	6,200,000	6,200,000	-
PB-22		increase APQ	5	APQ sufficient	15	15	-
pentedrone		increase APQ	5	APQ sufficient	15	15	-
pentylone		increase APQ	5	APQ sufficient	15	15	-

Number of registrants/entities commenting: 5
Number of drugs commented on: 32 32

CMEA Chemical	Company	Comment	Amount	Response	Proposed AAN	Establish AAN	Change

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

Additional Drug Considerations:

Drug	Response	Proposed APQ	Established APQ	Change
alfentanil	increase justified based on registrant applications	14,100	14,200	100
cocaine	increase justified based on increased demand	192,000	220,000	28,000
codeine-n-oxide	increase justified based on registrant applications	200	305	105

Additional Chemical Considerations:

Drug	Response	Proposed AAN	Established AAN	Change
ephedrine (for sale)	reviewed final AAN for 2011-2014, ave of AAN	3,000,000	4,000,000	1,000,000

(b)(4)

July 31, 2014

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

Attn: DEA Federal Register Representative [Docket No. DEA-393]

This letter constitutes (b)(4) comments on the Proposed Initial Aggregate Production Quotas for 2015, as published in Federal Register on July 2, FR Vol. 79, No. 127, pages 37772-37776. 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 its requests for increased manufacturing quotas, which are outlined below. Because this comment contains confidential business information on its manufacturing quota needs, we also request that DEA treat this entire document as confidential.

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

8333 4-Anilino-N-phenethyl-4-peperidine (ANPP)

(b)(4) requests that the initial aggregate be sufficient to include its request for 1,320,000 grams AA of 4-Anilino-N-phenethyl-4-peperidine manufacturing quota for 2015.

9120 Dihydrocodeine

(b)(4) requests that the initial aggregate be sufficient to include its request for 180,000 grams AA of Dihydrocodeine manufacturing quota for 2015.

9170 Diphenoxylate

(b)(4) requests that the initial aggregate be sufficient to include its request for 740,000 grams AA of Diphenoxylate manufacturing quota for 2015.

(b)(4)

RE: 2015 Revised Initial Aggregate Quota Requests for (b)(4);(b)(7)(E)

9801 Fentanyl

(b)(4) requests that the initial aggregate be sufficient to include its request for 940,000 grams AA of Fentanyl manufacturing quota for 2015.

9220 Levorphanol

(b)(4) requests that the initial aggregate be sufficient to include its request for 5,600 grams AA of Levorphanol manufacturing quota for 2015.

9143 Oxycodone (for conversion)

(b)(4) requests that the initial aggregate be sufficient to include its request for 3,000,000 grams AA of Oxycodone (for conversion) manufacturing quota for 2015.

9652 Oxymorphone (for sale)

(b)(4) requests that the initial aggregate be sufficient to include its request for 1,600,000 grams AA of Oxymorphone (for sale) manufacturing quota for 2015.

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)

July 30, 2014

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

RE: Docket No. DEA-393
(b)(4) **Comment to Federal Register Volume 79, Number 127 (Wednesday, July 2, 2014) Notices Pages 37772-37776 FR Doc No: 2014-15549**

Dear DEA Federal Register Representative:

(b)(4) herewith comment to a portion of the above referenced Federal Register proposal. Specifically, (b)(4) believes that Proposed 2015 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
Codeine (fs)	9050
Morphine for Conversion	9300
Oxymorphone for Conversion	9652
Hydrocodone (fs)	9193
Oripavine	9330
Hydromorphone	9150

Regards,

(b)(6)

Director, Controlled Substance Compliance

Substance	2011	2012	% Change	2013	% Change	2014*	% Change
Amphetamine (D,L)	**9,703.48**	**10,938.98**	**12.73%**	**10,928.32**	**-0.10%**	**11,781.22**	**7.80%**
Amphetamine (D)	**10,594.66**	**11,725.36**	**10.67%**	**11,597.18**	**-1.09%**	**12,428.08**	**7.16%**
Cocaine	48.53	44.03	-9.28%	39.63	-9.99%	37.76	-4.73%
Codeine	26,170.71	22,758.42	-13.04%	21,717.57	-4.57%	20,712.17	-4.63%
Dihydrocodeine	107.21	75.02	-30.03%	36.22	-51.72%	4.33	-88.04%
Diphenoxylate	462.60	413.01	-10.72%	406.21	-1.65%	387.76	-4.54%
Dronabinol	110.82	106.13	-4.24%	110.93	4.52%	115.72	4.32%
Ephedrine	1,535.52	1,973.12	28.50%	2,083.35	5.59%	2,175.64	4.43%
Fentanyl	539.85	575.08	6.53%	548.24	-4.67%	536.96	-2.06%
Hydrocodone	**64,934.12**	**63,178.66**	**-2.70%**	**61,628.67**	**-2.45%**	**59,076.69**	**-4.14%**
Hydromorphone	1,675.27	1,912.79	14.18%	1,926.37	0.71%	1,828.21	-5.10%
Levorphanol	0.32	1.54	378.02%	2.33	51.13%	2.61	11.65%
Lisdexamfetamine	**12,336.18**	**14,001.30**	**13.50%**	**13,653.66**	**-2.48%**	**14,195.78**	**3.97%**
Meperidine	2,303.07	1,885.75	-18.12%	1,537.43	-18.47%	1,296.65	-15.66%
Methadone	7,639.42	6,776.37	-11.30%	5,804.95	-14.34%	5,358.57	-7.69%
Methamphetamine	13.86	14.40	3.87%	13.09	-9.11%	12.33	-5.82%
Methylphenidate	**19,212.63**	**19,534.89**	**1.68%**	**17,949.19**	**-8.12%**	**17,989.12**	**0.22%**
Morphine	30,435.83	28,705.57	-5.68%	26,267.70	-8.49%	25,007.07	-4.80%
Nalbuphine	61.42	63.63	3.60%	42.05	-33.92%	39.10	-7.01%
Naloxone	391.27	430.32	9.98%	478.98	11.31%	502.16	4.84%
Naltrexone	4.56	0.00	-99.98%	0.00	-100.00%	0.00	0.00%
Opium	84.96	81.02	-4.63%	77.44	-4.43%	76.79	-0.84%
Oxycodone	**70,885.82**	**66,703.74**	**-5.90%**	**60,313.66**	**-9.58%**	**58,971.27**	**-2.23%**
Oxymorphone	**2,655.74**	**1,958.25**	**-26.26%**	**1,865.59**	**-4.73%**	**1,936.85**	**3.82%**
Pentazocine	839.71	698.43	-16.82%	563.20	-19.36%	412.71	-26.72%
Pentobarbital	79.12	46.62	-41.07%	24.25	-47.99%	22.90	-5.55%
Pseudoephedrine	104,476.73	93,933.95	-10.09%	93,208.94	-0.77%	92,381.64	-0.89%
Remifentanil	1.05	1.11	5.83%	1.16	5.10%	1.21	4.14%
Secobarbital	20.78	15.67	-24.59%	11.98	-23.55%	11.26	-6.01%
Sufentanil	0.05	0.05	-2.53%	0.05	-7.93%	0.04	-11.50%

*Estimates based on Jan-Jun 2014 Data

Basic Class:
Total PQ Req. 326,100.000

2015 Initial APQ

FDA Est: .015
IMS Est: -.021
(used fentanyl %)

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		1,320,000.000	1,040,000.000	777,862.000	777,876.940	1.000	326,093.737	210,831.000	0.000	1,205,129.000	520,039.000	938,123.250	938,123.250
		13,500.000	6,560.000	0.000	777,876.940	0.000	0.000	0.000	0.000	9,000.000	4,105.200	4,920.000	4,920.000
MQ Totals:		1,333,500.000	1,046,560.000										943,043.250

2014 Final Initial APQ:	2,150,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	2,182,250.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	2,105,710.000

APQ sufficient, no adjustment required

Basic Class:
Total PQ Requ.: 104.000

2015 Initial APQ Wo

FDA Est: n/a
IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	5,836.000	0.000	0.000	0.000	0.000	0.500	1.500	1.500	1.500
		14,100.000	14,080.000	5,836.000	5,836.000	1.000	104.000	6,937.000	0.000	13,760.000	6,936.000	17,262.750	9,361.000
MQ Totals:		14,102.000	14,082.000										9,362.500

2014 Final Initial APQ:	14,100.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	14,100.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	14,100.000

2015 Establish APQ:	14,200.000
2015 Establish APQ with 25% buffer:	17,750.000

Basic Class:
Total PC Request: 26,734,229,940

2015 Initial APQ Worksheets

FDA Est: -.04
IMS Est: -.046

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PC	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 60% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	26,011,178.526	0.000	0.000	1.800	0.000	5.000	1.000	5.100	-0.550	5.000
		100.000	100.000	1.039	26,011,178.526	0.000	1.146	43.893	0.000	26.000	104.093	107.920	-91.456	100.000
		628,000.000	0.000	0.000	26,011,178.526	0.000	0.000	0.000	0.000	558,670.000	0.000	0.000	558,670.000	558,670.000
		296,000.000	148,000.000	106,667.000	26,011,178.526	0.004	117,633.727	458,397.000	0.000	296,000.000	234,397.000	453,297.750	-424,104.841	296,000.000
		18,600,000.000	13,145,613.000	12,022,443.000	26,011,178.526	0.462	13,281,051.977	5,171,263.000	150,220.000	10,903,400.000	5,592,152.000	13,737,672.000	12,624,442.221	18,600,000.000
		25,501,000.000	17,231,565.000	13,170,419.000	26,011,178.526	0.506	14,549,200.358	5,127,800.000	0.000	18,166,000.000	8,923,000.000	16,769,525.750	19,303,026.698	19,303,026.698
		1,000.000	1,000.000	1.330	26,011,178.526	0.000	1.469	0.000	0.000	1,000.000	0.000	750.000	251.637	1,000.000
		4,935,000.000	2,354,914.000	711,641.000	26,011,178.526	0.027	786,141.086	0.000	0.000	3,478,000.000	147,330.000	1,916,185.500	2,544,490.857	2,544,490.857
MQ Totals:		43,161,105.000	33,081,197.000											34,503,292.555

2014 Final Initial APQ:	36,900,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	35,424,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	35,202,600.000

2015 Proposed Initial APQ:	36,900,000.000
2015 Established APQ:	39,600,000.000
2015 Established APQ w/ 25% buffer:	49,500,000.000

2015 3rd
APQ adjustment based on Noramco's increased export requirements

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 120268 | Date Submitted: 31-JUL-14

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

Schedule/List Number: 0
Drug Code: 9050-B
Quota Year: 2015

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 2013	2014	2015	Quota Requested
	15,730,716.0	17,231,565.0	0.0	25,501,000.0
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...	4,400,200.0	0.0	8,923,000.0	8,923,000.0
b.In-Process Material.....	727,600.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	5,127,800.0	0.0	8,923,000.0	8,923,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	10,848,619.0	0.0	19,168,000.0	19,168,000.0
b Exports.....	2,330,220.0	0.0	0.0	0.0
	13,178,839.0	0.0	19,168,000.0	19,168,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	25,501,000.0	25,501,000.0
	0.0	0.0	25,501,000.0	25,501,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% 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 loss estimated at 2,291,000 grams 1,000 grams to support reference standard business Replaces Application Reference# 119691

2014 exports = 1174?
2014 est ex = 6000
2015 est ex = 7992

Current Vintage
2,173
2,781
6,193
11,147 + exports + others

2014 Quota	Initial 2014 Grant	Comment
CPS-ACA	6,290	
Codeine For Sale (from (b)(4) CPS)	4,971	Total Codeine for Sale Initial grant 17,231,565 kgB

2014 (b)(4) Codeine Phosphate Inventory Calculations	With Current Quota
2013 Ending Inventory	2,522
Non saleable material	12
2013 Available End. Inv.	2,510
2014 API Quota	4,971
2014 Dispositions:	
Sales	4,755
Processing Losses	(592)
2014 Ending Inventory	2,135
Converted to % Yearend	59.9%

	kgs, base
2013 Dispositions	2,380
2014 Est. Dispositions	4,755
Average	3,567
50% Inventory Allowance	1,784

	ACTUAL YEAR TO DATE (JUNE 30, 2014)				ESTIMATE ON		
Description	Input to Step	Process Yield	Net output of step	Loss by step	Input to Step	Output of Step	Loss by step
CPS-ACA to Codeine for Sale	1,825	84.1%	1,535		4,085	3,436	
Codeine for Sale							
Codeine(fr CPS) to Codeine Phosphate	1,218	88.5%	1,079	(140)	3,683	3,438	(245)
Codeine Phosphate Finished	-	99.8%	-	0	4,517	4,510	(7)
Total				(140)			(252)

2014 CPS-Codeine Inventory Calculations	With Current Quota
2013 Ending Inventory	1,867
Non saleable material	
2013 Available End. Inv.	1,867
2014 API Quota	6,290
2014 Dispositions:	
Converted to ACA for Sale	5,910
2014 Ending Inventory	2,247
Converted to % Yearend	37.9%

	kgs, base
2013 Dispositions	5,941
2014 Est. Dispositions	5,910
Average	5,925
30% Inventory Allowance	1,778

2015 Quota	Apr-15	Aug-15	Delta	Comment
CPS-ACA	7,500	15,000	7,500	
Codeine For Sale	5,700	11,000	5,300	Total Codeine for Sale: 25,500 kgB

2015 (b)(4) Codeine Phosphate Inventory Calculations	
2014 Ending Inventory	2,135
Non saleable material	0
2014 Available End. Inv.	2,135
2015 API Quota	11,000
2015 Dispositions:	
Sales	7,992
Processing Losses	(1,276)
2015 Ending Inventory	5,867
Converted to % Yearend	60.7%

	kgs, base
2014 Est. Dispositions	4,755
2015 Est. Dispositions	7,992
Average	6,373
50% Inventory Allowance	3,187

2015 Quota Calc				
Description	Input to Step	Process Yield	Net output of step	Loss by step
CPS-ACA to Codeine for Sale	13,076	84.1%	11,000	
Codeine for Sale				
Codeine(fr CPS) to Codeine Phosphate	11,000	88.5%	9,740	(1,260)
Codeine Phosphate Finished	9,740	99.8%	9,724	(16)
Total				(1,276)

+8291 = 3,567

1276

2015 CPS-Codeine Inventory Calculations	
2014 Ending Inventory	2,247
Non saleable material	0
2014 Available End. Inv.	2,247
2015 API Quota	15,000
2015 Dispositions:	
Converted to ACA for Sale	13,076
2015 Ending Inventory	4,171
Converted to % Yearend	43.9%

	kgs, base
2014 Est. Dispositions	5,910
2015 Est. Dispositions	13,076
Average	9,493
30% Inventory Allowance	2,848

2015 Forecast			
Customer	DEA #	2015 Total, kg Salt	2015 Total, kgB
(b)(4)	EXPORT	8,000	5,920
	EXPORT	2,000	1,480
	EXPORT	600	444
	EXPORT	200	148
		10,800	7,992

→ 3996(inv) = 11,988 need (CPS)
+ 16,764 (import)
28,752
− 7,129 (VEI)
21,623
+ 3,567
25,190

2014 Quota	Initial 2014 Grant	Additional 2014 Grant	Comment
Morphine for Conversion for Cod for Sale	10,431	14,501	
Morphine for Conversion for 14-HM	0	999	
Total Morphine for Conversion	10,431	15,500	
Codeine For Sale (from Morphine)	12,260		Total Codeine for Sale Initial grant 17,231,565 kgB

2014 Morphine for Conversion Inventory Calculations	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	2,454	2,454
Non saleable material	3	3
2013 Available End. Inv.	2,451	2,451
2014 API Quota	10,431	14,501
2014 Dispositions:		
Converted to Codeine	13,120	13,120
Converted to 14-HM	0	999
Processing Losses	-	-
2014 Ending Inventory	-238	2,833
Converted to % Yearend	-2.2%	25.8%

	kgs, base
2013 Dispositions	7,872
2014 Est. Dispositions	14,119
Average	10,995
50% Inventory Allowance	5,498

2014 Codeine Phosphate from Morphine Inventory Calculations	With Current Quota
2013 Ending Inventory	2,644
Non saleable material	26
2013 Available End. Inv.	2,618
2014 API Quota	12,260
2014 Dispositions:	
Sales	11,360
Processing Losses	(772)
2014 Ending Inventory	2,747
Converted to % Yearend	24.8%

	kgs, base
2013 Dispositions	10,761
2014 Est. Dispositions	11,360
Average	11,060
50% Inventory Allowance	5,530

2015 Quota	April Submission	August revision	Delta	Comment
Morphine for Conversion	22,000	19,395	(2,605)	
Morphine for Conversion for 14-HM	0	6,855	6,855	
Total Morphine for Conversion	22,000	26,250	4,250	
Codeine For Sale	19,000	14,500	(4,500)	Total Codeine for Sale: 25,500 kgB

2015 Morphine for Conversion Inventory Calculations	
2014 Ending Inventory	2,833
Non saleable material	0
2014 Available End. Inv.	2,833
2015 API Quota	26,250
2015 Dispositions:	
Converted to Codeine	15,516
Converted to 14-HM	6,855
Processing Losses	-
2015 Ending Inventory	6,712
Converted to % Yearend	30.0%

	kgs, base
2014 Est. Dispositions	14,119
2015 Est. Dispositions	22,372
Average	18,245
50% Inventory Allowance	9,123

2015 Codeine Phosphate from Morphine Inventory Calculations	
2014 Ending Inventory	2,747
Non saleable material	0
2014 Available End. Inv.	2,747
2015 API Quota	14,500
2015 Dispositions:	
Sales	11,176
Processing Losses	(1,015)
2015 Ending Inventory	5,056
Converted to % Yearend	44.9%

	kgs, base
2014 Est. Dispositions	11,360
2015 Est. Dispositions	11,176
Average	11,268
50% Inventory Allowance	5,634

Description	ACTUAL YEAR TO DATE (JUNE 30, 2014) Input to Step	Process Yield	MWC	Net output of step	Loss by step	ESTIMATE ON REMAINING QUOTA Input to Step	Output of Step	Loss by step
CPS-AMA to Morphine for Conv	7,657	85.60%		6,554		4,529	3,876	
Codeine for Sale								
Morphine for Conv to Codeine for Sale	7,478	89.0%	1.05	6,988		5,642	5,272	
Codeine(fr Morph) to Codeine Phosphate	5,220	93.60%		4,886	(334)	5,775	5,406	(370)
Codeine Phosphate Finished	5,114	99.36%		5,081	(33)	5,490	5,455	(35)
Total					(367)			(405)

Description	2015 Quota Calc Input to Step	Process Yield	MWC	Net output of step	Loss by step
CPS-AMA to Morphine for Conv	30,666	85.60%		26,250	
Codeine for Sale					
Morphine for Conv to Codeine for Sale	15,516	89.00%	1.05	14,500	
Codeine(fr Morph) to Codeine Phosphate	14,500	93.60%		13,572	(928)
Codeine Phosphate Finished	13,572	99.36%		13,485	(87)
Total					(1,015)

2015 Forecast Customer	DEA #	2015 Total, kg Salt	2015 Total, kgB	Comment
(b)(4);(b)(7)(E)		1,900	1,406	
		300	222	
		158	117	
		300	222	
		300	222	
		12,100	8,954	Includes Generic Bidco RG0360115
		45	33	
Total		15,103	11,176	

5828 - 297
2514 - 275
2620 - 115
10,962

5,588 (inv)
16,764 need

COMBINED CODEINE INVENTORY (TASMAN AND MORPHINE CODEINE)

2014 Total Codeine Inventory Calculations	With Current Quota
2013 Ending Inventory	5,166
Non saleable material	38
2013 Available End. Inv.	5,128
2014 API Quota	17,232
2014 Dispositions:	
Sales	16,114
Processing Losses	(1,363)
2014 Ending Inventory	4,882
Converted to % Yearend	33.4%

	kgs, base
2013 Dispositions	13,141
2014 Est. Dispositions	16,114
Average	14,628
50% Inventory Allowance	7,314

2015 Total Codeine Inventory Calculations	
2014 Ending Inventory	4,882
Non saleable material	0
2014 Available End. Inv.	4,882
2015 API Quota	25,500
2015 Dispositions:	
Sales	19,168
Processing Losses	(2,291)
2015 Ending Inventory	8,923
Converted to % Yearend	50.6%

	kgs, base
2014 Est. Dispositions	16,114
2015 Est. Dispositions	19,168
Average	17,641
50% Inventory Allowance	8,821

2014
-CI
41882
2247
4129

Basic Class:
Total PQ Requests: 9,113.000

2015 Initial APQ Worksheets

Est:
IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	7,988.764	0.000	0.000	0.000	0.000	5.000	0.000	1.000	3.750	1.250	5.000
		5.000	5.000	0.764	7,988.764	0.000	0.872	14.945	0.000	3.000	0.000	15.946	14.959	-14.606	5.000
		160,000.000	80,000.000	7,987.000	7,988.764	1.000	9,110.988	202,423.000	0.000	184,250.000	0.000	122,387.000	211,617.250	-66,784.265	107,283.968
		1,000.000	250.000	0.200	7,988.764	0.000	0.228	135.960	0.000	1,000.000	0.000	0.000	290.220	675.625	675.625
MQ Totals:		161,010.000	80,260.000												107,969.813

2014 Final Initial APQ:	80,500.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	80,500.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	80,600.000
2015 Proposed Establish APQ:	81,100.000
2015 Established APQ:	81,100.000
with 25% buffer:	226,375.000

Basic Class:

Total PQ Request: 1.000

2015 Initial APQ Worksheets

IMS Est: - 043

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	702,222.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1.500	-1.000	2.000
		31,650.000	15,000.000	465.000	702,222.000	0.001	0.001	13,489.000	0.000	31,620.000	0.000	13,488.000	24,366.750	3,881.001	24,368.750
		740,000.000	690,000.000	703,577.000	702,222.000	1.002	1.002	265,969.000	18,400.000	712,056.000	0.000	347,826.000	681,978.750	-221,011.748	740,000.000
MQ Totals:		771,652.000	909,002.000												764,368.750

2014 Final Initial APQ:	600,000.000
2014 Final Revised APQ:	1,031,000.000
FDA Est (2014 Initial APQ * 1 + FDA Est):	500,000.000
IMS Est (2014 Initial APQ * 1 + IMS Est):	572,760.000
2015 Proposed Establish APQ:	1,031,000.000

APQ sufficient, no adjustment required

Basic Class:
Total PQ Requ. 1,007,216.255

2015 Initial APQ Works

FDA Est: .015
IMS Est: -.021

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 60% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	998,926.931	0.000	0.000	0.101	0.000	4.000	1.000	3.826	0.149	5.000
		200,000.000	151,000.000	36,960.000	998,926.931	0.037	37,266.703	53,892.000	0.000	200,000.000	50,000.000	153,669.000	79,441.378	153,669.000
		2.000	2.000	0.538	998,926.931	0.000	0.542	1.010	0.000	0.500	1.711	2.258	-1.332	2.000
		13,330.000	14,151.000	9,082.000	998,926.931	0.009	9,157.365	103.000	0.000	13,330.000	1,000.000	10,690.500	14,060.456	13,330.000
		600,000.000	461,271.000	245,042.000	998,926.931	0.245	247,075.415	230,548.000	0.000	600,000.000	236,303.000	518,865.000	332,342.018	518,865.000
		940,000.000	810,000.000	645,039.000	998,926.931	0.646	650,391.681	298,586.000	189,170.000	900,111.000	378,269.000	831,514.500	996,084.501	940,000.000
		33,000.000	16,000.000	4,460.000	998,926.931	0.004	4,497.910	17,597.000	0.000	33,000.000	13,000.000	25,197.750	9,024.263	25,197.750
		13,500.000	6,600.000	0.000	998,926.931	0.000	0.000	0.000	0.000	8,500.000	7,214.900	4,950.000	3,550.000	4,950.000
MQ Totals:		1,799,837.000	1,459,029.000											1,656,018.750

2014 Final Initial APQ: 1,687,000.000
2014 Final Revised APQ: 0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est): 1,712,305.000
IMS Est: (2014 Initial APQ * 1 + IMS Est): 1,652,247.800

APQ adjustment made based on conversion from ANPP and FDA estimate

2015 Establish APQ: 1,720,000.000
2015 Establish APQ with 25% buffer: 2,150,000.000

Basic Class:
Total PQ Request: 95,133,436.749

2015 Initial APQ Worksheets

FDA Est: -.022
IMS Est: -.046

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	45,068,169.355	0.000	0.000	0.051	0.000	4.000	1.000	3.788	0.199	5.000
		200,000.000	99,400.000	0.000	45,068,169.355	0.000	0.000	0.000	0.000	200,000.000	80,000.209	74,550.000	125,450.000	125,450.000
		20.000	20.000	3.575	45,068,169.355	0.000	7.546	74.093	0.000	5.000	69.094	70.570	-74.660	20.000
		355,000.000	175,079.000	39,742.000	45,068,169.355	0.001	63,890.541	12,258.000	0.000	355,000.000	5,000.000	140,502.750	347,295.927	347,295.927
		5,500.000	7,320.000	60,994.030	45,068,169.355	0.000	23,207.064	0.000	0.000	5,500.000	0.000	5,490.000	29,018.830	5,500.000
		610,000.000	3,200,000.000	3,230,559.000	45,068,169.355	0.072	6,819,316.183	5,043,303.000	0.000	610,000.000	1,993,302.000	6,182,477.250	1,890,844.729	610,000.000
		28,000,000.000	19,274,159.000	22,652,826.000	45,068,169.355	0.507	48,239,543.843	7,741,178.000	12,200.000	23,464,731.000	8,102,029.000	20,261,502.750	61,579,563.304	20,261,502.750
		3,602,000.000	1,885,910.000	148,721.000	45,068,169.355	0.003	313,831.891	2,031,970.000	0.000	3,100,000.000	1,983,000.000	2,938,410.000	46,042.489	2,938,410.000
		32,302,000.000	22,958,367.000	16,075,426.630	45,068,169.355	0.401	38,155,037.242	3,655,635.900	0.000	29,000,000.000	8,554,000.000	19,960,502.375	55,848,365.463	32,302,000.000
		10,000,000.000	2,184,719.000	605,442.000	45,068,169.355	0.013	1,276,044.622	2,209,940.000	0.000	8,456,000.000	6,550,000.000	3,295,994.250	4,205,039.028	4,205,039.026
		11,600,000.000	6,981,532.000	103,852.000	45,068,169.355	0.002	219,218.975	3,845,502.000	0.000	9,150,000.000	1,203,600.000	8,120,275.500	342,372.718	8,120,275.500
MQ Totals:		84,705,525.000	56,766,511.000											68,915,496.204

2014 Final Initial APQ: 79,700,000.000
2014 Final Revised APQ: 0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est): 77,945,500.000
IMS Est: (2014 Initial APQ * 1 + IMS Est): 76,400,420.000

APQ sufficient, no adjustment required

Basic Class:
Total PQ Requ... 5,507,526,429

2015 Initial APQ Work

FDA Est: .067
IMS Est: -.051

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	4.000	1.000	3.750	0.250	5.000
		64,080.000	76,700.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	60,000.000	28,000.000	57,525.000	-7,525.000	57,525.000
		30.000	30.000	2.921	3,574,775.079	0.000	4.500	49.447	0.000	14.000	63.848	59.585	-52.322	30.000
		116,000.000	78,000.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	112,470.000	0.000	58,500.000	53,970.000	78,000.000
		165,700.000	229,064.000	128,462.930	3,574,775.079	0.036	197,918.181	35,920.696	0.000	165,700.000	0.000	198,738.522	205,379.031	165,700.000
		625,178.000	558,298.000	679,036.334	3,574,775.079	0.190	1,047,556.353	209,218.035	5,900.000	568,344.000	130,000.000	574,137.026	1,257,247.906	574,137.026
		534,000.000	445,000.000	334,715.000	3,574,775.079	0.094	515,683.272	251,602.000	0.000	534,000.000	251,602.000	522,451.500	593,252.090	522,451.500
		1,180,000.000	1,179,810.000	997,252.000	3,574,775.079	0.279	1,536,430.020	392,859.000	1,780.000	937,820.000	535,939.000	1,175,501.750	1,582,421.025	1,175,501.750
		2,585,000.000	1,674,818.000	1,389,805.400	3,574,775.079	0.389	2,141,222.818	855,997.550	0.000	2,425,000.000	677,000.000	1,898,111.663	2,869,417.474	1,898,111.663
		300,000.000	97,711.000	44,542.000	3,574,775.079	0.012	68,624.245	31,189.000	0.000	133,500.000	84,000.000	96,675.000	114,808.057	114,808.057
MQ Totals:		5,569,993.000	4,337,436.000											4,590,259.995

2014 Final Initial APQ: 5,400,000.000
2014 Final Revised APQ: 0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est): 5,761,800.000
IMS Est: (2014 Initial APQ * 1 + IMS Est): 5,124,600.000

APQ adjustment based on increased export requirements for (b)(4)

2015 Establish APQ: 5,600,000.000
2015 Establish APQ with 25% buffer 7,000,000.000

2015 GWL

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 120281		Date Submitted	31-JUL-14
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
HYDROMORPHONE		Schedule/List Number	2
		Drug Code	9150-0
Name and Address of Registrant		Quota Year	2015
(b)(4)		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 2013	2014	2015	Quota Requested
	1,940,000.0	1,674,818.0	0.0	2,585,000.0
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...	855,997.55	0.0	677,000.0	677,000.0
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
	855,997.55	0.0	677,000.0	677,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	928,092.72	0.0	2,425,000.0	2,425,000.0
b Exports.....	462,731.07	0.0	0.0	0.0
	1,390,823.79	0.0	2,425,000.0	2,425,000.0
Acquisition/Production				
a.Domestic Sources.....	69,642.5	0.0	2,585,000.0	2,585,000.0
	69,642.5	0.0	2,585,000.0	2,585,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% 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 loss estimated at 3,000 grams 1,000 grams to support reference standard business Replaces application reference# 119634

2014 Quota	Initial 2014 Grant	Additional 2014 Grant
CPS AOA	5,139	5,850
Oripavine (TOR)	3,284	5,250
Hydromorphone (HMH)	1,675	2,110

2014 Inventory Calculations HMH	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	874	874
Non saleable material	18	18
2013 Available End. Inv.	856	856
2014 API Quota	1,675	2,110
2014 Dispositions:		
Sales	2,258	2,257.9
Processing Losses	(187)	(187.2)
2014 Ending Inventory	86	520.9
Converted to % Yearend	4.7%	28.6%

	kgs, base
2013 Dispositions	1,391
2014 Estimated Dispositions	2,258
Average	1,824
50% Inventory Allowance	912

	ACTUAL YEAR TO DATE (5/31/14)				REMAINING QUOTA			ADDITIONAL QUOTA		
Description	Input to Step	Process Yield	Net output of step	Loss by step	Input to Step	Output of Step	Loss by step	Input to Step	Output of Step	Loss by step
CPS-AOA Requirements										
CPS-AOA to Technical Oripavine (TOR)	1,977	90.12%	1,782		1,666	1,502		2,182	1,966	
Oripavine										
CPS-AOA to Technical Oripavine (TOR)	1,782	90.12%	1,606		1,502	1,353		2,182	1,966	
TOR to Dihydrooripavine (DHO)	1,606	87.30%	1,402	(204)	1,353	1,181	(172)	1,966	1,717	(250)
DHO to Purified Dihydrooripavine (pDHO)	1,412	82.50%	1,165	(237)	1,181	975	(207)	1,717	1,416	(300)
DHO to Purified Dihydrooripavine (pDHO) for Aesica	0	82.50%	0		0	0	0	0	0	0
Total				(451)			(379)			(550)
Hydromorphone For Sale										
pDHO to Hydromorphone (HMH)	1,030	78.00%	803		1,117	871		558	435	
HMH Sized & Packaged	1,294	99.87%	1,292	(2)	871	870	(1)	435	435	(1)
Reprocessing OOS HMH	877	79.04%	693	(184)						
Total				(185)			(1)			(1)

2014 Inventory Calculations TOR	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	161	161
Non saleable material	10	10
2013 Available End. Inv.	151	151
2014 API Quota	3,284	5,250
2014 Dispositions:		
Conversion to Hydromorphone	2,147	2,705
Exported to (b)(4)	0	0
Processing Losses	(830)	(1,380)
2014 Ending Inventory	458	1,316
Converted to % Yearend	17.4%	50.0%

2015 Quota	Apr-15	Aug-15	Delta
CPS AOA	5,139	7,000	1,861
Oripavine (TOR)	5,150	6,230	1,080
Hydromorphone (HMH)	2,059	2,584	525

2015 Inventory Calculations	
2014 Ending Inventory	521
Non saleable material	0
2014 Available End. Inv.	521
2015 API Quota	2,584
2015 Dispositions:	
Sales	2,425
Processing Losses	(3)
2015 Ending Inventory	677
Converted to % Yearend	28.9%

	kgs, base
2014 Estimated Dispositions	2,258
2015 Estimated Dispositions	2,425
Average	2,341
50% Inventory Allowance	1,171

	2015 Quota Calc			
Description	Input to Step	Process Yield	Net output of step	Loss by step
CPS-AOA Requirements				
CPS-AOA to Technical Oripavine (TOR)	6,182	90.12%	5,571	
Oripavine				
CPS-AOA to Technical Oripavine (TOR)	5,571	90.12%	5,020	
TOR to DHO	5,020	87.30%	4,383	(638)
DHO to pDHO	4,383	82.50%	3,616	(767)
DHO to Purified Dihydrooripavine (pDHO) for (b)(4)	303	82.50%	250	
Total				41,395)
Hydromorphone For Sale				
pDHO to HMH	3,313	78.00%	2,584	
HMH Sized & Packaged	2,584	99.87%	2,581	(3)
Reprocessing OOS HMH	0	79.04%	0	
Total				(3)

2015 Inventory Calculations TOR	
2014 Ending Inventory	1,316
Non saleable material	0
2014 Available End. Inv.	1,316
2015 API Quota	6,230
2015 Dispositions:	
Conversion to Hydromorphone	3,616
Exported to (b)(4)	350
Processing Losses	(1,405)
2015 Ending Inventory	3,176
Converted to % Yearend	65.2%

	kgs, base
2013 Dispositions	2,562
2014 Estimated Dispositions	2,705
Average	2,634
50% Inventory Allowance	1,317

2014 CPS-Oripavine Inventory Calculations	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	786	786
Non saleable material	2	2
2013 Available End. Inv.	784	784
2014 API Quota	5,139	5,850
2014 Dispositions:		
Converted to Oripavine	5,466	5,466
2014 Ending Inventory	457	1,168
Converted to % Yearend	12.2%	31.3%

	kgs, base
2013 Dispositions	2,004
2014 Estimated Dispositions	5,466
Average	3,735
30% Inventory Allowance	1,120

2014 Hydromorphone for Sale Forecast			
Customer	DEA #	2015 Total, kg Salt	2015 Total, kgB
(b)(4);(b)(7)(E)		50	45
		31	28
		130	116
		11	10
		542	482
		16	14
		10	9
		9	8
		184	164
		378	336
		411	366
		138	123
		200	178
		42	37
		2	2
		35	31
		150	134
		28	25
		47	42
		6	5
		26	23

	kgs, base
2014 Estimated Dispositions	2,705
2015 Estimated Dispositions	3,966
Average	3,335
50% Inventory Allowance	1,668

2015 CPS-Oripavine Inventory Calculations	
2014 Ending Inventory	1,168
Non saleable material	0
2014 Available End. Inv.	1,168
2015 API Quota	7,000
2015 Dispositions:	
Converted to Oripavine	6,182
2015 Ending Inventory	1,987
Converted to % Yearend	34.1%

	kgs, base
2014 Estimated Dispositions	5,466
2015 Estimated Dispositions	6,182
Average	5,824
30% Inventory Allowance	1,747

2015 Hydromorphone for Sale Forecast			
Customer	DEA #	2015 Total, kg Salt	2015 Total, kgB
(b)(4);(b)(7)(E)		50	45
		100	89
		350	312
		355	316
		540	481
		667	594
		104	93
		15	13
		2	2
		50	45
		8	7
		30	27
		100	89
		200	178
		136	121
		17	15
	Total	2,724	2,425

2015 Oripavine for Sale Forecast			
Customer	DEA #	2015 Total, kg Salt	2015 Total, kgB
(b)(4)	EXPORT		350

Basic Class:
Total PQ Requ... 4,347,000

2015 Initial APQ Worksh...

FDA Est:
IMS Est: .117

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		2,000	2,000	0.000	1,907.000	0.000	0.000	0.000	0.000	0.500	1,500	1,500	-1,000	2,000
		5,600.000	3,600.000	1,907.000	1,907.000	1.000	4,347.000	42.000	6.000	4,994.000	1,638.000	2,731.500	7,691.750	5,600.000
MQ Totals:		5,602.000	3,602.000											5,602.000

2014 Final Initial APQ:	1,600.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	1,600.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	1,786.400
2015 Proposed Initial APQ:	2,700.000
2015 Established APQ:	5,700.000
2015 Established APQ with 25% buffer:	7,125.000

Basic Class:
Total PQ Requ... 1,382,775.000

2016 Initial APQ Work

FDA Est:
IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 30% Invent	MQ
(b)(4);(b)(7)(E)		5.000	0.000	0.000	47,603,753.601	0.000	0.000	0.000	0.000	5.000	0.000	0.000	5.000	5.000
		749,000.000	0.000	0.000	47,603,753.601	0.000	0.000	0.000	0.000	749,000.000	0.000	0.000	749,000.000	749,000.000
		4,800,000.000	5,350,000.000	3,335,263.000	47,603,753.601	0.070	96,476.070	24,303.000	5,840,000.000	3,840,000.000	1,944,301.000	4,030,727.250	3,763,792.087	4,800,000.000
		37,000,000.000	44,000,000.000	36,564,556.000	47,603,753.601	0.768	1,057,569.114	12,904,910.000	0.000	37,123,902.000	9,983,206.000	42,678,582.500	-7,458,921.808	37,000,000.000
		2,000.000	2,875.000	160.000	47,603,753.601	0.000	4.628	69.210	0.000	2,000.000	0.000	2,208.158	-219.675	2,000.000
		26,251,000.000	15,500,000.000	7,877,794.000	47,603,753.601	0.165	227,873.685	2,451,207.000	0.000	22,371,000.000	6,712,000.000	13,483,465.250	8,579,835.062	19,857,202.625
		4,500,000.000	1,960,000.000	0.000	47,603,753.601	0.000	0.000	0.000	0.000	4,500,000.000	0.000	1,470,000.000	3,030,000.000	3,030,000.000
MQ Totals:		73,302,005.000	66,812,875.000											65,438,207.625

2014 Final Initial APQ:	73,000,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	73,000,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	73,000,000.000

APQ sufficient, no adjustment required

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 120271 | Date Submitted: 31-JUL-14

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

Schedule/List Number: 0
Drug Code: 9300-A
Quota Year: 2015

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 2013	2014	2015	Quota Requested
	12,796,000.0	15,500,000.0	0.0	26,251,000.0
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...	2,451,207.0	0.0	6,712,000.0	6,712,000.0
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
	2,451,207.0	0.0	6,712,000.0	6,712,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	5,787.0	0.0	22,371,000.0	22,371,000.0
b Exports.....	0.0	0.0	0.0	0.0
	5,787.0	0.0	22,371,000.0	22,371,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	26,251,000.0	26,251,000.0
	0.0	0.0	26,251,000.0	26,251,000.0

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	2015	% Yield
CODEINE (FOR SALE)	9050-B	10,276,811	7,400,960	14,500	91.45

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

22,371,000 grams for conversion to codeine for sale, of which 6,855,000 grams for conversion to 14-HM 1,000 grams to support reference standard business Replaces Application Reference# 119688

2014 Quota	Initial 2014 Grant	Additional 2014 Grant	Comment
Morphine for Conversion for Cod for Sale	10,431	14,501	
Morphine for Conversion for 14-HM	0	999	
Total Morphine for Conversion	10,431	15,500	
Codeine For Sale (from Morphine)	12,260		Total Codeine for Sale Initial grant 17,231.565 kgB

2014 Morphine for Conversion Inventory Calculations	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	2,454	2,454
Non saleable material	3	3
2013 Available End. Inv.	2,451	2,451
2014 API Quota	10,431	14,501
2014 Dispositions:		
Converted to Codeine	13,120	13,120
Converted to 14-HM	0	999
Processing Losses	-	-
2014 Ending Inventory	-238	2,833
Converted to % Yearend	-2.2%	25.9%

	kgs, base
2013 Dispositions	7,872
2014 Est. Dispositions	14,119
Average	10,995
50% Inventory Allowance	5,498

2014 Codeine Phosphate from Morphine Inventory Calculations	With Current Quota
2013 Ending Inventory	2,644
Non saleable material	26
2013 Available End. Inv.	2,618
2014 API Quota	12,260
2014 Dispositions:	
Sales	11,360
Processing Losses	(772)
2014 Ending Inventory	2,747
Converted to % Yearend	24.8%

	kgs, base
2013 Dispositions	10,761
2014 Est. Dispositions	11,360
Average	11,060
50% Inventory Allowance	5,530

2015 Quota	April Submission	August revision	Delta	Comment
Morphine for Conversion	22,000	19,395	(2,605)	
Morphine for Conversion for 14-HM	0	6,855	6,855	
Total Morphine for Conversion	22,000	26,250	4,250	
Codeine For Sale	19,000	14,500	(4,500)	Total Codeine for Sale: 25,500 kgB

2015 Morphine for Conversion Inventory Calculations	
2014 Ending Inventory	2,833
Non saleable material	0
2014 Available End. Inv.	2,833
2015 API Quota	26,250
2015 Dispositions:	
Converted to Codeine	15,516
Converted to 14-HM	6,855
Processing Losses	-
2015 Ending Inventory	6,712
Converted to % Yearend	30.0%

	kgs, base
2014 Est. Dispositions	14,119
2015 Est. Dispositions	22,372
Average	18,245
50% Inventory Allowance	9,123

2015 Codeine Phosphate from Morphine Inventory Calculations	
2014 Ending Inventory	2,747
Non saleable material	0
2014 Available End. Inv.	2,747
2015 API Quota	14,500
2015 Dispositions:	
Sales	11,176
Processing Losses	(1,015)
2015 Ending Inventory	5,056
Converted to % Yearend	44.9%

	kgs, base
2014 Est. Dispositions	11,360
2015 Est. Dispositions	11,176
Average	11,268
50% Inventory Allowance	5,634

Description	ACTUAL YEAR TO DATE (JUNE 30, 2014) Input to Step	Process Yield	MWC	Net output of step	Loss by step	ESTIMATE ON REMAINING QUOTA Input to Step	Output of Step	Loss by step
CPS-AMA to Morphine for Conv	7,657	85.60%		6,554		4,529	3,876	
Codeine for Sale								
Morphine for Conv to Codeine for Sale	7,478	89.0%	1.05	6,988		5,642	5,272	
Codeine(fr Morph) to Codeine Phosphate	5,220	93.60%		4,886	(334)	5,775	5,406	(370)
Codeine Phosphate Finished	5,114	99.36%		5,081	(33)	5,490	5,455	(35)
Total					(367)			(405)

Description	2015 Quota Calc Input to Step	Process Yield	MWC	Net output of step	Loss by step
CPS-AMA to Morphine for Conv	30,666	85.60%		26,250	
Codeine for Sale					
Morphine for Conv to Codeine for Sale	15,516	89.00%	1.05	14,500	
Codeine(fr Morph) to Codeine Phosphate	14,500	93.60%		13,572	(928)
Codeine Phosphate Finished	13,572	99.36%		13,485	(87)
Total					(1,015)

2015 Forecast Customer	DEA #	2015 Total, kg Salt	2015 Total, kgB	Comment
(b)(4);(b)(7)(E)		1,900	1,406	
		300	222	
		158	117	
		300	222	
		300	222	
		12,100	8,954	Includes Generic (b)(4)
		45	33	
Total		15,103	11,176	

COMBINED CODEINE INVENTORY (TASMAN AND MORPHINE CODEINE)

2014 Total Codeine Inventory Calculations	With Current Quota
2013 Ending Inventory	5,166
Non saleable material	38
2013 Available End. Inv.	5,128
2014 API Quota	17,232
2014 Dispositions:	
Sales	16,114
Processing Losses	(1,363)
2014 Ending Inventory	4,882
Converted to % Yearend	33.4%

	kgs, base
2013 Dispositions	13,141
2014 Est. Dispositions	16,114
Average	14,628
50% Inventory Allowance	7,314

2015 Total Codeine Inventory Calculations	
2014 Ending Inventory	4,882
Non saleable material	0
2014 Available End. Inv.	4,882
2015 API Quota	25,500
2015 Dispositions:	
Sales	19,168
Processing Losses	(2,291)
2015 Ending Inventory	8,923
Converted to % Yearend	50.6%

	kgs, base
2014 Est. Dispositions	16,114
2015 Est. Dispositions	19,168
Average	17,641
50% Inventory Allowance	8,821

2014 Quota	Initial 2014 Grant	Additional 2014 Grant	Delta
PSC-AOA	5,232	6,900	1,668
Morphine for Conversion	10,431	14,501	4,070
Oxymorphone Conversion Commercial	2,608	2,080	-528
Oxymorphone Conversion Development	0	671	671

2014 COMd Inventory Calculations	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	272	272
Non saleable material	3	3
2013 Available End. Inv.	269	269
2014 API Quota	2,608	2,080
2014 Development Quota (not included in inventory)		671
2014 Dispositions:		
Sales	1,588	1,588
Processing Losses	(13)	(10)
Non-saleable (Sent out to	(77)	(77)
2014 Ending Inventory	1,199	678
Converted to % Yearend	79.8%	44.9%

	kgs, base
2013 Dispositions	1,416
2014 Est. Dispositions	1,588
Average	1,502
50% Inventory Allowance	751

Description	ACTUAL YEAR TO DATE: CPS-AOA Input	Process Yield	MWC	Net output of step	QUOTA: CPS-AOA Input	MWC	Net output of step	WITH INCREASE: Input to Step	MWC	Net output of step
CPS-AOA to Crude Oxymorphone for Conversion	0	69.4%	1.0133	0	3,708	1.0133	2,608	6,427	1.0133	4,521

Description	ACTUAL YEAR TO DATE (JUNE 30, 2014): Input to Step	Process Yield	MWC	Net output of step	Less by step	QUOTA: Input to Step	Output of Step	Less by step	WITH INCREASE: Input to Step	Output of Step	Less by step
Oxymorphone For Conversion											
COM to COMd	0	99.5%	1.0000	0	0	2,608	2,594	(13)	4,529	4,505	24
Total					0			(13)			24

2014 CPS-Oripavine Inventory Calculations	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	758	758
Non saleable material	0	0
2013 Available End. Inv.	758	758
2014 API Quota	5,232	6,900
2014 Dispositions:		
Morphine for Conversion	-	1,190
Oxymorphone for Conversion	3,021	3,021
Oxymorphone for Sale	1,473	1,473
2014 Ending Inventory	1,496	1,975
Converted to % Yearend	33%	43%

	kgs, base
2013 Dispositions	3,464
2014 Est. Dispositions	5,683
Average	4,574
50% Inventory Allowance	1,372

2015 Quota	Apr-15	Aug-15	Delta
PSC-AOA	5,139	12,900	7,761
Morphine for Conversion	22,000	26,250	4,250
Oxymorphone Conversion	450	6,150	5,700
Oxymorphone Conversion Development	0	0	0

2015 COMd Inventory Calculations	
2014 Ending Inventory	674
Non saleable material	0
2014 Available End. Inv.	674
2015 API Quota	6,150
2015 Dispositions:	
Sales	5,130
Processing Losses	(31)
Validation Inventory	0
2015 Ending Inventory	2,663
Converted to % Yearend	49.3%

	kgs, base
2014 Est. Dispositions	3,588
2015 Est. Dispositions	5,130
Average	3,359
50% Inventory Allowance	1,679

Description	2015 Quota Calc: CPS-AOA Input	Process Yield	MWC	Net output of step	
CPS-AOA to Crude Oxymorphone for Conversion	8,745	69.4%	1.0133	6,150	

Description	2015 Quota Calc: Input to Step	Process Yield	MWC	Net output of step	Less by step
Oxymorphone For Conversion					
COM to COMd	6,150	99.5%	1.0000	6,119	(31)
Total					431)

2015 CPS-Oripavine Inventory Calculations	
2014 Ending Inventory	1,975
Non saleable material	0
2014 Available End. Inv.	1,975
2015 API Quota	12,900
2015 Dispositions:	
Morphine for Conversion	
Oxymorphone for Conversion	8,745
Oxymorphone for Sale	2,106
2015 Ending Inventory	3,023
Converted to % Yearend	34%

	kgs, base
2014 Est. Dispositions	5,683
2015 Est. Dispositions	10,851
Average	8,767
50% Inventory Allowance	2,630

(b)(4)

(b)(4) Customer has not told (b)(4) which grade will be ordered for 2015. Since more CPS is required for old process, using that as basis for 2015.

(b)(4) Confidential

7/30/2014

2014 Morphine for Conversion Inventory Calculations	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	2,454	2,454
Non saleable material	3	3
2013 Available End. Inv.	2,451	2,451
2014 APJ Quota	10,431	14,501
2014 Dispositions	-	
Converted to Codeine	13,120	13,120
Converted to 14-HM	999	999
Processing Losses	-	-
2014 Ending Inventory	-4,237	2,833
Converted to % Yearend	-18.8%	25.8%

	kgs, base
2013 Dispositions	7,872
2014 Est. Dispositions	14,119
Average	10,995
50% Inventory Allowance	5,498

Description	Number of Batches	Batch Input, KgB	Process Yield	Batch output, KgB	Loss by step, KgB	Total Input, KgB	Total Output, KgB	Total Loss KgB	Total output, kgB as AMA for Conversion
Validation Requirements									
Morphine For Conversion									
CPS AOA to 14HM	4	297	84%	250	[redacted]	1,199	999		949
Oxymorphone For Conversion (Commercial)									
14HM to COMH	3	263	85%	224	[redacted]	789	671		
COM to COM Dry	3	224	99%	221	(2)	671	663	(7)	
Validation Requirements									
Oxymorphone For Sale (Validation - Filing Impact)									
14HM to COM	0	132	88%	116		-	-		
COM to OMH Dry	0	116	74%	85	(31)	-	-	-	
OMH Dry to OMH Finished API	0	85	98%	83	(2)	-	-	-	
Overall Totals								-	

2014 Oxymorphone for Conversion Forecast				
Customer	DEA #	kgs salt	kgB	
(b)(4);(b)(7)(E)		1,857	1,588	

2015 Morphine for Conversion Inventory Calculations	
2014 Ending Inventory	2,833
Non saleable material	0
2014 Available End. Inv.	2,833
2015 APJ Quota	26,350
2015 Dispositions	
Converted to Codeine	15,516
Converted to 14-HM	6,855
Processing Losses	-
2015 Ending Inventory	6,712
Converted to % Yearend	34.8%

(b)(4) Customer has not sold [redacted] such grade will be ordered for 2015. Requesting morphine for conversion should the new grade be requested

	kgs, base
2014 Est. Dispositions	14,119
2015 Est. Dispositions	27,372
Average	18,245
50% Inventory Allowance	9,123

Description	Number of Batches	Batch Input, KgB	Process Yield	Batch output, KgB	Loss by step, KgB	Total Input, KgB	Total Output, KgB	Total Loss KgB	Total output, kgB as AMA for Conversion
Morphine For Conversion									
CPS AOA to 14HM	27.57	297	88%	262	[redacted]	8,200	7,216		6,855
Oxymorphone For Conversion									
14HM to COM	26.57	263	88%	231	[redacted]	6,989	6,150		
COM to COM Dry	26.57	231	99%	229	(2)	6,150	6,089	(61)	
Validation Requirements									
Oxymorphone For Sale									
14HM to COM	4	132	88%	116		526	463		
COM to OMH Dry	4	116	74%	85	(31)	463	341	(122)	
OMH Dry to OMH Finished API	4	85	98%	83	(2)	341	334	(7)	
Overall Totals								(129)	

2015 Oxymorphone for Conversion Forecast				
Customer	DEA #	kgs salt	kgB	
(b)(4);(b)(7)(E)		6,000	5,130	

Basic Class:
Total PQ Requ 1,130,005.000

2015 Initial APQ Worksh

FDA Est:
IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 80% Invent	MQ
(b)(4);(b)(7)(E)		53,450.000	35,000.000	21,054.000	386,654.000	0.054	61,530.788	14,352.000	0.000	36,000.000	19,000.000	37,014.000	74,311.485	37,014.000
		450,000.000	430,000.000	365,600.000	386,654.000	0.946	1,068,474.212	173,187.000	0.000	440,000.000	203,914.000	452,390.250	1,279,905.765	450,000.000
		40,000.000	0.000	0.000	386,654.000	0.000	0.000	0.000	0.000	40,000.000	0.000	0.000	40,000.000	40,000.000
MQ Totals:		543,450.000	465,000.000											527,014.000

2014 Final Initial APQ:	500,000.000
2014 Final Revised APQ:	0.000
FDA Est: [2014 Initial APQ * 1 + FDA Est]:	500,000.000
IMS Est: [2014 Initial APQ * 1 + IMS Est]:	500,000.000
2015 Proposed Initial APQ:	550,000.000

APQ sufficient, no adjustment required

Basic Class: 9330-0
Total PQ Requested: 3,251,005.000

2015 Initial APQ Worksheets

FDA Est: .07 (avg naloxone + naltrexone data)
IMS Est: .048 (naloxone data)

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	13,621,761.480	0.000	0.000	0.000	0.000	5.000	0.000	3.750	1.250	5.000
		1,200,000.000	1,100,000.000	639,490.000	13,621,761.480	0.047	152,622.346	3,167.000	0.000	1,200,000.000	0.000	827,375.250	562,610.932	1,200,000.000
		1,131,000.000	1,674,318.000	978,502.000	13,621,761.480	0.013	42,601.751	253,484.000	0.000	1,131,000.000	0.000	1,445,851.500	-324,970.311	1,131,000.000
		19,000,000.000	10,732,296.000	10,146,533.000	13,621,761.480	0.745	2,421,597.936	69,262.000	0.000	18,777,778.000	316,176.000	8,101,185.000	13,668,269.923	13,668,269.923
		6,231,000.000	3,283,650.000	2,585,244.480	13,621,761.480	0.188	612,227.015	151,100.000	350,000.000	3,966,000.000	2,176,000.000	2,576,062.500	2,457,447.394	3,283,650.000
		1,000,000.000	612,500.000	0.000	13,621,761.480	0.000	0.000	324,264.000	0.000	1,000,000.000	1,400,000.000	702,573.000	215,351.000	702,573.000
		1,000,000.000	430,000.000	0.000	13,621,761.480	0.000	0.000	0.000	0.000	1,400,000.000	23,000.000	322,500.000	1,080,500.000	1,000,000.000
MQ Totals:		29,562,005.000	17,832,771.000											21,903,497.923

2014 Final Initial APQ: 18,200,000.000
2014 Final Revised APQ: 0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est): 19,464,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est): 19,086,680.000

2015 Establish APQ: 28,000,000.000
2015 Establish APQ with 25% buffer: 35,000,000.000

APQ adjustment made based on increased dispersion of nal drugs to fed, state, local law enforcement
(same rationale for oxymorphone - for conversion)

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 118650		Date Submitted	26-MAR-14
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	2015
		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 2013	2014	2015	Quota Requested
	1,467,039.0	1,674,318.0	0.0	1,131,000.0
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...	253,484.0	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
	253,484.0	0.0	0.0	0.0
Disposition(Sale)/Utilization				
a.Domestic.....	154,943.0	0.0	1,131,000.0	1,131,000.0
b Exports.....	0.0	0.0	0.0	0.0
	154,943.0	0.0	1,131,000.0	1,131,000.0
Acquisition/Production				
a.Domestic Sources.....	154,690.0	0.0	1,131,000.0	1,131,000.0
	154,690.0	0.0	1,131,000.0	1,131,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% Yield
HYDROMORPHONE	9150-0	0	0	116,000	45.00
OXYMORPHONE (FOR SALE)	9652-B	35,053	17,237	166,000	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

Remarks

Quota is for supply of 500 Kg to (b)(4);(b)(7)(F) (b)(4) 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: 119726		Date Submitted	01-MAY-14
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	2015
		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			
	2013	2014	2015	Quota Requested
	1,000,000.0	1,100,000.0	0.0	1,200,000.0
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...	3,167.0	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
	3,167.0	0.0	0.0	0.0
Disposition(Sale)/Utilization				
a.Domestic.....	640,094.0	0.0	1,200,000.0	1,200,000.0
b Exports.....	0.0	0.0	0.0	0.0
	640,094.0	0.0	1,200,000.0	1,200,000.0
Acquisition/Production				
a.Domestic Sources.....	731,568.0	0.0	1,200,000.0	1,200,000.0
	731,568.0	0.0	1,200,000.0	1,200,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2012	2013	2015	

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

Oripavine mfg quota is requested to convert oripavine to a Buprenorphine Intermediate for (b)(4) As there is no specific drug code the the Intermediate quota is being requested for oripavine as we have been instructed in the past.. 1200 kg reflects modest growth for the product over 2014.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 119506 | Date Submitted: 29-APR-14

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

Schedule/List Number: 2
Drug Code: 9330-0
Quota Year: 2015

Name and Address of Registrant
(b)(4)

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 2013	2014	2015	Quota Requested
	10,400,000.0	10,732,298.0	0.0	19,000,000.0
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...	69,282.0	0.0	316,179.0	316,179.0
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
	69,282.0	0.0	316,179.0	316,179.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	18,777,778.0	18,777,778.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	18,777,778.0	18,777,778.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	19,000,000.0	19,000,000.0
	0.0	0.0	19,000,000.0	19,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% Yield
OXYMORPHONE (FOR CONVERSION)	9652-A	3,530,345	7,854,778	16,900 18,777,778	77.00
Hydromorphone				1,180.	

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. 120282		Date Submitted	31-JUL-14
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	2015
		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 2013	2014	2015	Quota Requested
	3,126,000.0	3,293,650.0	0.0	6,231,000.0
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	2,176,000.0	2,176,000.0
b.In-Process Material.....	151,100.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	151,100.0	0.0	2,176,000.0	2,176,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	4,676.705	0.0	3,616,000.0	3,616,000.0
b Exports.....	0.075	0.0	350,000.0	350,000.0
	4,676.78	0.0	3,966,000.0	3,966,000.0
Acquisition/Production				
a.Domestic Sources.....	2,003,510.0	0.0	5,151,000.0	5,151,000.0
	2,003,510.0	0.0	5,151,000.0	5,151,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% Yield
HYDROMORPHONE	9150-0	1,140,220	1,965,400.34	2,584,000	78.00
Oxymorphone				2,000	

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

3,616,000 grams for conversion to hydromorphone, Loss on production estimated at 1,405,000 grams 1,000 grams for oripavine reference standards/conversion to hydromorphone for reference standards Replaces application reference# 119630

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 119606 | Date Submitted: 30-APR-14

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

Schedule/List Number: 2
Drug Code: 9330-0
Quota Year: 2015

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 2013	2014	2015	Quota Requested
	700,000.0	612,500.0	0.0	1,000,000.0
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...	324,264.0	0.0	1,400,000.0	1,400,000.0
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
Disposition(Sale)/Utilization	324,264.0	0.0	1,400,000.0	1,400,000.0
a.Domestic.....	67.0	0.0	1,000,000.0	1,000,000.0
b Exports.....	0.0	0.0	0.0	0.0
Acquisition/Production	67.0	0.0	1,000,000.0	1,000,000.0
a.Domestic Sources.....	327,581.0	0.0	1,000,000.0	1,000,000.0
	327,581.0	0.0	1,000,000.0	1,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% Yield
Buprenorphine base	0000-0	0	0	500,000	50.00
Buprenorphine HCl	0000-0	0	0	500,000	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

Multistep conversion of intermediate purchased from a CMO against procurement quota to Buprenorphine base and Buprenorphine HCl against manufacturing quota.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 118690		Date Submitted	27-MAR-14
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	2015
		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			
	2013	2014	2015	Quota Requested
	0.0	430,000.0	0.0	1,000,000.0

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...	0.0	0.0	23,000.0	23,000.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	23,000.0	23,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	1,403,000.0	1,403,000.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	1,403,000.0	1,403,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	1,000,000.0	1,000,000.0
	0.0	0.0	1,000,000.0	1,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2012	2013	2015	

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

303,000g is planned for use in Hydromorphone and 1,100,000g is planned for use in Oxymorphone.

↓
250kg

Basic Class:

Total PQ Requ 5.000

2015 Initial APQ Wo

FDA Est:

IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	0.000	0.000	5,624,322.000	0.000	0.000	0.000	0.000	4.000	0.000	4.000	5.000
		3,000,000.000	6,157,639.000	5,624,322.000	5,624,322.000	1.000	5.000	972,879.000	0.000	2,807,018.000	5,347,888.500	-2,784,084.000	3,000,000.000
MQ Totals:		3,000,005.000	6,157,639.000										3,000,005.000

2014 Final Initial APQ:	7,400,000.000
2014 Final Revised APQ:	0.000
FDA Est: [2014 Initial APQ * 1 + FDA Est):	7,400,000.000
IMS Est: [2014 Initial APQ * 1 + IMS Est):	7,400,000.000

APQ sufficient, no adjustment required

2015 Initial APQ
Worksheets

Basic Class: 9652-A
Total PQ Requested: 6,226,005.000

FDA Est: .07 (avg naloxone + naltrexone data)
IMS Est: .048 (naloxone data)

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	0.000	0.000	7,793,766.000	0.000	0.000	0.000	0.000	4.000	1.000	0.000	4.000	5.000
		16,900,000.000	11,300,000.000	6,300,568.000	7,793,766.000	0.808	5,033,159.477	1,578,762.000	0.000	16,632,103.000	1,737,633.000	9,659,821.500	13,068,790.347	13,068,790.347
		1,000.000	0.000	0.000	7,793,766.000	0.000	0.000	0.000	0.000	1,000.000	0.000	0.000	1,000.000	1,000.000
		6,151,000.000	2,751,000.000	1,493,218.000	7,793,766.000	0.192	1,192,845.523	269,680.000	0.000	5,130,000.000	1,663,000.000	2,265,510.000	4,288,126.903	4,288,126.903
MQ Totals:		23,052,005.000	14,051,000.000											17,357,922.250

2014 Final Initial APQ:	20,000,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	21,390,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	20,968,000.000
2015 Establish APQ:	23,200,000.000
w/ 25% buffer:	29,000,000.000

APQ adjustment made based on increased dispersion of nal drugs to fed, state, local law enforcement (same rationale for oripavine)

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 119507		Date Submitted	29-APR-14
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
OXYMORPHONE (FOR CONVERSION)		Schedule/List Number	0
Name and Address of Registrant		Drug Code	9652-A
(b)(4)		Quota Year	2015
		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(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			
	2013	2014	2015	Quota Requested
	9,400,000.0	11,300,000.0	0.0	16,900,000.0
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...	1,579,762.0	0.0	737,633.0	737,633.0
b.In-Process Material.....	0.0	0.0	1,000,000.0	1,000,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	1,579,762.0	0.0	1,737,633.0	1,737,633.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	16,832,103.0	16,832,103.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	16,832,103.0	16,832,103.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	16,900,000.0	16,900,000.0
	0.0	0.0	16,900,000.0	16,900,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2012	2013	2015	
NOROXYMORPHONE (FOR SALE)	9668-B	0	0	6,707	63.00
NOROXYMORPHONE (FOR CONVERSION)	9668-A	3,328,952	4,333,939	16,825,396	63.00

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

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 119508 | Date Submitted: 29-APR-14

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

Schedule/List Number: 0
Drug Code: 9668-A
Quota Year: 2015

Name and Address of Registrant
(b)(4)

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

Contact Person: (b)(4)
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			
	2013	2014	2015	Quota Requested
	5,371,701.0	8,558,557.0	0.0	10,600,000.0
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...	745,529.0	0.0	1,230,032.0	1,230,032.0
b.In-Process Material.....	318,505.0	0.0	1,314,035.0	1,314,035.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	1,064,034.0	0.0	2,544,067.0	2,544,067.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	8,170,000.0	8,170,000.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	8,170,000.0	8,170,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	10,600,000.0	10,600,000.0
	0.0	0.0	10,600,000.0	10,600,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2012	2013	2015	
NALBUPHINE (EXCEPTED)	0000-0	0	0	575,900	70.00
NALTREXONE (EXCEPTED)	0000-0	0	0	6,887,361	85.00
NALOXONE (EXCEPTED)	0000-0	0	0	706,738	70.00

8,170kg

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. 119509		Date Submitted	29-APR-14
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
NOROXYMORPHONE (FOR SALE)		Schedule/List Number	0
Name and Address of Registrant		Drug Code	9668-B
(b)(4)		Quota Year	2015
		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			
	2013	2014	2015	Quota Requested
	2,618.0	2,364.0	0.0	3,000.0
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...	403.0	0.0	378.0	378.0
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
	403.0	0.0	378.0	378.0
Disposition(Sale)/Utilization				
a.Domestic.....	3.0	0.0	1,020.0	3,020.0
b Exports.....	1.0	0.0	0.0	0.0
	4.0	0.0	3,020.0	3,020.0
Acquisition/Production				
a.Domestic Sources.....	10.0	0.0	3,000.0	3,000.0
	10.0	0.0	3,000.0	3,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2012	2013	2015	

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: 119780 | Date Submitted: 02-MAY-14

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

Schedule/List Number: 0
Drug Code: 9652-A
Quota Year: 2015

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 2013	2014	2015	Quota Requested
	0.0	0.0	0.0	1,000.0
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
	0.0	0.0	0.0	0.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	1,000.0	1,000.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	1,000.0	1,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	1,000.0	1,000.0
	0.0	0.0	1,000.0	1,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% 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
to supporc reference standards business

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 120272 | Date Submitted: 31-JUL-14

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	0
Drug Code	9652-A
Quota Year	2015
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 2013	2014	2015	Quota Requested
	3,030,649.0	2,751,000.0	0.0	5,151,000.0
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...	269,680.0	0.0	1,663,000.0	1,663,000.0
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
	269,680.0	0.0	1,663,000.0	1,663,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	77,017.0	0.0	5,130,000.0	5,130,000.0
b Exports.....	1,416,201.0	0.0	0.0	0.0
	1,493,218.0	0.0	5,130,000.0	5,130,000.0
Acquisition/Production				
a.Domestic Sources.....	1,317,098.0	0.0	6,151,000.0	6,151,000.0
	1,317,098.0	0.0	6,151,000.0	6,151,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2012	2013	2015	% 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 loss estimated at 31,000 grams 1,000 grams to support reference standard business Replaces application reference# 119708

2014 Quota	Initial 2014 Grant	Additional 2014 Grant	Delta
PSC-AOA	5,232	6,900	1,668
Morphine for Conversion	10,451	14,501	4,050
Oxymorphone Conversion Commercial	2,608	2,080	-528
Oxymorphone Conversion Development	0	671	671

2014 COMd Inventory Calculations	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	272	272
Non saleable material	3	3
2013 Available End. Inv.	269	269
2014 API Quota	2,608	2,080
2014 Development Quota (not included in inventory)		671
2014 Dispositions:		
Sales	1,586	1,586
Processing Losses	(13)	(10)
Non-saleable (Sent out to Rev Dist)	(77)	(77)
2014 Ending Inventory	1,199	674
Converted to % Yearend	79.84%	44.9%

	kgs, base
2013 Dispositions	1,486
2014 Est. Dispositions	1,358
Average	1,502
50% Inventory Allowance	751

Description	ACTUAL YEAR TO DATE CPS-AOA Input	Process Yield	MWC	Net output of step	QUOTA CPS-AOA Input	MWC	Net output of step	WITH INCREASE Input to Step	MWC	Net output of step
CPS-AOA to Crude Oxymorphone for Conversion	0	69.4%	1.0133	0	3,708	1.0133	2,608	[illegible]	1.0133	[illegible]

Description	ACTUAL YEAR TO DATE (JUNE 30, 2014) Input to Step	Process Yield	MWC	Net output of step	Loss by step	QUOTA Input to Step	Output of Step	Loss by step	WITH INCREASE Input to Step	Output of Step	Loss by step
Oxymorphone For Conversion											
COM to COMd	0	99.5%	1.0000	0	0	2,608	2,594	13	[illegible]	[illegible]	9
Total					0			(13)			3

2014 CPS-Oripavine Inventory Calculations	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	758	758
Non saleable material	0	0
2013 Available End. Inv.	758	758
2014 API Quota	5,232	6,900
2014 Dispositions:		
Morphine for Conversion	-	1,190
Oxymorphone for Conversion	3,021	3,021
Oxymorphone for Sale	1,473	1,473
2014 Ending Inventory	1,496	1,975
Converted to % Yearend	33%	43%

	kgs, base
2013 Dispositions	3,464
2014 Est. Dispositions	5,685
Average	4,574
30% Inventory Allowance	1,372

2015 Quota	Apr-15	Aug-15	Delta
PSC-AOA	5,139	12,900	7,761
Morphine for Conversion	22,000	26,250	4,250
Oxymorphone Conversion	450	6,150	5,700
Oxymorphone Conversion Development	0	0	0

2015 COMd Inventory Calculations	
2014 Ending Inventory	674
Non saleable material	0
2014 Available End. Inv.	674
2015 API Quota	6,150
2015 Dispositions:	
Sales	5,810
Processing Losses	(33)
Validation Inventory	0
2015 Ending Inventory	1,663
Converted to % Yearend	29.5%

	kgs, base
2014 Est. Dispositions	1,588
2015 Est. Dispositions	5,180
Average	3,359
50% Inventory Allowance	1,629

Description	2015 Quota Calc CPS-AOA Input	Process Yield	MWC	Net output of step	
CPS-AOA to Crude Oxymorphone for Conversion	8,765	69.4%	1.0133	6,150	

Description	2015 Quota Calc Input to Step	Process Yield	MWC	Net output of step	Loss by step
Oxymorphone For Conversion					
COM to COMd	6,150	99.5%	1.0000	6,119	(31)
Total					(31)

2015 CPS-Oripavine Inventory Calculations	
2014 Ending Inventory	1,975
Non saleable material	0
2014 Available End. Inv.	1,975
2015 API Quota	12,900
2015 Dispositions:	
Morphine for Conversion	
Oxymorphone for Conversion	8,765
Oxymorphone for Sale	3,106
2015 Ending Inventory	1,003
Converted to % Yearend	34%

Customer has not told (b)(4) which grade will be ordered for 2015.
Since more CPS is required for old process, using this as basis for 2015.

	kgs, base
2014 Est. Dispositions	5,685
2015 Est. Dispositions	13,851
Average	8,767
30 % Inventory Allowance	2,630

2014 Morphine for Conversion Inventory Calculations	Initial 2014 Grant	Additional 2014 Grant
2013 Ending Inventory	2,454	2,454
Non saleable material	3	3
2013 Available End. Inv.	2,451	2,451
2014 API Quota	10,431	14,501
2014 Dispositions:		
Converted to Codeine	13,120	13,120
Converted to 14-HM	999	999
Processing Losses	-	-
2014 Ending Inventory	-1,237	2,833
Converted to % Yearend	-11.3%	25.8%

	kgs, base
2013 Dispositions	7,872
2014 Est. Dispositions	14,119
Average	10,995
50% Inventory Allowance	5,498

Description	Number of Batches	Batch Input, KgB	Process Yield	Batch output, KgB	Loss by step, KgB	Total Input, KgB	Total Output, KgB	Total Loss KgB	Total output, kgB as AMA for Conversion
Validation Requirements									
Morphine For Conversion									
CPS AOA to 14HM	4	297	84%	250	[redacted]	1,190	999		949
Oxymorphone For Conversion (Commercial)									
14HM to COM	3	263	93%	234	[redacted]	789	671		
COM to COM Dry	3	224	99%	221	(2)	671	664	(7)	
Validation Requirements									
Oxymorphone For Sale (Validation - Bling Impact)									
14HM to COM	0	132	88%	116	-	-	-	-	
COM to OMH Dry	0	116	74%	85	(31)	-	-	-	
OMH Dry to OMH Finished API	0	85	98%	83	(2)	-	-	-	
Overall Totals									

2014 Oxymorphone for Conversion Forecast				
Customer	DEA #	kgs salt	kgB	
(b)(4);(b)(7)(E)		1,857	1,588	

2015 Morphine for Conversion Inventory Calculations	
2014 Ending Inventory	2,833
Non saleable material	0
2014 Available End. Inv.	2,833
2015 API Quota	26,250
2015 Dispositions:	
Converted to Codeine	18,516
Converted to 14-HM	6,855
Processing Losses	-
2015 Ending Inventory	6,712
Converted to % Yearend	30.8%

(b)(4)

Customer has not told [redacted] which grade will be ordered for 2015.
Requesting morphine for conversion should the new grade be requested.

	kgs, base
2014 Est. Dispositions	14,119
2015 Es. Dispositions	22,372
Average	18,245
50% Inventory Allowance	9,123

Description	Number of Batches	Batch Input, KgB	Process Yield	Batch output, KgB	Loss by step, KgB	Total Input, KgB	Total Output, KgB	Total Loss KgB	Total output, kgB as AMA for Conversion
Morphine For Conversion									
CPS AOA to 14HM	27.57	297	88%	262	[redacted]	8,200	7,216		6,855
Oxymorphone For Conversion									
14HM to COM	26.57	263	88%	231	[redacted]	6,989	6,150		
COM to COM Dry	26.57	231	99%	229	(2)	6,150	6,089	(62)	
Validation Requirements									
Oxymorphone For Sale									
14HM to COM	4	132	88%	116		526	463		
COM to OMH Dry	4	116	74%	85	(31)	463	341	(122)	
OMH Dry to OMH Finished API	4	85	98%	83	(2)	341	334	(7)	
Overall Totals								(189)	

2015 Oxymorphone for Conversion Forecast				
Customer	DEA #	kgs salt	kgB	
(b)(4);(b)(7)(E)		6,000	5,130	

Basic Class:
Total PQ Requ 3,614,401.070

2015 Initial APQ Worksh

FDA Est: n/a
IMS Est: .038

Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 CEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	Calc Using CFR - 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	3,604,592.071	0.000	0.000	0.007	0.000	4.000	1.000	3.755	0.243	5.000
		60.000	60.000	4.211	3,604,592.071	0.000	0.000	4.222	215.888	0.000	10.000	256.268	206.901	-245.590	60.000
		166,000.000	143,000.000	6,820.000	3,604,592.071	0.002	5,844.001	23,682.000	0.000	166,000.000	25,000.000	125,011.500	46,123.002	166,000.000
		715,000.000	611,838.000	413,633.000	3,604,592.071	0.115	414,758.599	218,216.000	0.000	623,000.000	295,541.000	617,142.000	471,501.749	617,142.000
		1,600,000.000	2,810,558.000	2,802,150.000	3,604,592.071	0.777	2,809,775.353	1,132,591.000	0.000	1,442,681.000	584,319.000	2,857,391.750	1,714,360.691	1,600,000.000
		3,000.000	3,000.000	41,930.000	3,604,592.071	0.012	42,044.964	34,890.290	0.000	3,000.000	0.000	26,492.718	16,315.915	3,000.000
		3,501,000.000	1,183,734.000	330,495.000	3,604,592.071	0.092	331,364.380	310,739.000	0.000	1,277,000.000	387,000.000	1,120,854.750	492,703.450	1,183,734.000
		1,120,000.000	210,000.000	7,559.000	3,604,592.071	0.002	7,578.570	295,828.000	0.000	816,250.000	275,830.000	379,371.000	172,396.452	379,371.000
MQ Totals:		7,105,065.000	4,982,035.000											3,949,312.000

2014 Final Initial APQ:	6,200,000.000
2014 Final Revised APQ:	0.000
FDA Est: (2014 Initial APQ * 1 + FDA Est):	6,200,000.000
IMS Est: (2014 Initial APQ * 1 + IMS Est):	6,438,640.000

2015 pd efforts	561,297.000
2014 revised MQ	4,982,035.000
IMS est change	169,549.737
est need for APQ	5,712,881.737

APQ sufficient, no adjustment required

2015 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), and redelegated to the Deputy Administrator.

- DEA regulations allow the Deputy 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 2015 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.

- 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 1 Chemicals:

- OD is recommending an increase in the AAN for **ephedrine (for sale)**. The increase is based on increased domestic sales and import requirements from registrant applications and projected demand for allergy and flu season.

Controlled Substances:

- OD is recommending an increase in the APQ for **alfentanil.** The increase is based on the increased domestic sales and exports.

- OD is recommending an increase in the APQ for **cocaine.** The increase is based on the increased domestic product which leads to the production of cocaine as a by-product.

- OD is recommending an increase in the APQ for **codeine (for sale).** The increase is based on the increased domestic sales and exports.

- OD is recommending an increase in the APQ for **codeine-n-oxide.** The increase is based on the increased domestic sales and the need for increased reference standards.

- OD is recommending an increase in the APQ for **dihydrocodeine.** The increase is based on the increased domestic sales.

- OD is recommending an increase in the APQ for **fentanyl.** The increase is based on the increased domestic sales and product development efforts.

- OD is recommending an increase in the APQ for **hydromorphone.** The increase is based on the increased domestic sales and exports.

- OD is recommending an increase in the APQ for **levorphanol.** The increase is based on the increased domestic sales.

- 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 **oripavine.** The increase is based on the increased domestic sales and exports of hydromorphone and the non-controlled substances naltrexone, naloxone, and nalbuphine which utilize oripavine as the starting material.

- OD is recommending an increase in the APQ for **oxymorphone (for conversion).** The increase is based on the increased domestic sales and exports the non-controlled substances naltrexone, naloxone, and nalbuphine which utilize oxymorphone (for conversion) in the route of synthesis.

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-393]

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 2015

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

ACTION: Notice.

SUMMARY: This notice establishes the 2015 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.

FOR FURTHER INFORMATION CONTACT: (b)(6) Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (b)(6)

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 substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA) through 28 CFR 0.100(b). The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

Background

The 2015 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 2015 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 2, 2014, 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 2015," was published in the **Federal Register** (79 FR 37772). That notice proposed the 2015 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2015 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 1, 2014.

Comments Received

Five comments from DEA-registered manufacturers were received within the published comment period, offering comments on a total of 32 schedule I and II controlled substances. No comments were received for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Commenters stated that the proposed aggregate production quotas for 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone), 2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe), 2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe), 2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe), 2-(Methylamino)-1-phenylpentan-1-one (pentedrone), 3-Fluoro-*N*-methylcathinone (3-FMC), 4-Fluoro-*N*-methylcathinone (4-FMC), 4-

Anilino-*N*-phenethyl-4-piperidine (ANPP), 4-Methyl-*N*-ethylcathinone (4-MEC), 4-Methyl-α-pyrrolidinopropiophenone (4-MePPP), *alpha*-Pyrrolidinobutiophenone (α-PBP), *alpha*-Pyrrolidinopentiophenone (α-PVP), amphetamine (for sale), codeine (for sale), dihydrocodeine, diphenoxylate, fentanyl, hydrocodone (for sale), hydromorphone, levorphanol, marihuana, morphine (for conversion), *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), naphthylpyrovalerone (naphyrone), oripavine, oxycodone (for conversion), 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 2015 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2015 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 consideration of 2014 manufacturing quotas, current 2014 sales and inventories, 2015 export requirements, industrial use, additional applications for 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 and assessment of annual needs for alfentanil, cocaine, codeine-N-oxide, codeine (for sale), dihydrocodeine, fentanyl, hydromorphone, levorphanol, marihuana, oripavine, oxymorphone (for conversion), and ephedrine (for sale) are warranted. This notice reflects those adjustments.

Regarding 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone), 2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe), 2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe), 2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe), 2-(Methylamino)-1-phenylpentan-1-one (pentedrone), 3-Fluoro-*N*-methylcathinone (3-FMC), 4-Fluoro-*N*-methylcathinone (4-FMC), 4-Anilino-*N*-phenethyl-4-piperidine (ANPP), 4-Methyl-*N*-ethylcathinone (4-MEC), 4-Methyl-α-pyrrolidinopropiophenone (4-MePPP), *alpha*-Pyrrolidinobutiophenone (α-PBP), *alpha*-Pyrrolidinopentiophenone (α-PVP), amphetamine (for sale), dihydrocodeine, fentanyl, hydromorphone, levorphanol, marihuana, *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), naphthylpyrovalerone (naphyrone), oxycodone (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 2015 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This notice finalizes these aggregate production quotas at the same amounts as proposed.

As described in the previously published notice proposing the 2015 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.

In accordance with 21 USC 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Deputy Administrator hereby establishes the 2015 aggregate production quotas for the following schedule I and II controlled substances and the 2015 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 2015 Quotas (g)
Schedule I	
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	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-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)	15
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)	15
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)	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-Fluoro-*N*-methylcathinone (3-FMC)	15
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)	15
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-*N*-ethylcathinone (4-MEC)	15
4-Methyl-*N*-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15
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)	15
alpha-Pyrrolidinopentiophenone (α-PVP)	15
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	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	125,000
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)	15
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	15
N,*N*-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	15
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52

Normethadone	2
Normorphine	18
Phenomorphan	2
Psilocybin	30
Psilocyn	30
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	15
Tetrahydrocannabinols	497,500
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	21,875,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	275,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	49,500,000
Dextropropoxyphene	19
Dihydrocodeine	226,375
Diphenoxylate	1,337,500
Ecgonine	174,375
Ethylmorphine	3
Fentanyl	2,150,000
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	5
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	6,250,000
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	83,750,000
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	35,000,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	137,500,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Deputy 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. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy

Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as needed.

Dated:

Thomas M. Harrigan,
Deputy Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
ODW:_____
ODQ:_____
ODQ (b)(6) 08-15-14
Webcims # ODEQ 14 -
(DFN#: 680-03 Drug control files - Manufacturing and Procurement quotas)

equipment manufacturers, separation system designers, and end users.

Patricia A. Brink,
Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2014-21266 Filed 9-5-14; 8:45 am]
BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-393]

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 2015

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

ACTION: Notice.

SUMMARY: This notice establishes the initial 2015 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 date:* Effective September 8, 2014.

FOR FURTHER INFORMATION CONTACT: Imelda Paredes, Executive Assistant, 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), parts 1300 to 1321. 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 providing 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 establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA through 28 CFR 0.100(b). The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

Background

The 2015 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 2015 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 2, 2014, 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 2015" was published in the Federal Register, 79 FR 37772. This notice proposed the 2015 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2015 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 1, 2014.

Comments Received

Five comments were received from DEA-registered manufacturers within the published comment period, offering comments on a total of 32 schedule I and II controlled substances. None of the respondents commented on the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Commenters stated that the proposed aggregate production quotas for 1-(1,3-Benzodioxol-5-yl)-2-(methylamino) butan-1-one (butylone), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino) pentan-1-one (pentylone), 2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe), 2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe), 2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe), 2-(Methylamino)-1-phenylpentan-1-one (pentedrone), 3-Fluoro-*N*-methylcathinone (3-FMC), 4-Fluoro-*N*-methylcathinone (4-FMC), 4-Anilino-*N*-phenethyl-4-piperidine (ANPP), 4-Methyl-*N*-ethylcathinone (4-MEC), 4-Methyl-α-pyrrolidinopropiophenone (4-MePPP), *alpha*-Pyrrolidinobutiophenone (α-PBP), *alpha*-Pyrrolidinopentiophenone (α-PVP), amphetamine (for sale), codeine (for sale), dihydrocodeine, diphenoxylate, fentanyl, hydrocodone (for sale), hydromorphone, levorphanol, marihuana, morphine (for conversion), *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), naphthylpyrovalerone (naphyrone), oripavine, oxycodone (for conversion), 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 2015 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2015 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 consideration of 2014 manufacturing quotas, current 2014 sales and inventories, 2015 export requirements, industrial use, additional applications for 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 and assessment of annual needs for alfentanil, cocaine, codeine-N-oxide, codeine (for sale), dihydrocodeine, fentanyl, hydromorphone, levorphanol, marihuana, oripavine, oxymorphone (for conversion), and ephedrine (for sale) are warranted. This notice reflects those adjustments.

Regarding 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone), 2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe), 2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe), 2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe), 2-(Methylamino)-1-phenylpentan-1-one (pentedrone), 3-Fluoro-*N*-methylcathinone (3-FMC), 4-Fluoro-*N*-methylcathinone (4-FMC), 4-Anilino-*N*-phenethyl-4-piperidine (ANPP), 4-Methyl-*N*-ethylcathinone (4-MEC), 4-Methyl-α-pyrrolidinopropiophenone (4-MePPP), *alpha*-Pyrrolidinobutiophenone (α-PBP), *alpha*-Pyrrolidinopentiophenone (α-PVP), amphetamine (for sale), dihydrocodeine, fentanyl, hydromorphone, levorphanol, marihuana, *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), naphthylpyrovalerone (naphyrone), oxycodone (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 2015 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This notice finalizes these aggregate production quotas at the same amounts as proposed.

As described in the previously published notice proposing the 2015 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 resulting 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.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Deputy Administrator hereby establishes the 2015 aggregate production quotas for the following schedule I and II controlled substances and the 2015 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 2015 quotas (g)
Schedule I	
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	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-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)	15
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)	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30

Basic class	Established 2015 quotas (g)
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)	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-Fluoro-*N*-methylcathinone (3-FMC)	15
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)	15
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-*N*-ethylcathinone (4-MEC)	15
4-Methyl-*N*-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15
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)	15
alpha-Pyrrolidinopentiophenone (α-PVP)	15
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	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	125,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5

Basic class	Established 2015 quotas (g)
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-*N*-oxide	350
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	15
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	15
N,*N*-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	15
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	18
Phenomorphan	2
Psilocybin	30
Psilocyn	30
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	15
Tetrahydrocannabinols	497,500
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	21,875,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	275,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	49,500,000
Dextropropoxyphene	19
Dihydrocodeine	226,375
Diphenoxylate	1,337,500
Ecgonine	174,375
Ethylmorphine	3
Fentanyl	2,150,000
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	5
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	6,250,000
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	83,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000

Basic class	Established 2015 quotas (g)
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	35,000,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	137,500,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	6,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Deputy 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 Deputy Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as needed.

Dated: September 2, 2014.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2014-21280 Filed 9-5-14; 8:45 am]

BILLING CODE 4410-09-P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

National Nanotechnology Coordination Office

Nanoscale Science, Engineering, and Technology Subcommittee; Committee on Technology, National Science and Technology Council; Meeting

ACTION: Notice of public meeting.

SUMMARY: The National Nanotechnology Coordination Office (NNCO), on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC), will hold a technical interchange meeting entitled "Realizing the Promise of Carbon Nanotubes—Challenges, Opportunities and the Pathway to Commercialization" on September 15, 2014. The meeting will be sponsored by the National Nanotechnology Initiative (NNI) and co-sponsored by the National Aeronautics and Space Administration (NASA). The objectives of this meeting are to identify, discuss, and report the technical barriers preventing the production of carbon nanotube-based materials with electrical and mechanical properties approaching theoretical values, and to explore ways to overcome these barriers. Obstacles preventing the full exploitation of the multifunctional nature of carbon nanotube materials will also be discussed. This one-day meeting will assemble some of the Nation's leading experts in carbon nanotube research and development, as well as executives and experts from the Federal government, academia, and private sector.

DATES: The technical interchange meeting will be held Monday, September 15, 2014 from 8:00 a.m. until 5:15 p.m.

ADDRESSES: The technical interchange meeting will be held at the National Aeronautics and Space Administration (NASA) Headquarters, 300 E Street Southwest, Washington, DC 20546.

FOR FURTHER INFORMATION, CONTACT: Dr. Tarek Fadel, 703-292-7926, *tfadel@nnco.nano.gov*, NNCO. Additional information is posted at: *http://nano.gov/2014CNTTechInterchange.*

Registration: Registration opens on September 8, 2014. Due to space limitations, pre-registration for the technical interchange meeting is required. Written notices of participation by email should be sent to *dpetreski@nnco.nano.gov* or mailed to Diana Petreski, 4201 Wilson Blvd., Stafford II, Suite 405, Arlington, VA 22230. Please provide your full name, title, affiliation and email or mailing address when registering. Registration is on a first-come, first-served basis until capacity is reached. Written or electronic comments should be submitted by email to *dpetreski@nnco.nano.gov* until close of business September 10, 2014.

Meeting Accommodations: Individuals requiring special accommodation to access this meeting should contact Diana Petreski at 703-292-7922 at least five business days prior to the meeting so that appropriate arrangements can be made.

Ted Wackler,

Deputy Chief of Staff and Assistant Director.

[FR Doc. 2014-21201 Filed 9-5-14; 8:45 am]

BILLING CODE P

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**	**38.880**	**-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 mehtylphenidate

*** corrected based on IMS capture of OTC market

IMS DATA 2012 - 2015 (est)

management strategies for Fire Island National Seashore for the next 15 to 20 years to support the protection of important natural resources and processes; significant recreation resources; cultural resources of national, state, and local significance; and residential communities.

The park is composed of two distinct units—the barrier island that runs parallel to the south shore of Long Island and the 613-acre William Floyd Estate situated on the south shore of Long Island near the east end of Fire Island. To address the specific needs of these two distinct units, the Draft GMP/EIS includes two sets of alternatives. One addresses park-wide alternatives for Fire Island National Seashore with a primary emphasis on the barrier island and includes a no-action alternative and two action alternatives. The other set of alternatives focuses specifically on the William Floyd Estate and includes a no-action and a single action alternative. The Draft GMP/EIS also incorporates plans for the Otis Pike High Dunes Fire Island Wilderness and includes a draft Wilderness Stewardship Plan for public review concurrent with the Draft GMP/EIS.

FOR FURTHER INFORMATION CONTACT: Ellen Carlson, NPS/Northeast Region, 15 State Street, Boston, MA 02019. Phone: (617) 223-5048. Email: *Fire_Island_GMP@nps.gov.*

Dated: June 1, 2015.

Michael A. Caldwell,

Regional Director, Northeast Region, National Park Service.

[FR Doc. 2015-14927 Filed 6-16-15; 8:45 am]

BILLING CODE 4310-WV-P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701-TA-456 and 731-TA-1151-1152 (Review)]

Citric Acid and Certain Citrate Salts From Canada and China

Determination

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930, that revocation of the countervailing duty order on citric acid and certain citrate salts from China and the antidumping duty orders on citric acid and certain citrate salts from China and Canada would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

Background

The Commission, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), instituted these reviews on April 1, 2014 (79 FR 18311) and determined on July 7, 2014 that it would conduct full reviews (79 FR 42049, July 18, 2014). Notice of the scheduling of the Commission's reviews and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on November 14, 2014 (79 FR 68299). The hearing was held in Washington, DC, on March 26, 2015, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on June 11, 2015. The views of the Commission are contained in USITC Publication 4538 (June 2015), entitled *Citric Acid and Certain Citrate Salts from Canada and China: Investigation Nos. 701-TA-456 and 731-TA-1151-1152 (Review).*

By order of the Commission.

Issued: June 12, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015-14863 Filed 6-16-15; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Manufacturer of Controlled Substances Registration: Siemens Healthcare Diagnostics, Inc.

ACTION: Notice of registration.

SUMMARY: Siemens Healthcare Diagnostics, Inc. applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Siemens Healthcare Diagnostics, Inc. registration as a manufacturer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated January 9, 2015, and published in the **Federal Register** on January 26, 2015, 80 FR 3982, Siemens Healthcare Diagnostics, Inc., Attn: RA, 100 GBC Drive, Mailstop 514, Newark, Delaware 19702 applied to be registered as a manufacturer of certain basic classes of controlled substances. No comments or objections were submitted to this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Siemens Healthcare Diagnostics, Inc. to manufacture the basic classes of controlled substances 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. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed:

Controlled substance	Schedule
Tetrahydrocannabinols (7370)	I
Ecgonine (9180)	II
Morphine (9300)	II
Thebaine (9333)	II

The company plans to produce the listed controlled substances in bulk to be used in the manufacture of reagents and drug calibrator controls which are DEA exempt products.

In reference to drug code 7370 the company plans to bulk manufacture a synthetic tetrahydrocannabinol. No other activity for this drug code is authorized for this registration.

Dated: June 11, 2015.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2015-14912 Filed 6-16-15; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-411F]

[redacted]

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the adjusted 2015 aggregate production quotas for difenoxin, diphenoxylate (for conversion), and marijuana.

DATES: This order is effective June 17, 2015.

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

SUPPLEMENTARY INFORMATION:

Legal Authority

The 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 purposes 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 providing 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 establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II each year. The Attorney General has delegated this function to the Administrator of the DEA, 28 CFR 0.100.

Background

The DEA established the initial 2015 aggregate production quotas and assessments for annual need on September 8, 2014 (79 FR 53216). That notice stipulated that, as provided for in 21 CFR 1303.13 and 21 CFR 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment. Based on unanticipated medical, scientific, research, and industrial needs of the United States, the DEA proposed to adjust the established 2015 aggregate production quotas for the schedule I and II controlled substances difenoxin, diphenoxylate (for conversion), and marijuana to be manufactured in the United States in 2015. The notice of proposed adjustment was published in the **Federal Register** on Wednesday, April 8, 2015 (80 FR 18867). All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas on or before May 8, 2015.

Comments Received

Two companies, one institution of higher education, and five private citizens submitted timely comments in response to the proposed adjustment of these three controlled substances. The comments from the institution of higher education and one of the private citizens were in support of the proposed increases for these three controlled substances. The two companies and one private citizen supported the proposed adjustment and requested further increases to the APQs to support research, additional product development efforts, and increases in manufacturing demands. Further comments received from three private citizens were outside the scope of the proposed APQ notice. The DEA appreciates the support for this adjusted 2015 aggregate production quota for difenoxin, diphenoxylate (for conversion), and marijuana, which is intended to provide for the estimated scientific, research, and industrial needs of the United States.

Determination for Adjusting the Aggregate Production Quotas for Difenoxin, Diphenoxylate (for Conversion), and Marijuana

In accordance with 21 CFR 1303.13, the DEA has taken into consideration the above comments along with the relevant 2014 year-end inventories, initial 2015 manufacturing quotas, 2015 export requirements, actual and projected 2015 sales, research and product development requirements, and information derived from additional applications for manufacturing quota received since the April 8, 2015 publication of the notice of proposed adjustments to the aggregate production quotas for difenoxin, diphenoxylate (for conversion), and marijuana. Upon consideration of the above, the Acting Administrator has determined to increase the 2015 aggregate production quotas for difenoxin and marijuana beyond that which was previously proposed. Regarding the aggregate production quota for diphenoxylate (for conversion), the Acting Administrator has determined that the proposed aggregate production quota adjustment for this substance is sufficient to meet the current 2015 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock.

Pursuant to the above, the Acting Administrator hereby establishes the 2015 aggregate production quotas for difenoxin, diphenoxylate (for conversion), and marijuana, expressed in grams of anhydrous acid or base, as follows:

Basic class—schedule I	Previously established 2015 quota (g)	Adjusted 2015 quota (g)
Difenoxin	50	11,000
Marijuana	125,000	658,000

Basic class—schedule II	Previously established 2015 quota (g)	Adjusted 2015 quota (g)
Diphenoxylate (for conversion)	0	75,000

Dated: June 11, 2015.
Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2015-14910 Filed 6-16-15; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-410F]

Controlled Substances: 2015 Established Aggregate Production Quotas for Three Temporarily Controlled Synthetic Cannabinoids

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2015 aggregate production quotas for three temporarily controlled 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).

DATES: Effective June 17, 2015.

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:

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: June 11, 2015.
Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2015-14909 Filed 6-16-15; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration: Mylan Technologies, Inc.

ACTION: Notice of registration.

SUMMARY: Mylan Technologies, Inc. applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Mylan Technologies, Inc. registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated February 11, 2015, and published in the **Federal Register** on February 19, 2015, 80 FR 8902, Mylan Technologies, Inc., 110 Lake Street, Saint Albans, Vermont 05478 applied to be registered as an importer of certain basic classes of controlled substances. 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 Mylan Technologies, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under

COLORADO

Park County

Tarryall Rural Historic Landscape, Cty. Rd. 77, Mileposts 2.4 to 41.8, Jefferson, 15000170

San Juan County

Sound Democrat Mill and Mine and Silver Queen Mine, (Mining Resources of San Juan County, Colorado MPS) Address Restricted, Silverton, 15000171

MARYLAND

Baltimore Independent city

McDonogh Place Historic District, N. Broadway, E. Eager, McDonogh & E. Chase Sts., Baltimore, 15000172

Charles County

Mallows Bay—Widewater Historic and Archeological District, Off Charles County shoreline at Sandy Pt., Nanjemoy, 15000173

MISSOURI

St. Louis Independent city

Woodward and Tierman Printing Company Building, 1519 Tower Grove Ave., St. Louis, 15000174

NEW HAMPSHIRE

Coos County

Burgess, George E., School—Notre Dame High Schol, 411 School St., Berlin, 15000175

NEW JERSEY

Sussex County

Waterloo Village (Boundary Increase), Musconetcong R. & Cty. Rd. 604, Byram Township, 15000176

NEW YORK

Bronx County

Crotona Play Center, 1700 Fulton Ave., Bronx, 15000177

Suffolk County

Sylvester Manor, 80 N. Ferry Rd., Shelter Island, 15000178

NORTH CAROLINA

Ashe County

Ashe County Memorial Hospital, (Ashe County, North Carolina, c. 1799–1955 MPS) 410 McConnell St., Jefferson, 15000179

Beaufort County

Belhaven Commercial Historic District, 260–292 E. Main & 246–288, 251–279 Pamlico Sts., Belhaven, 15000180

Guilford County

Willis, James H. and Anne B., House, 707 Blair St., Greensboro, 15000181

Harnett County

Erwin Commercial Historic District, 100 Denim Drive, 101–127 E. H & 103–111 S. 13th Sts., Erwin, 15000182

Mecklenburg County

Outen, R.F., Pottery, 430 Jefferson St., Matthews, 15000183

OHIO

Hamilton County

United States Post Office and Court House, 100 E. 5th St., Cincinnati, 15000184

Ottawa County

Perry's Victory and International Peace Memorial (Boundary Increase), 93 Delaware Ave., Put-in-Bay, 15000185

TENNESSEE

Grundy County

Christ Episcopal Church, 530 10th St., Tracy City, 15000186

Shelby County

One Hundred North Main Building, 100 N. Main St. Mall, Memphis, 15000187

WEST VIRGINIA

Marion County

Dunbar School, 103 High St., Fairmont, 15000188

WISCONSIN

Sheboygan County

Prange, Eliza, House, 605 Erie Ave., Sheboygan, 15000189

WYOMING

Teton County

Hardeman Barns, 5450 W. WY 22, Wilson, 15000190

[FR Doc. 2015-08007 Filed 4-7-15; 8:45 am]

BILLING CODE 4312-51-P

INTERNATIONAL TRADE COMMISSION

Public Availability of FY 2013 Service Contract Inventory Analysis, FY 2014 Service Contract Inventory, and FY 2014 Service Contract Inventory Planned Analysis

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111–117), the U.S. International Trade Commission is publishing this notice to advise the public of the availability of the FY 2013 Service Contract Inventory Analysis, the FY 2014 Service Contract Inventory, and the FY 2014 Service Contract Inventory Planned Analysis. The FY 2013 inventory analysis provides information on specific service contract actions that were analyzed as part of the FY 2013 inventory. The 2014 inventory provides information on service contract actions over $25,000 which were made in FY 2014. The inventory information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at *http://www.whitehouse.gov/sites/default/files/omb/procurement/memo/service-contract-inventories-guidance-11052010.pdf*. The FY 2014 inventory planned analysis provides information on which functional areas will be reviewed by the agency. The United States International Trade Commission has posted its FY 2014 inventory, FY 2014 planned analysis, and FY 2013 inventory analysis at the following link: *http://www.usitc.gov/procurement/*.

FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Debra Bridge, U.S. International Trade Commission, Office of Procurement, 500 E Street SW., Washington, DC 20436, or at 202–205–2004 or *debra.bridge@usitc.gov*.

By order of the Commission.

Dated: April 3, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015-08050 Filed 4-7-15; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-411N]

Controlled Substances: Proposed Adjustments to the Aggregate Production Quotas for Difenoxin, Diphenoxylate (for conversion), and Marijuana

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration is proposing to adjust the established 2015 aggregate production quota for difenoxin, diphenoxylate (for conversion), and marijuana which are schedule I and II controlled substances under the Controlled Substances Act.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13. Electronic comments must be submitted, and written comments must be postmarked, on or before May 8,

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.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–411N" 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/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, 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 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 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 and confidential business information identified and located as directed above will generally be made available in redacted form. If a comment has 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

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 providing 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 each year. The Attorney General has delegated this function to the Administrator of the DEA, 28 CFR 0.100.

Background

The DEA established the initial 2015 aggregate production quotas and assessments of annual need on September 8, 2014 (79 FR 53216). That notice stipulated that, as provided for in 21 CFR 1303.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Based on unanticipated medical, scientific, research, and industrial needs of the United States the DEA proposes to adjust the established 2015 aggregate production quotas for the schedule I and II controlled substances difenoxin, diphenoxylate (for conversion), and marijuana to be manufactured in the United States in 2015. The adjustment is necessary 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.

In proposing the adjustment, the Administrator has taken into account the following criteria in accordance with 21 CFR 1303.13: (1) Changes in demand for the basic class, changes in the national rate of net disposal for the class, and changes in the rate of net disposal by the registrants holding individual manufacturing quotas for the class; (2) whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; (3) whether any increased demand for that class can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota; (4) whether any decreased demand will result in excessive inventory accumulation by all persons registered to handle the class; and (5) other factors affecting the medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Administrator finds relevant.

Analysis for Adjusting the Established 2015 Aggregate Production Quota for Difenoxin and Diphenoxylate (for Conversion)

Since the establishment of the initial 2015 aggregate production quotas, the DEA has received requests from DEA registered manufacturers to manufacture difenoxin and diphenoxylate (for conversion) to support the manufacture

of prescription drug products approved by the Food and Drug Administration (FDA) for the treatment of chronic diarrhea and for the treatment of diarrhea associated with irritable bowel syndrome (IBS).[1] These FDA approved products have not been manufactured since 2009 due to FDA-regulated manufacturing issues and there is no existing generic or therapeutic equivalent.

Analysis for Adjusting the Established 2015 Aggregate Production Quota for Marijuana

Since the establishment of the initial 2015 aggregate production quotas, the DEA has received notification from DEA registered manufacturers that research and product development involving cannabidiol, is increasing beyond that previously anticipated for 2015. The associated product development activities are related to process validation and commercialization activities, including qualification activities related to potential U.S. Food and Drug Administration submission support.

Additionally, the DEA has also received notification from the National Institute on Drug Abuse (NIDA) that it required additional supplies of marijuana to be manufactured in 2015 to provide for ongoing and anticipated research efforts involving marijuana. NIDA is a component of the National Institutes of Health and the U.S. Department of Health and Human Services which oversees the cultivation, production and distribution of research-grade marijuana on behalf of the United States Government, pursuant to the Single Convention on Narcotic Drugs (March 30, 1961, 18 UST 1407).

The Administrator, therefore, proposes to adjust the 2015 aggregate production quotas for difenoxin, diphenoxylate (for conversion), and marijuana, expressed in grams of anhydrous acid or base, as follows:

Basic class-schedule I	Previously established 2015 quota	Adjusted 2015 quota
Difenoxin ...	50 g	9,000 g
Marijuana ..	125,000 g	400,000 g

Basic class-schedule II	Previously established 2015 quota	Adjusted 2015 quota
Diphenoxylate (for conversion).	Zero	75,000 g

[1] Difenoxin (schedule I) is the active pharmaceutical ingredient in the diarrhea preparation (schedule V).

Dated: April 1, 2015.

Michele M. Leonhart,

Administrator.

[FR Doc. 2015-08042 Filed 4-7-15; 8:45 am]

BILLING CODE 4410-09-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (15-026)]

Notice of Intent To Grant a Partially Exclusive License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of Intent to Grant Partially Exclusive License.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant a partially exclusive license in the United States to practice the invention described and claimed in U.S. Patent No. 7,086,593 B2 titled "Magnetic Field Response Measurement Acquisition System," NASA Case No. LAR-16908-1; U.S. Patent No. 7,159,774 B2 titled "Magnetic Field Response Measurement Acquisition System," NASA Case No. LAR-17280-1; U.S. Patent No. 7,075,295 B2 titled "Magnetic Field Response Sensor for Conductive Media," NASA Case No. LAR-16571-1; U.S. Patent No. 7,589,525 B2 titled "Magnetic Field Response Sensor for Conductive Media," NASA Case No. LAR-16571-2; U.S. Patent No. 7,759,932 B2 titled "Magnetic Field Response Sensor for Conductive Media," NASA Case No. LAR-16571-3; U.S. Patent No. 8,430,327 B2 titled "Wireless Sensing System Using Open-Circuit, Electrically-Conductive Spiral-Trace Sensor," NASA Case No. LAR-17294-1; U.S. Patent No. 7,683,797 B2 titled "Damage Detection/Locating System Providing Thermal Protection," NASA Case No. LAR-17295-1; U.S. Patent No. 7,902,815 B2 titled "Wireless System and Method for Collecting Motion and Non-Motion Related Data of a Rotating System," NASA Case No. LAR-17433-1; U.S. Patent No. 8,042,739 B2 titled "Wireless Tamper Detection Sensor and Sensing System," NASA Case No. LAR-17444-1; U.S. Patent No. 7,711,509 B2 titled "Method of Calibrating a Fluid-Level Measurement System," NASA Case No. LAR-17480-1; U.S. Patent No. 7,814,786 B2 titled "Wireless Sensing System for Non-Invasive Monitoring of Attributes of Contents in a Container," NASA Case No. LAR-17488-1; U.S. Patent No. 8,673,649 B2 titled "Wireless Chemical Sensor and Sensing Method for Use Therewith," NASA Case No. LAR-17579-1; U.S. Patent Application No. 14/215,793 titled "Wireless Chemical Sensor and Sensing Method for Use Therewith," NASA Case No. LAR-17579-2; U.S. Patent No. 8,167,204 B2 titled "Wireless Damage Location Sensing System," NASA Case No. LAR-17593-1; U.S. Patent No. 8,179,203 B2 titled "Wireless Electrical Device Using Open-Circuit Elements Having No Electrical Connections," NASA Case No. LAR-17711-1; U.S. Patent Application No. 14/193,861 titled "Wireless Temperature Sensing Having No Electrical Connections and Sensing Method for Use Therewith," NASA Case No. LAR-17747-1-CON; U.S. Patent Application No. 13/796,626 titled "Method of Mapping Anomalies in Homogenous Material," NASA Case No. LAR-17848-1 to GLSEQ, LLC having its principal place of business in Owens Cross Roads, Alabama. The fields of use may be limited to, but not necessarily be limited to, safety related and non-safety related instrumentation and control systems for nuclear facilities, including advanced safety related and non-safety related instrumentation systems for severe accident monitoring within nuclear power plants and nuclear storage facilities. The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective partially exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

DATES: The prospective partially exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated partially exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

ADDRESSES: Objections relating to the prospective license may be submitted to Patent Counsel, Office of Chief Counsel, NASA Langley Research Center, MS 30,

Dated: June 11, 2015.
Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2015–14910 Filed 6–16–15; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–410F]

[redacted]

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2015 aggregate production quotas for three temporarily controlled 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).

DATES: Effective June 17, 2015.

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:

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: June 11, 2015.
Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2015–14909 Filed 6–16–15; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration: Mylan Technologies, Inc.

ACTION: Notice of registration.

SUMMARY: Mylan Technologies, Inc. applied to be registered as an importer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Mylan Technologies, Inc. registration as an importer of those controlled substances.

SUPPLEMENTARY INFORMATION: By notice dated February 11, 2015, and published in the **Federal Register** on February 19, 2015, 80 FR 8902, Mylan Technologies, Inc., 110 Lake Street, Saint Albans, Vermont 05478 applied to be registered as an importer of certain basic classes of controlled substances. 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 Mylan Technologies, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under

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 and the State of Indiana* v. *Exide Technologies*, D.J. Ref. No. 90–5–2–1–11003. 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 Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html*. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs (at 25 cents per page). Please mail your request and a check or money order payable to the United States Treasury to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

The cost for a paper copy of the Consent Decree is $8.25.

Randall M. Stone,

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

[FR Doc. 2015–06369 Filed 3–19–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–410]

Controlled Substances: 2015 Proposed Aggregate Production Quotas for Three Temporarily Controlled Synthetic Cannabinoids

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: 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) were temporarily placed in schedule I of the Controlled Substances Act by a final order published by the Drug Enforcement Administration on January 30, 2015 (80 FR 5042). This means that any person that wishes to manufacture AB-CHMINACA, AB-PINACA, or THJ-2201 after January 30, 2015, must be registered with the Drug Enforcement Administration and have obtained a manufacturing quota pursuant to 21 CFR part 1303.

The Drug Enforcement Administration cannot issue individual manufacturing quotas for AB-CHMINACA, AB-PINACA, or THJ-2201 until it establishes aggregate production quotas. Therefore, this notice proposes the 2015 aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c). Electronic comments must be submitted, and written comments must be postmarked, on or before April 20, 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.

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 her 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 2015 aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–410" 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 an electronic submission 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/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, 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 and will 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.

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. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket. Comments containing personal identifying information or confidential

business information identified as directed above will be made publicly available in redacted form.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference. If you wish to personally inspect the comments and materials received, these materials will be available for public inspection by appointment. To arrange a viewing, please see the FOR FURTHER INFORMATION CONTACT paragraph above.

Legal Authority and Background

Section 306 of the Controlled Substances Act (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 each year. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

The DEA established the 2015 aggregate production quotas for substances in schedules I and II on September 8, 2014 (79 FR 53216). Subsequently, on December 19, 2014, DEA published in the Federal Register a notice of intent to temporarily place 3 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 (79 FR 75767). On January 30, 2015, the DEA published in the Federal Register a final order to temporarily place these three synthetic cannabinoids in schedule I of the CSA (80 FR 5042), making all regulatory controls pertaining to schedule I controlled substances applicable to the manufacture of these three synthetic cannabinoids, including the requirement to establish an aggregate production quota pursuant to 21 U.S.C. 826 and 21 CFR part 1303.

AB-CHMINACA, AB-PINACA, and THJ-2201 were non-controlled substances when the aggregate production quotas for schedule I and II substances were established. Therefore no aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201 were established at that time.

In determining the 2015 aggregate production quotas of these three synthetic cannabinoids, the Administrator considered the following factors in accordance with 21 U.S.C. 826(a) and 21 CFR 1303.11(b): (1) Total net disposal of the class by all manufacturers during the current and 2 preceding years; (2) trends in the national rate of net disposal of the class; (3) total estimated inventories of the basic class and of all substances manufactured from the class, and trends in inventory accumulation; (4) projected demand for each class as indicated by procurement quotas requested pursuant to 21 CFR 1303.12; and (5) other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

The Administrator, therefore, proposes that the annual 2015 aggregate production quotas for the following temporarily controlled schedule I controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic class—schedule I	Proposed 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

Dated: March 12, 2015.

Michele M. Leonhart,

Administrator.

[FR Doc. 2015-06456 Filed 3-19-15; 8:45 am]

BILLING CODE 4410-09-P

MORRIS K. UDALL AND STEWART L. UDALL FOUNDATION

Sunshine Act Meetings

TIME AND DATE: 9:00 a.m. to 4:00 p.m., Thursday, April 16, 2015.

PLACE: The offices of the Morris K. Udall and Stewart L. Udall Foundation, 130 South Scott Avenue, Tucson, AZ 85701.

STATUS: This meeting of the Board of Trustees will be open to the public.

MATTERS TO BE CONSIDERED: (1) Chair's Remarks; (2) Executive Director's Remarks; (3) Overview of Trustee Responsibilities; (4) Board Officers & Committee Elections; (5) Consent Agenda Approval, including program reports of the Education Programs, U.S. Institute for Environmental Conflict Resolution, and Udall Center for Studies in Public Policy/Native Nations Institute for Leadership, Management, and Policy/Udall Archives, and resolutions related to the Operating Procedures of the Board of Trustees and the Parks in Focus Fund, Inc. (6) Financial and Internal Controls Update; (7) Ethics Briefing; (8) Program Panel & Discussion; and (9) Appropriations Update.

CONTACT PERSON FOR MORE INFORMATION: Philip J. Lemanski, Executive Director, 130 South Scott Avenue, Tucson, AZ 85701, (520) 901-8500.

Dated: March 16, 2015.

Philip J. Lemanski,

Executive Director, Morris K. Udall and Stewart L. Udall Foundation, and Federal Register Liaison Officer.

[FR Doc. 2015-06556 Filed 3-18-15; 4:15 pm]

BILLING CODE 6820-FN-P

NUCLEAR REGULATORY COMMISSION

[NRC-2015-0001]

Sunshine Act Meetings

DATES: March 23, 30, April 6, 13, 20, 27, 2015.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of March 23, 2015—Tentative

Thursday, March 26, 2015

9:30 a.m. Briefing on Security Issues (Closed—Ex. 1)

1:30 p.m. Briefing on Security Issues (Closed—Ex. 1)

Friday, March 27, 2015

9:30 a.m. Briefing on Threat Environment Assessment (Closed—Ex. 1)

2015 Revised APQ Worksheets

Basic Class: 9050-B
PQ Total(CM+PD): 27,218,758.001

FDA Est: -.034
IMS Est: .299

Company	DEA Num	2015 MQ Request	2015 MQ	2014 Sales	2014 Total Sales	% of 2014 Sales	Share of 2015 Total PQ	2014 Inventory	2015 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	25,605,542.319	0.000	0.000	1.600	0.000	-1.600	-1.600	0.000
		100.000	100.000	33.826	25,605,542.319	0.000	35.959	42.664	0.000	4.053	10.742	0.000
		626,000.000	626,000.000	0.000	25,605,542.319	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		296,000.000	296,000.000	241,282.000	25,605,542.319	0.009	256,483.393	247,156.000	0.000	66,272.411	103,768.741	0.000
		18,400,000.000	11,600,000.000	8,778,025.000	25,605,542.319	0.343	9,332,128.330	3,913,296.000	2,088,849.000	10,406,314.295	12,133,484.226	0.000
		1,000.000	1,000.000	4.168	25,605,542.319	0.000	4.431	501.534	0.000	-495.774	-494.954	0.000
		25,501,000.000	16,770,000.000	15,665,650.000	25,605,542.319	0.612	16,648,487.216	4,380,520.000	0.000	17,571,912.381	20,699,901.520	0.000
		3,670,000.000	1,916,186.000	699,547.000	25,605,542.319	0.027	743,620.278	7,546.000	0.000	959,158.362	1,096,864.058	0.000
MQ Totals:		46,496,105.000	31,431,291.000	25,605,541.996				8,449,068.798	2,088,849.000	29,022,165.157		0.000

Final Initial APQ:	33,600,000.000	
Proposed Revised:	51,052,320.000	(IMS pct chg applied to current APQ then rounded up)
Proposed Revised (with 25% buffer):	63,815,400.000	(64,000,000 rounded up)
Final Revised APQ:	0.000	
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	867,777.203	CFR 50%: 564,473.202
2014 Initial APQ:	36,000,000.000	
FDA Est = 2014 APQ * (1 + FDA Est):	35,630,640.000	
IMS Est = 2014 APQ * (1 + IMS Est):	47,571,480.000	

Pending requests:

Company	DEA Num	current MQ	2015 MQ Request	Possible grant	difference
(b)(4);(b)(7)(E)		11,600,000.000	16,400,000.000	13,600,000.000	2,000,000.000
		16,770,000.000	28,250,000.000	24,531,000.000	7,761,000.000
		1,916,186.000	3,670,000.000	3,670,000.000	1,753,814.000
					11,514,814.000

(b)(4)

May 14, 2015

Dr. Christine Sannerud
Drug Enforcement Administration
Office of Diversion Control
8701 Morisette Drive
Springfield, VA 22152

Dear Dr. Sannerud:

(b)(4);(b)(7)(E) is requesting an increase in 2015 CPS morphine (9670) and CPS codeine (9670) procurement quota. (b)(4) also requests additional 2015 morphine for sale (9300), morphine for conversion (9300), and codeine for sale (9050) manufacturing quota.

Quota Category	Material Name	2015 Granted Quota (kg)	Requested Quota(kg)	Increase (kg)
Procurement	CPS-Morphine – 9670 NET	38,999	80,000	41,001
	CPS-Morphine – 9670 as kgB	31,199	64,000	32,801
Procurement	CPS-Codeine – 9670 NET	6,366	9,988	3,622
	CPS-Codeine – 9670 as kgB	5,417	8,500	3,083
Manufacturing	**Total Morphine for Conversion - 9300**	**13,463**	**24,500**	**11,037**
	Morphine for Conversion for Codeine	24,097	10,634	24,097
	Morphine for Conversion for oxymorphone	403	403	403
Manufacturing	Morphine for Sale – 9300	19,546	26,000	6,454
Manufacturing	Codeine For Sale - 9050	16,769	28,250	11,481

Current Situation

- CPS Morphine is the starting material for two (b)(4) drug products: Morphine Sulfate and Codeine Phosphate (via morphine for conversion category).
- Morphine sales have increased over 2014. (b)(4) holds a contract with (b)(4);(b)(7)(E) and (b)(4);(b)(7)(E) requiring supply of 80% of their requirements. As a result of exhausting inventory from another supplier, (b)(4) will require (b)(4) to begin supplying in 2015. (b)(4) has already supplied initial, un-forecasted quantities. (b)(4) expects demand to be approximately 4,000 to 6, 000 kg salt due in part to base business not previously supplied by (b)(4) but also driven by substitution for hydrocodone.
- (b)(4) Codeine sales have increased significantly compared to recent years. This may potentially be attributed to the rescheduling of hydrocodone and the movement of physicians to other schedule III-V pain medication. (b)(4) key codeine customer, (b)(4) has requested supply increase for 2015 of 18,000 kg salt and is predicting 22,000 kg salt requirement for 2016.

- Tasman codeine sales slowly increase as US customers on board and (b)(4) international sites consume the Tasman API. (b)(4) has supplied (b)(4) historically since the Tasman introduction. In 2014 (b)(4) received qualification samples with bulk API delivered in 2015. (b)(4) will be requiring qualification material in 2015 with commercial volume in 2016.
- The requested quota increases will provide adequate morphine and codeine inventory to support our first quarter 2015 sales and will be under the 50% year-end level requirement.
- With the recent change to reporting CPS as net and with the increase API demand, the initial CPS Morphine and CPS Codeine procurement quota grant does not provide enough material to support the (b)(4) 2015 production plan for both morphine for sale and codeine for sale while allowing for adequate year-end inventory to support 1Q2016. The CPS needed to produce the planned volumes of morphine and codeine can be found in Appendix A.

Timing

- The current CPS Morphine and CPS Codeine procurement quota grant will impact the supply chain in November.
- The additional morphine for sale quota is required in the fall to support the remaining 2015 production and provide adequate year-end inventory.
- The additional codeine is required by June to support the remaining 2015 production and provide adequate year-end inventory.

Quota Justification – Process Losses, Morphine Sales

- (b)(4) is notifying DEA in this letter of the actual processing losses for the purified morphine sulfate steps (PMS) and codeine phosphate steps (CPH). The quota requested includes replacement quota for the material lost in the waste water streams. The process losses for both products can be found in Appendix A.
- 2015 Morphine sales are shown in Table I and the 2015 Codeine sales are shown in Table II. Supporting POs available can be found in Appendix B.

Table I: 2015 Codeine for Sale YTD Sales and Forecast

2015 Codeine from Morphine Sales, kg Base						
Customer	Reg #	Jan - April	May - June	July- Sept	Oct- Dec	2015 Total
(b)(4);(b)(7)(E)		0.1	-	-	-	0.1
		-	44.4	88.8	-	133.2
		0.1	-	-	-	0.1
		50.1	166.5	111.0	134.7	462.3
		-	-	-	-	-
		372.2	370.0	1,462.2	1,446.7	3,651.2
		42.3	421.8	252.3	-	716.5
		1.0	-	0.7	-	1.7
		101.9	11.8	44.4	96.2	254.3
		0.2	-	-	-	0.2
		858.2	606.1	966.4	-	2,430.7
		75.5	-	18.5	-	94.0
		2.2	-	-	-	2.2
		-	-	-	-	-
		-	-	-	-	-
		111.0	111.0	481.0	1,342.4	2,045.4
		692.6	865.8	1,858.9	2,516.0	5,933.3
		-	-	-	-	-
Total		2,307.4	2,597.4	5,284.3	5,535.9	15,725.1
Intercompany Movement for testing	(b)(4);(b)(7)(E)	0.8	-	-	-	
2015 Codeine from Tasman Sales, kg Base						
(b)(4);(b)(7)(E)		1,110.0	1,184.0	740.0	1,480.0	4,514.0
		37.7	-	-	-	37.7
		107.3	-	-	-	107.3
		0.0	-	-	-	0.0
		-	296.0	-	370.0	666.0
Total		1,255.1	1,480.0	740.0	1,850.0	5,325.1
Intercompany Movement for testing	(b)(4);(b)(7)(E)	0.5	-	-	-	

not granted yet

(5,878,533 granted)

Table II: 2015 Morphine for Sale YTD Sales and Forecast

Customer	Reg #	Jan - April	May - June	July - Sept	Oct - Dec	2015 Total
(b)(4);(b)(7)(E)		0.5	-	-	-	0.5
		-	-	-	-	-
		-	-	-	-	-
		0.2	-	-	-	0.2
		657.3	1,630.5	-	1,687.5	3,975.3
		-	-	-	-	-
		-	-	-	-	-
		7.5	-	14.3	-	21.8
		-	-	-	-	-
		233.3	36.8	-	298.5	568.5
		-	-	600.0	-	600.0
		0.7	-	-	-	0.7
		86.4	95.3	150.0	-	331.6
		-	-	-	-	-
		-	-	-	-	-
		1.5	-	0.8	0.8	3.0
		-	-	-	159.0	159.0
		-	-	198.8	-	198.8
		150.0	-	150.0	225.0	525.0
		-	18.8	-	37.5	56.3
		73.0	-	60.0	-	133.0
		-	-	-	-	-
		-	-	-	-	-
		-	-	-	-	-
		-	300.0	300.0	300.0	900.0
		-	9.0	-	-	9.0
		-	-	-	-	-
		3,369.4	-	4,500.0	750.0	8,619.4
		-	-	51.0	-	51.0
		22.1	-	-	-	22.1
		-	257.3	198.0	-	455.3
		83.0	-	-	-	83.0
		481.9	360.3	543.8	915.0	2,301.0
		3.8	-	-	-	3.8
		116.6	749.7	-	-	866.3
Total		**5,287.1**	**3,457.5**	**6,766.5**	**4,373.3**	**19,884.3**
Intercompany Movement for testing	(b)(4);(b)(7)(E)	1.0	-	-	-	

Inventory

As noted in the tables below, the current quota grants do not provide (b)(4) sufficient quota to meet our projected 2015 dispositions nor to end 2015 with sufficient inventory to meet first quarter 2016 projected dispositions. The quantities requested take into account processing losses.

Table III: CPS-Morphine Procurement Quota Request

	kg Base		kg NET	
2015 CPS-Morphine Inventory Calculations	**With Current Quota**	**Additional 2015 Grant**	**With Current Quota**	**Additional 2015 Grant**
2014 Ending Inventory	8,101	8,101	10,107	10,107
Non saleable material	2	2	2	2
2014 Available End. Inv.	**8,099**	**8,099**	**10,105**	**10,105**
2015 CPS Quota kgB	31,199	64,000	38,999	80,000
2015 Dispositions:				
Converted to AMA for Sale	30,110	30,110	37,638	37,638
Converted to AMA for Conv	28,024	28,024	35,030	35,030
2015 Ending Inventory	**-18,836**	**13,965**	**-23,564**	**17,437**
Converted to % Yearend	**-41.1%**	**30.5%**		

	kgs, base
2014 Dispositions	33,516
2015 Estimated Dispositions	58,134
Average	45,825
30% Inventory Allowance	13,748

Table IV: Morphine for Conversion Manufacturing Quota Request

	Initial 2015 Grant	Additional 2015 Grant
2014 Ending Inventory	1,999	1,999
Non saleable material	3	3
2014 Available End. Inv.	**1,996**	**1,996**
2015 API Quota	13,463	24,500
2015 Dispositions:		
Converted to Codeine	23,059	23,059
Converted to 14-HM	0	403
Processing Losses		
2015 Ending Inventory	**-7,600**	**3,035**
Converted to % Yearend	**-42.2%**	**16.8%**

	kgs, base
2014 Dispositions	12,572
2015 Est. Dispositions	23,059
Average	17,815
50% Inventory Allowance	8,908

Table V: Morphine for Sale Manufacturing Quota Request

	Initial 2015 Grant	Additional 2015 Grant
2014 Ending Inventory	6,951	6,951
Non saleable material	56	56
2014 Available End. Inv.	6,895	6,895
2015 API Quota	19,546	26,000
2015 Dispositions:		
Sales	19,884	19,884
Processing Losses	(3,931)	(5,468)
2015 Ending Inventory	2,626	7,543
Converted to % Yearend	14.6%	41.9%

	kgs, base
2014 Dispositions	16,113
2015 Estimated Dispositions	19,884
Average	17,999
50% Inventory Allowance	8,999

Table VI: CPS-Codeine Procurement Quota Request

2015 CPS-Codeine Inventory Calculations	kg Base		kg NET	
	With Current Quota	Additional 2015 Grant	With Current Quota	Additional 2015 Grant
2014 Ending Inventory	1,787	1,787	2,100	2,100
Non saleable material	0	0	0	0
2014 Available End. Inv.	**1,787**	**1,787**	**2,100**	**2,100**
2015 CPS Quota (kgB)	5,417	8,500	6,366	9,988
2015 Dispositions:				
Converted to ACA for Sale	8,036	8,036	9,443	9,443
2015 Ending Inventory	**-832**	**2,251**	**-977**	**2,646**
Converted to % Yearend	**-11.8%**	**32.1%**		

	kgs, base
2014 Dispositions	6,007
2015 Est. Dispositions	8,036
Average	7,021
30% Inventory Allowance	2,106

Table VII: Codeine from Morphine for Sale Manufacturing Quota Request

	With Current Quota	Additional 2015 Grant
2014 Ending Inventory	2,372	2,372
Non saleable material	28	28
2014 Available End. Inv.	**2,344**	**2,344**
2015 API Quota	12,581	21,500
2015 Dispositions:		
Sales	15,725	15,725
Processing Losses	(939)	(1,569)
2015 Ending Inventory	**-1,738**	**6,550**
Converted to % Yearend	**-13.0%**	**49.0%**

	kgs, base
2014 Dispositions	11,001
2015 Est. Dispositions	15,725
Average	13,363
50% Inventory Allowance	6,681

Table VIII: Codeine from Tasman for Sale Manufacturing Quota Request

	With Current Quota	Additional 2015 Grant
2014 Ending Inventory	2,045	2,045
Non saleable material	9	9
2014 Available End. Inv.	**2,036**	**2,036**
2015 API Quota	4,188	6,750
2015 Dispositions:		
Sales	5,325	5,325
Processing Losses	(883)	(883)
2015 Ending Inventory	**16**	**2,578**
Converted to % Yearend	**0.3%**	**50.2%**

	kgs, base
2014 Dispositions	4,941
2015 Est. Dispositions	5,251
Average	5,096
50% Inventory Allowance	2,548

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

APPENDIX A-1
CPS- Morphine Requirements and Morphine Production, kg BASE

	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
CPS-AMA Requirements							
CPS-AMA to Morphine for Sale	22,636	86.35%	19,546		7,474	6,454	
CPS-AMA to Morphine for Conv	7,657	85.64%	6,557		20,367	17,443	
TOTAL CPS-AMA kgB	30,293				27,842		

[1] Standard processing yields are used to determine output.

APPENDIX A-2
Morphine for Sale 2015 Production and Estimated Process Loss, kg BASE

	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
Morphine for Sale							
Morphine to Morphine Sulfate	19,546	80.13%	15,662	(3,884)	7,642	6,124	(1,518)
Morphine Sulfate Finishing	15,662	99.70%	15,615	(47)	6,124	6,105	(18)
Total				(3,931)			(1,537)

APPENDIX A-3
Codeine for Sale (Morphine) 2015 Production and Estimated Process Loss, kg BASE

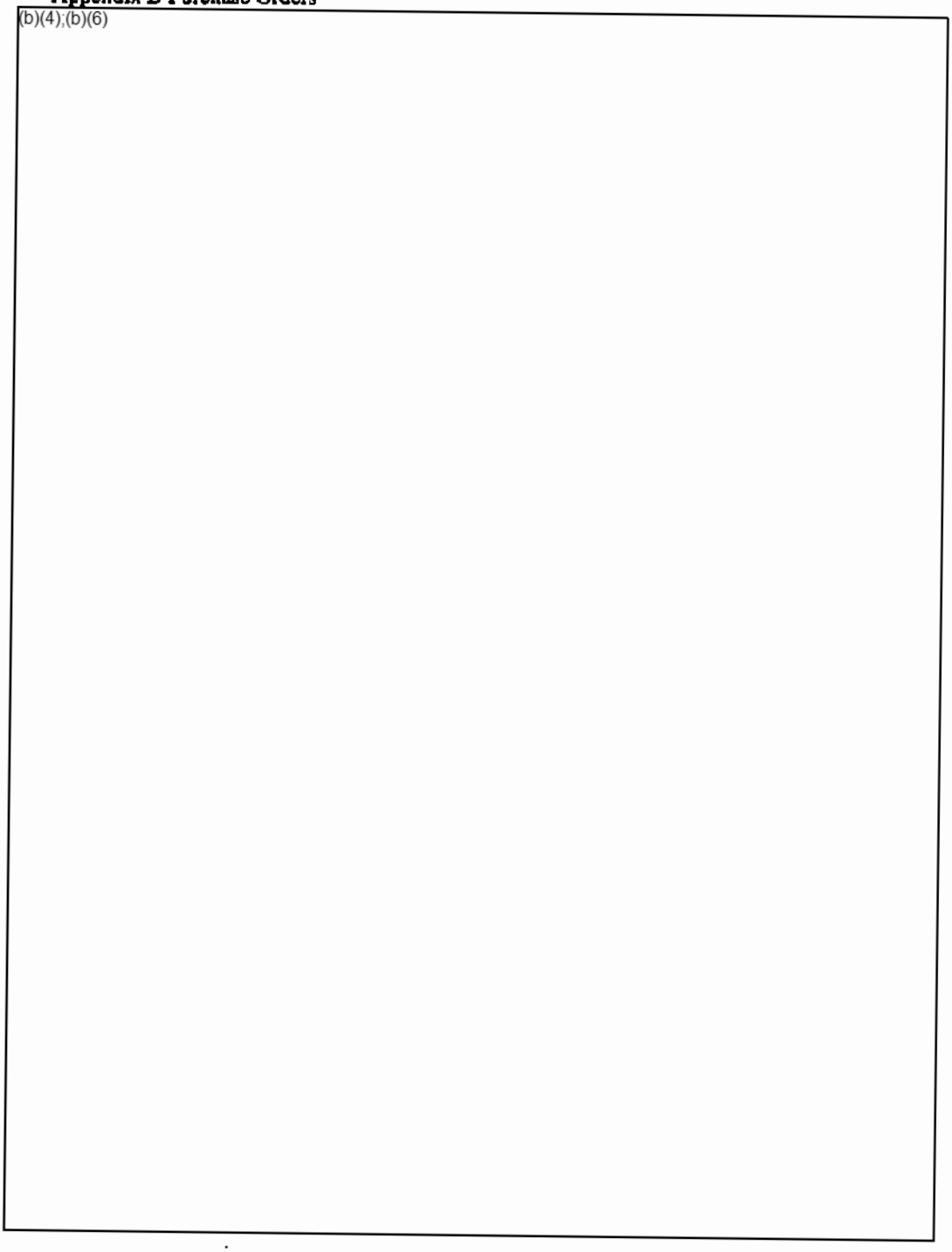
	PROCESS LOSSES BASED ON 2014 YIELDS FOR CURRENT GRANT					ESTIMATE WITH ADDITIONAL QUOTA		
Description	Input to Step	Process Yield	MWC	Net output of step	Loss by step	Input to Step	Output of Step	Loss by step
CPS-AMA to Morphine for Conv	15,720	85.64%		13,463		12,304	10,537	
Codeine for Sale								
Morphine for Conv to Codeine for Sale	13,493	88.8%	1.05	12,581		9,566	8,919	
Codeine(fr Morph) to Codeine Phosphate	12,581	93.60%		11,776	(805)	9,422	8,819	(603)
Codeine Phosphate Finished	11,776	99.28%		11,691	(85)	8,903	8,839	(64)
Total					(890)			(667)

APPENDIX A-4
Codeine for Sale (Tasman) 2015 Production and Estimated Process Loss, kg BASE

	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
CPS-ACA to Codeine for Sale	4,986	84.0%	4,188		3,050	2,562	
Codeine for Sale							
Codeine(fr CPS) to Codeine Phosphate	4,188	87.8%	3,677	(511)	2,692	2,364	(328)
Codeine Phosphate Finished	3,677	99.3%	3,650	(26)	2,364	2,347	(17)
Total				(537)			(346)

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

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



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

(b)(4);(b)(6);(b)(7)(E)

(b)(4);(b)(6);(b)(7)(E)

(b)(4);(b)(6);(b)(7)(E)

(b)(4);(b)(6);(b)(7)(E)

(b)(4);(b)(6);(b)(7)(E)

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

2015 Revised APQ Worksheets

Basic Class: 9801-0

PQ Total(CM+PD): 1,131,004.000

FDA Est: -.009

IMS Est: -.01

Company	DEA Num	2015 MQ Request	2015 MQ	2014 Sales	2014 Total Sales	% of 2014 Sales	Share of 2015 Total PQ	2014 Inventory	2015 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	1,190,169.467	0.000	0.000	0.100	0.000	-0.100	-0.100	0.000
		200,000.000	153,669.000	39,813.000	1,190,169.467	0.033	37,833.824	55,805.000	0.000	-6,621.029	1,440.530	0.000
		216,000.000	138,000.000	112,060.000	1,190,169.467	0.094	106,508.301	6,740.110	180,000.000	311,720.682	334,415.267	0.000
		2.000	2.000	0.467	1,190,169.467	0.000	0.444	2.282	0.000	-1.705	-1.611	0.000
		13,330.000	10,690.000	10,174.000	1,190,169.467	0.009	9,668.932	2,503.000	0.000	10,065.702	12,125.790	0.000
		680,000.000	518,865.000	273,105.000	1,190,169.467	0.229	259,528.459	367,124.000	0.000	-49,737.004	5,562.823	0.000
		990,000.000	631,515.000	736,639.000	1,190,169.467	0.621	701,919.925	232,756.000	331,081.000	1,010,620.903	1,160,384.057	0.000
		3,000.000	0.000	0.000	1,190,169.467	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		43,000.000	25,000.000	16,356.000	1,190,169.467	0.014	15,544.814	14,180.000	0.000	8,048.259	9,360.518	0.000
		10,500.000	0.000	0.000	1,190,169.467	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		2,077,637.000	1,675,746.000	1,190,169.467				899,090.492	511,081.000	1,282,295.708		0.000

Final Initial APQ:	1,720,000.000
Proposed Revised:	1,840,000.000
Proposed Revised (with 25% buffer):	2,300,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-678,330.492
2014 Initial APQ:	1,687,000.000
FDA Est = 2014 APQ * (1 + FDA Est):	1,676,540.600
IMS Est = 2014 APQ * (1 + IMS Est):	1,669,961.300

CFR 50%: -883,539.125

Pending requests from:

Company	DEA Num	2015 MQ Request	current MQ	possible grant	difference
(b)(4);(b)(7)(E)		990,000.000	631,515.000	990,000.000	158,485.000 (ref # 123233; should be granted 158kg but limited to 40kg by APQ)
		3,000.000	0.000	400.000	400.000 (ref # 123549; granted .4kg)

115,885.000 total

1,254.000 remaining APQ

FENTANYL

2015 Revised APQ Worksheets

Basic Class: 0143-8
PQ Total(CM+PQ): 67,545,603.000

FDA Est: -.016
IMS Est: .012

Company	DEA Num	2015 MQ Request	2015 MQ	2014 Sales	2014 Total Sales	% of 2014 Sales	Share of 2015 Total PQ	2014 Inventory	2015 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	75,172,840.417	0.000	0.000	1.635	0.000	-1.635	-1.635	0.000
		60.000	60.000	6.417	75,172,840.417	0.000	7.937	800.025	0.000	-790.153	-788.429	0.000
		6,425,000.000	4,842,015.000	263,725.000	75,172,840.417	0.004	238,019.231	116,390.000	0.000	191,035.000	245,065.268	0.000
		100,000.000	100,000.000	0.000	75,172,840.417	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		5,100,000.000	1,350,000.000	0.000	75,172,840.417	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		4,650,000.000	2,460,622.000	1,322,385.000	75,172,840.417	0.018	1,193,471.809	384,873.000	0.000	1,166,840.092	1,457,757.761	0.000
		15,900,000.000	15,900,000.000	7,714,405.000	75,172,840.417	0.103	6,962,457.510	14,545,073.000	0.000	-5,493,865.237	-3,913,387.363	0.000
		69,002,000.000	65,470,000.000	47,157,246.000	75,172,840.417	0.627	42,660,740.695	19,579,710.000	0.000	35,749,253.293	45,410,527.745	0.000
		2,000.000	2,000.000	0.000	75,172,840.417	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		18,536,000.000	14,303,000.000	18,095,391.000	75,172,840.417	0.241	16,331,599.380	9,317,932.000	4,800,000.000	16,693,147.194	20,400,414.975	0.000
		4,516,000.000	2,610,000.000	619,760.000	75,172,840.417	0.008	559,296.681	822,634.000	0.000	104,151.688	231,311.852	0.000
MQ Totals:		123,533,070.000	108,937,707.000	75,172,840.417				44,569,513.664	4,800,000.000	48,429,770.240		0.000

Final Initial APQ:	110,000,000.000
Proposed Revised:	111,320,000.000 (IMS pct chg)
Proposed Revised (with 25% buffer):	139,150,000.000
Final Revised APQ:	0.000
MQ Needs/PQ* 1.5 - Revised MQ - Inventory:	-49,738,816.180
2014 Initial APQ:	119,500,000.000
FDA Est = 2014 APQ * (1 + FDA Est):	117,349,000.000
IMS Est = 2014 APQ * (1 + IMS Est):	120,934,000.000

CFR 50%: -47,907,000.606

Pending Requests:

Company	DEA Num	2015 MQ Request	current MQ	possible grant	difference
(b)(4);(b)(7)(E)		5,100,000.000	1,350,000.000	5,100,000.000	3,750,000.000
		18,536,000.000	14,303,000.000	17,270,000.000	2,967,000.000

6,717,000.000

3,062,293.000 current available APQ

3,654,707.000 difference

Row Labels	Sum of Drug Amount 1	2015 Current Quota
(b)(4);(b)(7)(E)	1,338.322	
	18.184	
	881,350.943	Ø
	102,201.000	Ø
	80,685.000	4,053,555
	2,273.000	- 5,910
	454.600	
	37.922	
	2.278	
	181,525.113	874,312
	15,240.500	181,373
	6,705.350	Ø
	512.370	125,000
	7.465	
	229.067	
	40,923.092	574,200
	26.385	
	27.462	
	991.529	5,720
	290.035	
Grand Total	1,314,839.617	5,814,160

2015 Revised APQ Worksheets

Basic Class: 9739-0
PQ Total(Old+PD): 2,078.000

FDA Est: .057
IMS Est: .037

Company	DEA Num	2015 MQ Request	2015 MQ	2014 Sales	2014 Total Sales	% of 2014 Sales	Share of 2015 Total PQ	2014 Inventory	2015 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	459.789	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,300.000	1,155.000	0.000	459.789	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		5.000	5.000	0.000	459.789	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,620.000	1,620.000	459.000	459.789	0.998	2,074.434	2,055.000	0.000	641.764	652.793	0.000
		1,000.000	0.000	0.000	459.789	0.000	0.000	483.945	0.000	-483.945	-483.945	0.000
		5.000	5.000	0.789	459.789	0.002	3.566	0.016	0.000	4.618	4.637	0.000
MQ Totals:		4,135.000	2,990.000	459.789				2,539.963	0.000	162.437		0.000

Final Initial APQ:	3,000.000	
Proposed Revised:	3,350.400	
Proposed Revised (with 25% buffer):	4,188.000	(4,200 rounding up)
Final Revised APQ:	0.000	
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-2,411.983	**CFR 50%:** -2,816.516
2014 Initial APQ:	3,000.000	
FDA Est = 2014 APQ * (1 + FDA Est):	3,172.200	
IMS Est = 2014 APQ * (1 + IMS Est):	3,111.300	

Pending Requests:

Company	DEA Num	2015 MQ Request	2015 MQ	
(b)(4);(b)(7)(E)		1,300.000	1,155.000	quota granted was short 200g; ref # 121501

2015 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 notice, prepared for your signature, proposes to adjust the calendar year 2015 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 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.

- The Federal Drug Administration (FDA) has responded to DEA's annual letter, which requests 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 proposed initial AAN & APQ values:

List I chemicals

- No changes proposed.

Schedule I substances

- The APQ for **(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone), 2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36), 2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82), 3-Fluoro-N-methylcathinone (3-FMC), 4-Fluoro-N-methylcathinone (4-FMC), 4-Methyl-N-ethylcathinone (4-MEC), 4-Methyl-α-pyrrolidinopropiophenone (4-MePPP), alpha-Pyrrolidinobutiophenone (α-PBP), alpha-Pyrrolidinopentiophenone (α-PVP), Desomorphine, N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48), N-(1-Amino-3,3-dimethyl-1-**

oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA), N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA), Naphthylpyrovalerone (naphyrone), Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22), Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC), Heroin, Normorphine, and **Tilidine,**. The manufacturing of these substances will be used for analytical standards, reference, and research material. New DEA registrant(s) entering the reference standard market at the bulk manufacturing level.

- The APQ for **Para-Fluorofentanyl, Parahexyl,** and **Pholcodine** were increased from zero due to requests to manufacture these substances for analytical standards, reference, and research material.

- The APQ for **Tetrahydrocannabinols** was increase due to increased product development efforts by DEA registered manufacturers.

Schedule II substances

- The APQ for **Dextropropoxyphene, Levomethorphan, Meperidine-Intermediate B,** and **Phencyclidine** were increased due to increased registrant requirements. The manufacturing of these substances will be used for analytical standards, reference, and research material. New DEA registrant(s) entering the reference standard market at the bulk manufacturing level.

- The APQ for **Codeine (for sale)** is proposed to increase based on analysis of IMS Health 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 .

- The APQ for **Fentanyl** is proposed to increase based on a DEA registered bulk manufacturer's improvement of their synthesis route to manufacture fentanyl from ANPP.

- The APQ for **Methylphenidate** is proposed to increase 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. This will avert a possible shortage due to APQ limitations.

- The APQ for **Oxycodone (for sale)** is proposed to increase based on additional product development efforts as dosage form manufacturers qualify a second supplier of API as required by the FDA.

- The APQ for **Remifentanil** was increased due to new applications from registrants conducting bulk API product development efforts or supporting dosage form manufacturers in dosage form product development efforts.

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-411]

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 2015

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

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2015 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 1303.11(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 midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-411" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov*. Paper comments that duplicate electronic submissions are

not necessary. Should you, however, wish to submit written comments via regular or express mail, they should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

All comments received are considered part of the public record and will 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 (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 the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the "For Further Information Contact" paragraph above.

Legal Authority

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and 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. This responsibility has been delegated to the Administrator of the DEA pursuant to 28 CFR 0.100(b). The Administrator, in turn, has redelegated that authority to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

The DEA published the established aggregate production quotas for schedule I and II controlled substances and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine for 2015 in the *Federal Register* (79 FR 53216) on September 8, 2014. 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 2015 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2015 aggregate production quotas for certain schedule I and II controlled substances to be manufactured in the United States in 2015 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. The DEA also proposes to adjust the established 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported to the United States in 2015 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.

In proposing the adjustment, the DEA has taken into account the criteria that the DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine 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 Deputy Administrator finds relevant.

The DEA also considered updated information obtained from 2014 year-end inventories, 2014 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 DEA 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 2015 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 2015 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 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 Deputy Administrator, therefore, proposes to adjust the 2015 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 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Schedule I		
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15	25
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15	25
[1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15	no change
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15	25
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-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-*n*-propylphenyl)ethanamine (2C-P)	30	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-Dimethoxyphenyl)ethanamine (2C-H)	30	no change
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe;	15	25

25B; Cimbi-36)		
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)	15	25
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-(Methylamino)-1-phenylpentan-1-one (pentedrone)	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-Fluoro-*N*-methylcathinone (3-FMC)	15	25
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-Fluoro-*N*-methylcathinone (4-FMC)	15	25
4-Methoxyamphetamine	100	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-Methyl-*N*-ethylcathinone (4-MEC)	15	25
4-Methyl-*N*-methylcathinone (mephedrone)	45	no change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15	25
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68	no change
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-	53	no change

phenol (cannabicyclohexanol or CP-47,497.C8-homolog)		
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change
5-Methoxy-*N*,*N*-diisopropyltryptamine	25	no change
5-Methoxy-*N*,*N*-dimethyltryptamine	25	15[1] change
Acetyl-*alpha*-methylfentanyl	2	no change
Acetyldihydrocodeine	2	no change
Acetylmethadol	2	no change
Allylprodine	2	no change
Alphacetylmethadol	2	no change
alpha-Ethyltryptamine	25	no change
Alphameprodine	2	no change
Alphamethadol	2	no change
alpha-Methylfentanyl	2	no change
alpha-Methylthiofentanyl	2	no change
alpha-Methyltryptamine (AMT)	25	no change
alpha-Pyrrolidinobutiophenone (α-PBP)	15	25
alpha-Pyrrolidinopentiophenone (α-PVP)	15	25
Aminorex	25	no change
Benzylmorphine	2	no change
Betacetylmethadol	2	no change
beta-Hydroxy-3-methylfentanyl	2	no change
beta-Hydroxyfentanyl	2	no change
Betameprodine	2	no change
Betamethadol	4	no change
Betaprodine	2	no change
Bufotenine	3	no change
Cathinone	70	no change
Codeine methylbromide	5	no change
Codeine-*N*-oxide	305	no change
Desomorphine	5	25
Diethyltryptamine	25	no change
Difenoxin	11,000	no change
Dihydromorphine	3,990,000	no change
Dimethyltryptamine	35	no change
Dipipanone	5	no change

Fenethylline	5	no change
gamma-Hydroxybutyric acid	70,250,000	no change
Heroin	25	50
Hydromorphinol	2	no change
Hydroxypethidine	2	no change
Ibogaine	5	no change
Lysergic acid diethylamide (LSD)	35	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-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	15	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA)	15	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA)	15	no change
N,*N*-Dimethylamphetamine	25	no change
Naphthylpyrovalerone (naphyrone)	15	25
N-Benzylpiperazine	25	no change
N-Ethyl-1-phenylcyclohexylamine	5	no change
N-Ethylamphetamine	24	no change
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Noracymethadol	2	no change
Norlevorphanol	52	no change
Normethadone	2	no change
Normorphine	18	40

Para-fluorofentanyl	zero	5
Parahexyl	zero	5
Phenomorphan	2	no change
Pholcodine	zero	5
Psilocybin	30	no change
Psilocyn	30	no change
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15	25
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	15	25
Tetrahydrocannabinols	497,500	511,250
Thiofentanyl	2	no change
Tilidine	10	25
Trimeperidine	2	no change
Schedule II		
1-Phenylcyclohexylamine	5	no change
1-Piperidinocyclohexanecarbonitrile	5	no change
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500	no change
Alfentanil	17,750	no change
Alphaprodine	3	no change
Amobarbital	25,125	no change
Amphetamine (for conversion)	21,875,000	no change
Amphetamine (for sale)	37,500,000	no change
Carfentanil	19	no change
Cocaine	275,000	no change
Codeine (for conversion)	50,000,000	no change
Codeine (for sale)	49,500,000	63,900,000
Dextropropoxyphene	19	45
Dihydrocodeine	226,375	no change
Diphenoxylate (for conversion)	75,000	no change
Diphenoxylate (for sale)	1,337,500	no change
Ecgonine	174,375	no change
Ethylmorphine	3	no change
Fentanyl	2,150,000	2,300,000
Glutethimide	3	no change
Hydrocodone (for conversion)	137,500	no change

Hydrocodone (for sale)	99,625,000	no change
Hydromorphone	7,000,000	no change
Isomethadone	5	no change
Levo-alphacetylmethadol (LAAM)	4	no change
Levomethorphan	5	30
Levorphanol	7,125	no change
Lisdexamfetamine	29,750,000	no change
Meperidine	6,250,000	no change
Meperidine Intermediate-A	6	no change
Meperidine Intermediate-B	11	32
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	83,750,000	87,500,000
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	no change
Opium (powder)	112,500	no change
Opium (tincture)	687,500	no change
Oripavine	35,000,000	no change
Oxycodone (for conversion)	8,350,000	no change
Oxycodone (for sale)	137,500,000	139,150,000
Oxymorphone (for conversion)	29,000,000	no change
Oxymorphone (for sale)	7,750,000	no change
Pentobarbital	35,000,000	no change
Phenazocine	6	no change
Phencyclidine	19	38
Phenmetrazine	3	no change
Phenylacetone	9,375,000	no change

Racemethorphan	3	no change
Remifentanil	3,750	4,200
Secobarbital	215,003	no change
Sufentanil	6,255	no change
Tapentadol	12,500,000	no change
Thebaine	125,000,000	no change
List I Chemicals		
Ephedrine (for conversion)	1,000,000	no change
Ephedrine (for sale)	4,000,000	no change
Phenylpropanolamine (for conversion)	44,800,000	no change
Phenylpropanolamine (for sale)	8,500,000	no change
Pseudoephedrine (for conversion)	7,000	no change
Pseudoephedrine (for sale)	224,500,000	no change

The Deputy 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. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as needed.

Comments

Pursuant to 21 CFR 1303.11(c) and 1315.11(d), any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this notice, the Deputy Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.11(c) and 1515.11(e). In the event the Deputy Administrator decides to hold such a hearing, the Deputy Administrator will publish a notice of the hearing in the *Federal Register*. After consideration of any comments or objections, or after a hearing, if one is held, the Deputy Administrator will issue and publish in the *Federal Register* a final order establishing any adjustment of

2015 aggregate production quota for each basic class of controlled substance and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.11(c) and 1315.11(f).

Dated:

John J. Riley,
Acting Deputy Administrator.

OC:_____

OD:_____

OD/D:_____

ODX:_____

ODXS:_____

ODW:_____

$ODW_{Analyst}$:_____

ODQ:_____

ODQ: (b)(6) (date)

SBF-CM # ODEQ

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~~(DFW# 6867)~~

Dated: July 1, 2015.
Robert W. Middleton,
Deputy Chief, Office of Offshore Regulatory Programs.
[FR Doc. 2015–16675 Filed 7–7–15; 8:45 am]
BILLING CODE 4310–VH–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–418P]

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 2015

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2015 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and the 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 7, 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.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–418P" 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, 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 and will 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 (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 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 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 the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made available in the public docket. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

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 determine the total quantity and 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. This responsibility has been delegated to the Administrator of the DEA. 28 CFR 0.100(b).

The DEA established the 2015 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 September 8, 2014 (79 FR 53216). 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 2015 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2015 aggregate production quotas for certain schedule I and II controlled substances to be manufactured in the United States in 2015 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 do not include imports of controlled substances for use in industrial processes. The DEA is not proposing to adjust the established 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported into the United States in 2015 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.

In proposing the adjustment, the DEA has taken into account the criteria that the DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and assessment of annual needs for ephedrine, pseudoephedrine,

and phenylpropanolamine 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.

The DEA also considered updated information obtained from 2014 year-end inventories, 2014 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 DEA 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 2015 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 previously described in the published notice establishing the 2015 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 results 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 to adjust the 2015 aggregate production quotas for certain schedule I and II controlled substances expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Schedule I		
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15	25
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15	25
[1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15	no change
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15	25
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-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-*n*-propylphenyl)ethanamine (2C-P)	30	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-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).	15	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	no change

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82).	15	25
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-(Methylamino)-1-phenylpentan-1-one (pentedrone)	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-Fluoro-*N*-methylcathinone (3–FMC)	15	25
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-Fluoro-*N*-methylcathinone (4–FMC)	15	25
4-Methoxyamphetamine	100	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-Methyl-*N*-ethylcathinone (4–MEC)	15	25
4-Methyl-*N*-methylcathinone (mephedrone)	45	no change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15	25
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68	no change
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog).	53	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
Acetyl-*alpha*-methylfentanyl	2	no change
Acetyldihydrocodeine	2	no change
Acetylmethadol	2	no change
Allylprodine	2	no change
Alphacetylmethadol	2	no change
alpha-Ethyltryptamine	25	no change
Alphameprodine	2	no change
Alphamethadol	2	no change
alpha-Methylfentanyl	2	no change
alpha-Methylthiofentanyl	2	no change
alpha-Methyltryptamine (AMT)	25	no change
alpha-Pyrrolidinobutiophenone (α-PBP)	15	25
alpha-Pyrrolidinopentiophenone (α-PVP)	15	25
Aminorex	25	no change
Benzylmorphine	2	no change
Betacetylmethadol	2	no change
beta-Hydroxy-3-methylfentanyl	2	no change
beta-Hydroxyfentanyl	2	no change
Betameprodine	2	no change
Betamethadol	4	no change
Betaprodine	2	no change
Bufotenine	3	no change
Cathinone	70	no change
Codeine methylbromide	5	no change
Codeine-*N*-oxide	305	no change
Desomorphine	5	25
Diethyltryptamine	25	no change
Difenoxin	11,000	no change
Dihydromorphine	3,990,000	no change
Dimethyltryptamine	35	no change
Diphanone	5	no change
Ethylmethylthiambutene	5	no change
gamma-Hydroxybutyric acid	70,250,000	no change
Heroin	25	50
Hydromorphinol	2	no change

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Hydroxypethidine	2	no change
Ibogaine	5	no change
Lysergic acid diethylamide (LSD)	35	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-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	15	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB–PINACA)	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB–FUBINACA).	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB–CHMINACA).	15	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB–PINACA)	15	no change
N,*N*-Dimethylamphetamine	25	no change
Naphthylpyrovalerone (naphyrone)	15	25
N-Benzylpiperazine	25	no change
N-Ethyl-1-phenylcyclohexylamine	5	no change
N-Ethylamphetamine	24	no change
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Noracymethadol	2	no change
Norlevorphanol	52	no change
Normethadone	2	no change
Normorphine	18	40
Para-fluorofentanyl	zero	5
Parahexyl	zero	5
Phenomorphan	2	no change
Pholcodine	zero	5
Psilocybin	30	no change
Psilocyn	30	no change
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB–22; 5F–PB–22)	15	25
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB–22; QUPIC)	15	25
Tetrahydrocannabinols	497,500	511,250
Thiofentanyl	2	no change
Tilidine	10	25
Trimeperidine	2	no change
Schedule II		
1-Phenylcyclohexylamine	5	no change
1-Piperidinocyclohexanecarbonitrile	5	no change
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500	no change
Alfentanil	17,750	no change
Alphaprodine	3	no change
Amobarbital	25,125	no change
Amphetamine (for conversion)	21,875,000	no change
Amphetamine (for sale)	37,500,000	no change
Carfentanil	19	no change
Cocaine	275,000	no change
Codeine (for conversion)	50,000,000	no change
Codeine (for sale)	49,500,000	63,900,000
Dextropropoxyphene	19	45
Dihydrocodeine	226,375	no change
Diphenoxylate (for conversion)	75,000	no change
Diphenoxylate (for sale)	1,337,500	no change
Ecgonine	174,375	no change
Ethylmorphine	3	no change
Fentanyl	2,150,000	2,300,000
Glutethimide	3	no change
Hydrocodone (for conversion)	137,500	no change
Hydrocodone (for sale)	99,625,000	no change
Hydromorphone	7,000,000	no change
Isomethadone	5	no change
Levo-alphacetylmethadol (LAAM)	4	no change
Levomethorphan	5	30
Levorphanol	7,125	no change

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Lisdexamfetamine	29,750,000	no change
Meperidine	6,250,000	no change
Meperidine Intermediate-A	6	no change
Meperidine Intermediate-B	11	32
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	83,750,000	87,500,000
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	no change
Opium (powder)	112,500	no change
Opium (tincture)	687,500	no change
Oripavine	35,000,000	no change
Oxycodone (for conversion)	8,350,000	no change
Oxycodone (for sale)	137,500,000	139,150,000
Oxymorphone (for conversion)	29,000,000	no change
Oxymorphone (for sale)	7,750,000	no change
Pentobarbital	35,000,000	no change
Phenazocine	6	no change
Phencyclidine	19	38
Phenmetrazine	3	no change
Phenylacetone	9,375,000	no change
Racemethorphan	3	no change
Remifentanil	3,750	4,200
Secobarbital	215,003	no change
Sufentanil	6,255	no change
Tapentadol	12,500,000	no change
Thebaine	125,000,000	no change
List I Chemicals		
Ephedrine (for conversion)	1,000,000	no change
Ephedrine (for sale)	4,000,000	no change
Phenylpropanolamine (for conversion)	44,800,000	no change
Phenylpropanolamine (for sale)	8,500,000	no change
Pseudoephedrine (for conversion)	7,000	no change
Pseudoephedrine (for sale)	224,500,000	no change

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 further adjust the 2015 aggregate production quotas and assessment of annual needs as needed.

Comments

In accordance with 21 CFR 1303.13(c) and 1315.13(d), any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this notice, the Acting Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.13(c) and 1315.13(e). In the event the Acting Administrator decides to hold such a hearing, the Acting Administrator will publish a notice of the hearing in the **Federal Register**. 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 the 2015 aggregate production quota for each basic class of controlled substance 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 1, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015–16699 Filed 7–7–15; 8:45 am]

BILLING CODE P

Drug	Company	Comment	Amount	Response	Proposed APQ	Revised APQ	Change
codeine (for sale)	(b)(4)	increase APQ	5,484,000	sufficient APQ available	63,900,000	63,900,000	-
codeine (for sale)		increase APQ	6,636,000	sufficient APQ available	see above	see above	see above
codeine (for sale)		increase APQ	3,884,067	sufficient APQ available	see above	see above	see above
fentanyl		increase APQ	38,485	sufficient APQ available	2,300,000	2,300,000	-
gamma hydroxybutric acid		increase APQ	7,500	sufficient APQ available	70,250,000	70,250,000	-
hydrocodone (for sale)		increase APQ	1,830,000	sufficient APQ available	99,625,000	99,625,000	-
methadone		increase APQ	2,718,159	sufficient APQ available	31,875,000	31,875,000	-
methadone intermediate		increase APQ	1,800,634	sufficient APQ available	34,375,000	34,375,000	-
methylphenidate		increase APQ	9,186,236	adjust APQ	87,500,000	96,750,000	9,250,000
morphine (for conversion)		increase APQ	4,499,987	sufficient APQ available	91,500,000	91,500,000	-
oripavine		increase APQ	1,823,038	sufficient APQ available	35,000,000	35,000,000	-
oxycodone (for sale)		increase APQ	2,510,000	adjust APQ	139,150,000	141,375,000	2,225,000
oxymorphone (for conversion)		increase APQ	3,190,000	sufficient APQ available	29,000,000	29,000,000	-
oxymorphone (for sale)		increase APQ	150,000	sufficient APQ available	7,750,000	7,750,000	-

Number of registrants/entities commenting: 5
Number of drugs commented on: 12

12

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		Response	Proposed	Revised	Change
dihydroetorphine	(b)(4)	- no available APQ drug code 9334	-	3	3
ethylmorphine		- no available APQ, drug code 9190	3	5	2
etorphine HCl		- no available APQ drug code 9059	-	3	3
racemethorphan		- no available APQ drug code 9732	3	5	2
racemorphan		- no available APQ drug code 9733	-	3	3
fentanyl	(b)(4)	pending application # 123706, 123955	2,300,000	see above	see above

Additional Chemical Considerations:

Drug	Response	Proposed	Revised	Change
				-
				-
				-

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

AUG 1 0 2015

August 6, 2015

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

Subject: Docket No. DEA-418P

Dear Sirs:

I, (b)(6) of (b)(6) manufacturing registration (b)(4);(b)(7)(E) am submitting this comment on the 2015 Proposed Adjustments to the Aggregate Production Quota for various products as published in the July 8, 2015 Federal Register. We consider the information in this first paragraph to be "PERSONAL IDENTIFYING INFORMATION" and this information should not be released under the Freedom of Information Act per 5 USC Sec. 552(b)(4). In addition, the following information is "CONFIDENTIAL BUSINESS INFORMATION". The following items' manufacturing quota should be increased by the identified quantity: (i) Hydrocodone (for sale) by 1,830,000 grams as base. As noted herein, this first paragraph of this letter contains personal identifying and confidential business information and should be redacted in its entirety from any public docket.

We feel the proposed quantities for the material mentioned above are 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 needs. For these items an appropriate Electronic DEA Quota Application Form 189 will be submitted shortly pertaining to the items for which we are submitting comments.

Very truly yours

PUBLIC SUBMISSION

As of: 8/7/15 10:21 AM
Received: August 04, 2015
Status: DoNotPost
Tracking No. 1jz-8kda-l0sr
Comments Due: August 07, 2015
Submission Type: Web

Docket: DEA-2015-0011
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 2015

Comment On: DEA-2015-0011-0001
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 2015

Document: DEA-2015-0011-DRAFT-0005
Comment on FR Doc # N/A

Submitter Information

Name: (b)(6)

General Comment

Re: Comments on 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 2015 on behalf of the following registrant:

(b)(4)

Attachments

Docket No. DEA-418P (b)(4) Comment

(b)(4)

August 4, 2015

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

Attn: DEA Federal Register Representative [Docket No. DEA-418P]

This letter constitutes (b)(4) comments on the Proposed Revised Aggregate Production Quotas for 2015, as published in Federal Register on July 8, 2015, FR Volume 80, No. 130, pages 39156-39160. 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 proprietary 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").

9050 Codeine (for Sale)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 6,636,000 grams AA of codeine (for Sale) manufacturing quota for 2015, reference DEA online submission number 123843.

9801 Fentanyl

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 38,485 grams AA of fentanyl manufacturing quota for 2015, reference DEA online submission number 124116.

2010 Gamma Hydroxybutyric Acid

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 7,500 grams AA of gamma hydroxybutyric acid manufacturing quota for 2015, reference DEA online submission number 124113.

9250 Methadone

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 2,718,159 grams AA of methadone manufacturing quota for 2015, reference DEA online submission number 124112.

9170 Methadone Intermediate

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 1,800,634 grams AA of Methadone Intermediate manufacturing quota for 2015, reference DEA online submission number 124111.

9330 Oripavine

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 1,823,038 grams AA of oripavine manufacturing quota for 2015, reference DEA online submission number 124115.

All other quota requests remain unchanged from (b)(4) original request.

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

(b)(4)

(b)(6)

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

PUBLIC SUBMISSION

As of: 8/7/15 9:44 AM
Received: August 04, 2015
Status: Pending_Post
Tracking No. 1jz-8kd8-q82k
Comments Due: August 07, 2015
Submission Type: Web

Docket: DEA-2015-0011
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 2015

Comment On: DEA-2015-0011-0001
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 2015

Document: DEA-2015-0011-DRAFT-0003
Comment on FR Doc # N/A

Submitter Information

Name: (b)(4)
Address: United States,
Email: (b)(4);(b)(6)

General Comment

See attached file(s)

Attachments

Docket DEA-418P (b)(4) Comment

(b)(4)

Confidential Business Information

August 4, 2015

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

RE: **Docket No. DEA-418P Teva Pharmaceuticals Comment**

Dear DEA Federal Register Representative,

Confidential Business Information	(b)(4) hereby requests an increase to the 2015 adjusted aggregate production quota for codeine (for sale), CSA code 9050. (b)(4) believes the proposed new level of 63.9 metric tons may not be adequate for the medical, scientific, research and industrial needs of the United States. Since the rescheduling of hydrocodone combination products from schedule III to schedule II in October 2015, the codeine combination products market has observed a significant increase in sales, specifically in sales of APAP/codeine combination tablets, which remain schedule III.

Confidential Business Information	(b)(4) itself has observed a 70.7% increase in APAP/codeine combination tablets (in terms of codeine base content). Our market share, per IMS, has remained relatively steady, indicating all manufacturers are observing similar increases in sales. Reference Table 1 for year-by-year APAP/Codeine tablet sales (kg codeine base).

Confidential Business Information	(b)(4) is requesting DEA take into account our sales data (in kg codeine base), and the corresponding % increase relative to 2014 sales when calculating a 2015 Final Aggregate Production Quota. (b)(4) 2014 sales of 4.499 MT base codeine represented 9.8% of the 2014 Final Aggregate Production Quota. (b)(4) projected 2015 sales of 7.822 MT are 12.2% of the 2015 Proposed Adjusted Aggregate Production Quota and represent a **70.7% increase** over 2014 sales. To reiterate, DEA proposed adjusted aggregate of 63.9 metric tons represents an increase of just **38.5%** over the 2014 final adjusted aggregate production quota of 46.125 MT.

Administrative Offices:
(b)(4)

Confidential Business Information

Confidential Business Information	Table 1. (b)(4)	Codeine/APAP Combination Tablet Historical and Projected Sales in Terms of Codeine Base Content				
		kg codeine base	kg codeine base	kg codeine base	kg codeine base	kg codeine base
	Year	2011 (actual)	2012 (actual)	2013 (actual)	2014 (actual)	2015 (Projected)
	Sales	4556.151	4638.916	4633.833	4499.778	7822.236*
	Notes	2011-2014 (b)(4) yearly codeine/APAP combination products sales average, in terms of codeine base content = 4582.169 kg.				2015 projected sales represent an increase of 3240.067 kg base over 2011-2014 yearly sales average (or 70.7%)
	*Projected sales = 2015 sales (as of 30June2015) x 365 / day of year = 3878.972 kg x 365/181 = 7822.236.					

Confidential Business Information

In addition to the commercial quota needs outlined above, (b)(4) also plans to consume 644 kg of codeine base for site transfer purposes (development quota). If you have any questions, please feel free to contact me at (b)(6) (b)(6) or by email at (b)(4);(b)(6)

Sincerely,

(b)(4)

(b)(6)

Senior Manager DEA Compliance

Confidential Business Information

Docket No. DEA-418P

2014 and Projected 2015 Acetominophen/Codeine Tablet Sales

(b)(4)

Confidential Business Information

2014 Sales	Potency	units/bottle	Day of Year	Unit Sold	salt (kg)	base (kg)
ACETAMINOPHEN & CODEINE TB 300/15MG 100	15	100	365	2,231	40.158	29.717
ACETAMINOPHEN & CODEINE TB 300/30MG 100	30	100	365	18,133	580.779	429.776
ACETAMINOPHEN & CODEINE TB 300/30MG 1000	30	1000	365	8,642	3470.94	2568.496
ACETAMINOPHEN & CODEINE TB 300/60MG 100	60	100	365	18,283	1314.924	973.044
ACETAMINOPHEN & CODEINE TB 300/60MG 500	60	500	365	1,695	610.2	451.548
ACETAMINOPHEN & CODEINE TB 300/60MG 1000	60	1000	365	89	63.78	47.197
				Total	6080.781	4499.778

2015 Proj Sales (Jan-Jun Avg)	Potency	units/bottle	Day of Year	Mo Avg	salt	base
ACETAMINOPHEN & CODEINE TB 300/15MG 100	15	100	181	18,750	50.668	37.493
ACETAMINOPHEN & CODEINE TB 300/30MG 100	30	100	181	183,638	1110.859	822.110
ACETAMINOPHEN & CODEINE TB 300/30MG 1000	30	1000	181	81,092	4906.842	3630.323
ACETAMINOPHEN & CODEINE TB 300/60MG 100	60	100	181	228,516	2740.718	2028.132
ACETAMINOPHEN & CODEINE TB 300/60MG 500	60	500	181	19,352	1170.743	866.349
ACETAMINOPHEN & CODEINE TB 300/60MG 1000	60	1000	181	4,690	591.663	437.831
				Total	10570.592	7822.238

(b)(4)

(b)(4)

July 31, 2015

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

RE: Docket No. DEA-418P
Noramco Comment to Federal Register Volume 80, Number 130/Wednesday, July 8, 2015
Notices Pages 39156-39160 FR Doc No: 2015-16699

Dear DEA Federal Register Representative:

(b)(4) herewith comment to a portion of the above referenced Federal Register proposal. Specifically, (b)(4) believes that 2015 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
Methylphenidate	1724
Codeine	9050
Morphine for Conversion	9300
Oxymorphone for Conversion	9652
Oxymorphone	9652

Regards,

(b)(6)

Director, Controlled Substance Compliance

(b)(4)

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

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

July 15, 2015

Subject: Docket No. DEA-418P – Oxycodone (for sale)

Dear Federal Register Representative,

"PERSONAL IDENTIFYING INFORMATION" to be redacted is (b)(4) (b)(4) registration number (b)(4);(b)(7)(E) **"CONFIDENTIAL BUSINESS INFORMATION"** to be redacted includes increased sales volumes from 694 kg (624 kg as base) in 2014 to 2,469 kg (2,222 kg as base) in 2015 and a 33% manufacturing loss.

(b)(4) is a registered manufacturer (b)(4);(b)(7)(E) of Oxycodone (for sale). (b)(4) is providing comment to the Proposed Adjustments to the Aggregate Production Quota for 2015 for Oxycodone (for sale) based on the information provided below.

On June 12, 2015, (b)(4) requested an increase of 3,514 kg in its 2015 Oxycodone (for sale) manufacturing quota over its then granted quota of 2,510 kg. On June 29, 2015, (b)(4) was only granted an increase of 1,004 kg "due to the limitations of the currently established aggregate production quota, no additional oxycodone (for sale) can be authorized at this time."

(b)(4) was granted 502 kg for a new high ABUK process and 502 kg for our regular low impurity material. One batch of Oxycodone Base which consumes 502 kg of quota will yield ~375 kg (337.5 kg as base) of saleable Oxycodone HCl, Low Impurity material. (b)(4) has 545 kg (490.5 kg as base) of low impurity sales for fourth quarter 2015 and currently has no saleable low impurity inventory.

(b)(4) is requesting that the aggregate production quota for Oxycodone (for sale) be increased by 1,506 kg to allow (b)(4) to make three additional batches. These batches will be used to meet the balance of 2015 sales plus January through April 2016 sales of 1040 kg (936 kg as base).

A table detailing customers' registration numbers, their actual year to date purchases, their open 2015 purchase orders and their forecasts for the balance of 2015 was provided to DEA with our quota request Reference # 123773.

(b)(4)

In your calculations it is important to remember that there is an ~33% manufacturing loss between the point that DEA requires (b)(4) to count quota as consumed and the final saleable product. Therefore, the additional 1,506 kg of quota to be requested will only yield approximately 1,125 kg (1,012.5 kg as base) of saleable product.

(b)(4) respectfully requests that the 2015 aggregate production quota for Oxycodone (for sale) be increased by at least 1,506,000 grams to allow for its request.

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)(6)

(b)(4)

AUG 0 7 RECD

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

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

August 5, 2015

Subject: Docket No. DEA-418P – Oxycodone (for sale) AMENDED

Dear Federal Register Representative,

"PERSONAL IDENTIFYING INFORMATION" to be redacted is (b)(4) (b)(4) egistration number (b)(4);(b)(7)(E) **"CONFIDENTIAL BUSINESS INFORMATION"** to be redacted includes increased sales volumes from 694 kg (624 kg as base) in 2014 to 3,862 kg (3,476 kg as base) in 2015 and a 33% manufacturing loss.

(b)(4);(b)(7)(E) is a registered manufacturer (b)(4);(b)(7)(E) of Oxycodone (for sale). (b)(4) is providing comment to the Proposed Adjustments to the Aggregate Production Quota for 2015 for Oxycodone (for sale) based on the information provided below.

On June 12, 2015, (b)(4) requested an increase of 3,514 kg in its 2015 Oxycodone (for sale) manufacturing quota over its then granted quota of 2,510 kg. On June 29, 2015, (b)(4) was only granted an increase of 1,004 kg "due to the limitations of the currently established aggregate production quota, no additional oxycodone (for sale) can be authorized at this time."

(b)(4) was granted 502 kg for a new high ABUK process and 502 kg for our regular low impurity material. It is important to remember that there is an ~33% manufacturing loss between the point that DEA requires (b)(4) to count quota as consumed and the final saleable product. Therefore, one batch of Oxycodone Base consumes 502 kg of quota but yields only ~375 kg (337.5 kg as base) of saleable Oxycodone Hydrochloride, Low Impurity material.

On July 27, (b)(4) received a purchase order for 1500 kg for low impurity material for fourth quarter 2015. A copy will be provided to DEA with the quota application. Purchase orders for fourth quarter total 1,540 kg (1,386 kg as base) for low impurity material. (b)(4) currently has no saleable low impurity inventory.

(b)(4) is requesting that the aggregate production quota for Oxycodone (for sale) be increased by 2,510 kg to allow (b)(4) to make five additional batches. These batches plus

(b)(4)

the one batch granted at the end of June will yield ~2,250 kg of saleable product. See table below for inventory numbers.

Low Impurity		
Open 2015 PO's	1540	kg
2015 Forecast	205	kg
2016 Q1 Sales	500	kg
Total Sales	2245	kg
Make 6 batches	2250	kg
Balance	5	kg

High ABUK		
Make	375	kg
Sell	160	kg
Available	215	kg

A table detailing customers' registration numbers, their actual year to date purchases, their open 2015 purchase orders and their forecasts for the balance of 2015 was provided to DEA with quota request Reference # 123773. An updated version will be provided with the next quota request.

(b)(4) respectfully requests that the 2015 aggregate production quota for Oxycodone (for sale) be increased by at least 2,510,000 grams to allow for its request.

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)(6)

Request ID	Status	Date Submitted	Quota Type	DEA Number	Company	Drug Name	Drug Code	Quota Year	Requested Quota	Current Quota	Increase/Decrease
123712	Pending	02-JUN-15	MAN	(b)(4);(b)(7)(E)		4-ANILINO-N-PHENETHYL-4-PIPERIDINE (ANPP)	8333-0	2015	235,400.000	215,000.000	20,400.000
123843	New	25-JUN-15	MAN			CODEINE (FOR SALE)	9050-B	2015	20,000,000.000	13,363,697.000	6,636,303.000
124044	New	22-JUL-15	MAN			CODEINE (FOR SALE)	9050-B	2015	27,251,000.000	21,767,000.000	5,484,000.000
											12,120,303.000
124116	New	04-AUG-15	MAN			FENTANYL	9801-0	2015	910,000.000	871,515.000	38,485.000
[redacted]											
123955	New	09-JUL-15	MAN	(b)(4);(b)(7)(E)		FENTANYL	9801-0	2015	195,800.000	136,000.000	59,800.000
											98,285.000
124113	New	04-AUG-15	MAN			GAMMA HYDROXYBUTYRIC ACID	2010-0	2015	7,500.000	0.000	7,500.000
124014	Pending	16-JUL-15	MAN			HYDROCODONE (FOR SALE)	9193-B	2015	5,900.000	5,900.000	0.000
124163	New	08-AUG-15	MAN			HYDROCODONE (FOR SALE)	9193-B	2015	2,461,653.000	1,241,653.000	1,220,000.000
124112	New	04-AUG-15	MAN			METHADONE	9250-0	2015	14,100,000.000	11,381,841.000	2,718,159.000
124111	New	04-AUG-15	MAN			METHADONE-INTERMEDIATE	9254-0	2015	16,000,000.000	14,199,366.000	1,800,634.000
124036	Pending	22-JUL-15	MAN			METHYLPHENIDATE	1724-0	2015	28,187,000.000	27,949,764.000	237,236.000
											237,236.000
124042	New	22-JUL-15	MAN			MORPHINE (FOR CONVERSION)	9300-A	2015	23,501,000.000	19,001,013.000	4,499,987.000
124061	New	23-JUL-15	MAN			NOROXYMORPHONE (FOR CONVERSION)	9668-A	2015	1,329,265.000	729,265.000	600,000.000
[redacted]											
124126	New	05-AUG-15	MAN	(b)(4);(b)(7)(E)		ORIPAVINE	9330-0	2015	12,300,000.000	10,476,962.000	1,823,038.000
124161	New	07-AUG-15	MAN			OXYCODONE (FOR SALE)	9143-B	2015	6,024,000.000	3,514,000.000	2,510,000.000
											2,510,000.000
124049	Pending	22-JUL-15	MAN			OXYMORPHONE (FOR CONVERSION)	9652-A	2015	5,456,000.000	2,268,000.000	3,190,000.000

2015 pending MQ requests as of 8-10-15

IMS data 2012-2015 (jun) opiate salts

Molecule	2012 KG	2013 KG	2014 KG	6months 2015 KG	est year 2015 KG
CODEINE	22,756.7281	21,747.8088	21,719.2066	13,853.5453	27,707.0906
HYDROCODONE	63,179.5151	61,711.0281	56,376.7266	24,594.5385	49,189.077
HYDROMORPHONE	1,913.0402	1,927.6179	1,834.5971	852.8523	1705.7046
MORPHINE	28,706.4431	26,272.7352	24,604.3908	11,924.7271	23,849.4542
OXYCODONE	66,704.849	60,357.3128	58,914.83	29,802.5075	59,605.015
OXYMORPHONE	1,958.2805	1,863.4005	1,930.5344	980.6512	1961.3024

with c.f.

Molecule	2012 KG	2013 KG	2014 KG	2015 KG	2015 est. KG	% chg
CODEINE	16,839.9788	16,093.3785	16,072.2129	10,251.6235	20,503.247	27.6%
HYDROCODONE	38,539.5042	37,643.7271	34,389.8032	15,002.6685	30,005.337	-12.7%
HYDROMORPHONE	1,702.6058	1,715.5799	1,632.7914	759.0385	1,518.0771	-7.0%
MORPHINE	21,529.8323	19,704.5514	18,453.2931	8,943.5453	17,887.0907	-3.1%
OXYCODONE	60,034.364	54,321.582	53,023.347	26,822.257	53,644.514	1.2%
OXYMORPHONE	1,742.8696	1,658.4264	1,718.1756	872.7796	1,745.5591	1.6%

KG Audit from July 2009 to June 2015.
A. Includes all available columns.
Title NSP KG
Sub Title
Audit NSPKG
--- Report Filters ---
Molecule CODEINE, HYDROCODONE, HYDROMORPHONE, MORPHINE, OXYCODONE, OXYMORPHONE, 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 2012, 2013, 2014, 2015

2015 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 2015 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 1 Chemicals:

- No further adjustments

Controlled Substances:

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

- OD is recommending an increase in the APQ for **Methylphenidate** 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. This will avert a possible shortage due to APQ limitations.

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

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-418F]

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 2015

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the final adjusted 2015 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act 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: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 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. 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 purposes 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 providing 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 for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA. 28 CFR 0.100(b).

Background

The DEA established the initial 2015 aggregate production quotas for controlled substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on September 8, 2014. 79 FR 53216. That notice stated that the DEA could adjust, as needed, the established aggregate production quotas and assessment of annual needs in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The proposed adjusted 2015 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 8, 2015, 80 FR 39156, in consideration of the

outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted 2015 aggregate production quotas and assessment of annual needs on or before August 7, 2015.

Analysis for Final Adjusted 2015 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the July 8, 2015, notice of proposed adjusted aggregate production quotas and assessment of annual needs, 80 FR 39156, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Five companies submitted timely comments regarding twelve schedule I and II controlled substances. These comments suggested that the proposed adjusted aggregate production quotas for codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate, methylphenidate, morphine (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), and oxymorphone (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. The DEA did not receive any comments related to the proposal not to adjust the 2015 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

In accordance with 21 CFR 1303.13, the DEA has taken into consideration the above comments along with the relevant 2014 year-end inventories, initial 2015 manufacturing and import quotas, 2015 export requirements, actual and projected 2015 sales, research and product development requirements, and the additional quota applications received. Upon consideration of the above, the Administrator determined that the proposed

adjusted 2015 aggregate production quotas for dihydroetorphine, ethylmorphine, etorphine HCl, racemethorphan, racemorphan, methylphenidate, and oxycodone (for sale) required additional consideration and hereby further adjusts the proposed 2015 aggregate production quotas for these substances. Regarding codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate, morphine (for conversion), oripavine, oxymorphone (for conversion), and oxymorphone (for sale) the Administrator hereby determines that the proposed adjusted 2015 aggregate production quotas for these substances as published in the *Federal Register* on July 8, 2015, 80 FR 39156, are sufficient to meet the current 2015 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock.

As described in the previously published notice establishing the 2015 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 included in all 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 final 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 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 2015 aggregate production quotas for the following schedule I and II controlled substances and the 2015 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	Final Adjusted 2015 Quotas (g)
Schedule I	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	25
[1-(5-Fluoro-pentyl)-1H-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)	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-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	100

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-[(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-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	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
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-1H-indazole-3-carboxamide (AKB48)	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	25
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
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	30
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
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	21,875,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	275,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	63,900,000
Dextropropoxyphene	45
Dihydrocodeine	226,375
Dihydroetorphine	3
Diphenoxylate (for conversion)	75,000
Diphenoxylate (for sale)	1,337,500
Ecgonine	174,375
Ethylmorphine	5
Etorphine hydrochloride	3
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4

Levomethorphan	30
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	6,250,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	32
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	35,000,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	141,375,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	38
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	5
Racemorphan	3
Remifentanil	4,200
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000
Thebaine	125,000,000

List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

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:_____

AX:_____

OC:_____

OD:_____

CCR:_____CCO:_____CC:_____

ODX:_____

ODXL:_____

ODW:_____

$ODW_{analyst}$:_____

ODQ: _____

ODEQ_(b)(6)

DFN: 630-07-Federal Register

SBF-CM # ODEQ-15-841

Jean Sonneman,
Bureau of Land Management, Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2015-23257 Filed 9-15-15; 8:45 am]
BILLING CODE 4310-84-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-418F]

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 2015

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the final adjusted 2015 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective September 16, 2015.

FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 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, 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 purposes 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 providing 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 for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA. 28 CFR 0.100(b).

Background

The DEA established the initial 2015 aggregate production quotas for controlled substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on September 8, 2014, 79 FR 53216. That notice stated that the DEA could adjust, as needed, the established aggregate production quotas and assessment of annual needs in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The proposed adjusted 2015 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 8, 2015, 80 FR 39156, in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted 2015 aggregate production quotas and assessment of annual needs on or before August 7, 2015.

Analysis for Final Adjusted 2015 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the July 8, 2015, notice of proposed adjusted aggregate production quotas and assessment of annual needs, 80 FR 39156, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Five companies submitted timely comments regarding twelve schedule I and II controlled substances. These comments suggested that the proposed adjusted aggregate production quotas for codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate, methylphenidate, morphine (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), and oxymorphone (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. The DEA did not receive any comments related to the proposal not to adjust the 2015 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

In accordance with 21 CFR 1303.13, the DEA has taken into consideration the above comments along with the relevant 2014 year-end inventories, initial 2015 manufacturing and import quotas, 2015 export requirements, actual and projected 2015 sales, research and product development requirements, and the additional quota applications received. Upon consideration of the above, the Administrator determined that the proposed adjusted 2015 aggregate production quotas for dihydroetorphine, ethylmorphine, etorphine HCl, racemethorphan, racemorphan, methylphenidate, and oxycodone (for sale) required additional consideration and hereby further adjusts the proposed 2015 aggregate production quotas for these substances. Regarding codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate, morphine (for conversion), oripavine, oxymorphone (for conversion), and oxymorphone (for sale) the Administrator hereby determines that the proposed adjusted 2015 aggregate production quotas for these substances as published in the **Federal Register** on July 8, 2015, 80 FR 39156, are sufficient to meet the current 2015 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock.

As described in the previously published notice establishing the 2015 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 included in all 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 final 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 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 2015 aggregate production quotas for the following schedule I and II controlled substances and the 2015 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	Final adjusted 2015 quotas (g)
Schedule I	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144)	25
[1-(5-Fluoro-pentyl)-1H-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)	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-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	100
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-[(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-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
Acetyl-alpha-methylfentanyl	2

Basic class	Final adjusted 2015 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	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
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-1H-indazole-3-carboxamide (AKB48)	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB–PINACA)	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB–FUBINACA)	25
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
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	30
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

Basic class	Final adjusted 2015 quotas (g)
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	21,875,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	275,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	63,900,000
Dextropropoxyphene	45
Dihydrocodeine	226,375
Dihydroetorphine	3
Diphenoxylate (for conversion)	75,000
Diphenoxylate (for sale)	1,337,500
Ecgonine	174,375
Ethylmorphine	5
Etorphine hydrochloride	3
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	30
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	6,250,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	32
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	86,750,000
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	35,000,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	141,375,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	38
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	5
Racemorphan	3
Remifentanil	4,200
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000
Thebaine	125,000,000

Basic class	Final adjusted 2015 quotas (g)
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

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: September 10, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015-23199 Filed 9-15-15; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF LABOR

Office of the Secretary

Establishing a Minimum Wage for Contractors, Notice of Rate Change in Effect as of January 1, 2016

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Notice.

SUMMARY: The Wage and Hour Division (WHD) of the U.S. Department of Labor (the Department) is issuing this notice to announce the applicable minimum wage rate to be paid to workers performing work on or in connection with Federal contracts covered by Executive Order 13658, beginning January 1, 2016.

Executive Order 13658, Establishing a Minimum Wage for Contractors (the Executive Order or the Order), was signed by President Barack Obama on February 12, 2014, and raised the hourly minimum wage paid by contractors to workers performing work on covered Federal contracts to: $10.10 per hour, beginning January 1, 2015; and beginning January 1, 2016, and annually thereafter, an amount determined by the Secretary of Labor (the Secretary) in accordance with the methodology set forth in the Order. *See* 79 FR 9851. The Secretary's determination of the Executive Order minimum wage rate also affects the minimum hourly cash wage that must be paid to tipped employees performing work on or in connection with covered contracts beginning January 1, 2016. *See* 79 FR 9851–52. The Secretary is required to provide notice to the public of the new minimum wage rate at least 90 days before such rate is to take effect. *See* 79 FR 9851.

Pursuant to Executive Order 13658 and its implementing regulations at 29 CFR part 10, notice is hereby given that beginning January 1, 2016, the Executive Order minimum wage rate that generally must be paid to workers performing work on or in connection with covered contracts is $10.15 per hour. Notice is also hereby given that, beginning January 1, 2016, the required minimum cash wage that generally must be paid to tipped employees performing work on or in connection with covered contracts is $5.65 per hour.

DATES: This notice is effective on September 16, 2015.

FOR FURTHER INFORMATION CONTACT: Robert Waterman, Acting Director, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–0406 (this is not a toll-free number). Copies of this notice may be obtained in alternative formats (Large Print, Braille, Audio Tape, or Disc), upon request, by calling (202) 693–0023 (not a toll-free number). TTY/TTD callers may dial toll-free (877) 889–5627 to obtain information or request materials in alternative formats.

SUPPLEMENTARY INFORMATION:

I. Executive Order 13658 Background and Requirements for Determining Annual Increases to the Minimum Wage Rate

Executive Order 13658 was signed by President Barack Obama on February 12, 2014, and raised the hourly minimum wage paid by contractors to workers performing work on or in connection with covered Federal contracts to $10.10 per hour, beginning January 1, 2015; and beginning January 1, 2016, and annually thereafter, an amount determined by the Secretary pursuant to the Order. *See* 79 FR 9851. The Executive Order directed the Secretary to issue regulations to implement the Order's requirements. *See* 79 FR 9852. Accordingly, after engaging in notice-and-comment rulemaking, the Department published a Final Rule on October 7, 2014 to implement the Executive Order. *See* 79 FR 60634. The final regulations, set forth at 29 CFR part 10, established standards and procedures for implementing and enforcing the minimum wage protections of the Order.

The Executive Order and its implementing regulations require the Secretary to determine the applicable minimum wage rate to be paid to workers performing work on or in connection with covered contracts on an annual basis, beginning January 1, 2016. *See* 79 FR 9851; 29 CFR 10.1(a)(2), 10.5(a)(2), 10.12(a). Sections 2(a) and (b) of the Order establish the methodology that the Secretary must use to determine the annual inflation-based increases to the minimum wage rate. *See* 79 FR 9851. These provisions, which are implemented in 29 CFR 10.5(b), explain that the applicable minimum wage determined by the Secretary for each calendar year shall be:

(i) Not less than the amount in effect on the date of such determination;

(ii) Increased from such amount by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W) (United States city average, all items, not seasonally adjusted), or its successor publication, as determined by the Bureau of Labor Statistics (BLS); and

(iii) Rounded to the nearest multiple of $0.05.

Section 2(b) of the Executive Order further provides that, in calculating the annual percentage increase in the CPI for purposes of determining the new minimum wage rate, the Secretary shall compare such CPI for the most recent month, quarter, or year available (as selected by the Secretary prior to the first year for which a minimum wage is in effect) with the CPI for the same month in the preceding year, the same quarter in the preceding year, or the preceding year, respectively. *See* 79 FR 9851. In order to calculate the annual percentage increase in the CPI, the Department elected in its Final Rule