Basis Class: 9737-6

2013 Initial APQ Worksheets

Total PQ Requested: 432.000

FDA Est: 3.30%

INS Est: 00%

Company	DEA Num	2013 Requested MQ	2013 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 60% Invent	proposed MQ
(b)(4);(b)(7)(E)		5.000.000	0.000	0.000	9,979.000	0.000	0.000	0.000	0.000	4,500.000	0.000	0.000	4,500.000	4,500.000
		2.000	2.000	0.000	9,979.000	0.000	0.000	0.000	0.000	0.500	0.000	1.333	-1.000	1.500
		25,520.000	14,998.000	9,979.000	9,979.000	1.000	432.000	177.000	23,740.000	24,640.000	0.000	10,119.667	37,494.500	37,494.500
MQ Totals:		30,522.000	15,000.000											41,996.000

2012 Final Initial APQ: 11,000.000

2012 Final Revised APQ: 19,500.000

FDA Est (2012 Initial APQ * FDA %): 363.000

INS Est (2012 Initial APQ * INS %): 0.000

2013 Proposed Initial APQ: 30,800.000

Basic Class: 9055-0

2013 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est: 00%

IMS Est: 00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 80% Invent	proposed MQ
(b)(4),(b)(7)(E)		5.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1.000	0.000	0.000	1.000	5.000
MQ Totals:		5.000	0.000											5.000

2012 Final Initial APQ: 0.000
2012 Final Revised APQ: 0.000
FDA Est: (2012 Initial APQ * FDA %): 0.000
IMS Est: (2012 Initial APQ * IMS %): 0.000

2013 Proposed Initial APQ: 5.000

Basic Class: 9273-0

Total PQ Requested: 74.000

2013 Initial APQ Worksheets

FDA Est: 00%

INS Est: 00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 80% Invent	proposed MQ
(b)(4),(b)(7)(E)		5.000	5.000	0.000	8,576,267.480	0.000	0.000	0.000	0.000	4.000	0.000	3.333	0.250	5.000
		10.000	2.000	0.460	8,576,267.480	0.000	0.000	1.073	0.000	1.000	0.000	2.049	-1.573	10.000
MQ Totals:		15.000	7.000											15.000

2013 Final Initial APQ:	7.000
2013 Final Revised APQ:	7.000
FDA Est: (2013 Initial APQ * FDA %):	0.000
INS Est: (2013 Initial APQ * INS %):	0.000
2013 Proposed Initial APQ:	15.000

Basis Class: 9120-I

Total PQ Requested: 514.000

2013 Initial APQ Worksheets

FDA Est: 00%

IMS Est: 00%

Company	DEA Num	2013 Requested MQ	2013 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using Company Invent	proposed MQ
(b)(4),(b)(7)(E)		5.000	5.000	0.000	90,338.076	0.000	0.000	0.000	0.000	4.000	0.000	3.333	1.000	5.000
		5.000	5.000	0.736	90,338.076	0.000	0.004	11.375	0.000	4.000	0.000	10.917	11.379	5.000
		80,000.000	280,000.000	90,291.000	90,338.076	0.999	543.732	110,786.000	0.000	87,000.000	0.000	200,524.000	147,819.732	80,000.000
		500.000	300.000	46.290	90,338.076	0.001	0.263	191.550	0.000	500.000	0.000	327.700	200.263	326.000
MQ Totals:		80,510.000	280,310.000											80,336.000

2012 Final Initial APQ:	400,000.000
2012 Final Revised APQ:	400,000.000
FDA Est: (2012 Initial APQ * FDA %):	0.000
IMS Est: (2012 Initial APQ * IMS %):	0.000
2013 Proposed Initial APQ:	200,000.000

Basic Class: 9145-0

2013 Initial APQ Worksheets

Total PQ Requested: 11.000

FDA Est: 00%
IMS Est: 00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 84% Invent	proposed MQ
(b)(4),(b)(7)(E)		5.000	5.000	0.000	2,379,522.700	0.000	0.000	0.000	0.000	4.000	0.000	3.333	0.250	0.250
		5.000	5.000	0.000	2,379,522.700	0.000	0.000	2.335	0.000	1.000	0.000	4.890	-5.085	6.335
		281,100.000	285,000.000	305,611.700	2,379,522.700	0.128	1.413	12,970.200	0.000	281,100.000	0.000	198,646.800	54,381.506	54,381.506
		900,000.300	1,150,000.000	441,560.000	2,379,522.700	0.186	2.041	418,150.000	0.000	870,413.000	0.000	1,045,433.333	-410,534.449	696,000.041
		2,000,000.300	1,754,000.000	1,632,361.000	2,379,522.700	0.686	7.546	350,900.000	0.000	1,975,461.000	0.000	1,403,326.867	311,960.433	311,960.433
MQ Totals:		3,181,110.000	3,199,010.000											1,064,407.625

2012 Final Initial APQ:	3,008,000.000
2012 Final Revised APQ:	3,808,000.000
FDA Est (2012 Initial APQ * FDA %):	0.000
IMS Est: (2013 Initial APQ * IMS %):	0.000
2013 Proposed Initial APQ:	3,300,000.000

Basic Class: 9170-B

Total PQ Requested: 1.000

2013 Initial APQ Worksheets

FDA Est: -1.80%

IMS Est: 00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 40% Invent	proposed MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	507,950.000	0.000	0.000	0.000	0.000	0.500	0.000	1.333	-1.000	2.000
		9,300.000	23.000.000	0.000	507,950.000	0.000	0.000	0.000	0.000	4,650.000	0.000	15,333.333	-12,600.000	9,300.000
		570,000.000	856,000.000	507,950.000	507,950.000	1.000	1.000	308,577.000	0.000	508,000.000	0.000	776,384.667	-444,575.750	570,000.000
MQ Totals:		579,302.000	879,002.000											579,302.000

2012 Final Initial APQ:	900.000.000
2012 Final Revised APQ:	900,000.000
FDA Est: (2012 Initial APQ * FDA %):	583,800.000
IMS Est: (2012 Initial APQ * IMS %):	0.000
2013 Proposed Initial APQ:	600,000.000

Basic Class: 9801.0

Total PQ Requested: 1,141,893.242

2013 Initial APQ Worksheets

FDA Est: 0.60%

IMS Est: .00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 50% Invent	proposed MQ
(b)(4),(b)(7)(E)		5.000	5.000	0.000	1,112,159.039	0.000	0.000	0.001	0.000	4.000	0.000	3.334	0.249	5.000
		250,000.000	80,500.000	30,401.000	1,112,159.039	0.027	31,213.788	102,363.000	0.000	199,500.000	0.000	121,908.667	75,779.235	122,000.000
		100,000.000	55,000.000	59,830.286	1,112,159.039	0.054	61,429.883	6,598.946	100,000.000	100,000.000	0.000	42,399.297	226,938.407	100,000.000
		2.000	2.000	0.000	1,112,159.039	0.000	0.000	0.228	0.000	0.500	0.000	1.485	-1.226	2.000
		155,000.000	7,600.000	7,695.000	1,112,159.039	0.007	7,900.730	1,400.000	0.000	155,000.000	0.000	6,133.333	157,625.913	81,250.000
		1,400.000	0.000	279.753	1,112,159.039	0.000	287.232	0.000	0.000	1,400.000	0.000	0.000	1,759.040	1,400.000
		500,000.000	474,000.000	361,198.000	1,112,159.039	0.325	370,854.833	294,415.000	0.000	316,000.000	0.000	512,276.667	129,653.542	500,000.000
		930,000.000	779,000.000	652,755.000	1,112,159.039	0.587	670,206.775	357,329.000	95,600.000	890,360.000	0.000	757,552.667	882,139.469	882,139.469
MQ Totals:		1,936,407.000	1,396,307.000											1,686,796.469

2012 Final Initial APQ:	1,428,000.000
2012 Final Revised APQ:	1,428,000.000
FDA Est: (2012 Initial APQ * FDA %):	1,522,248.000
IMS Est: (2012 Initial APQ * IMS %):	0.000
2013 Proposed Initial APQ:	1,687,000.000

Basic Class: 9200-0

Total PQ Requested: 21.000

2013 Initial APQ Worksheets

FDA Est: 00%

IMS Est: 00%

Company	DEA Num	2013 Requested MQ	2013 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 80% Invent	proposed MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	3.570	0.000	0.000	0.000	0.000	4.000	0.000	3.333	0.250	5.000
		5.000	5.000	3.570	3.570	1.000	21.000	5.111	0.000	5.000	0.000	6.741	22.389	5.000
		15.000	0.000	0.000	3.570	0.000	0.000	7.976	0.000	0.000	0.000	5.251	-7.976	15.000
MQ Totals:		25.000	10.000											25.000

2012 Final Initial APQ:	20.000
2012 Final Revised APQ:	20.000
FDA Est: (2012 Initial APQ * FDA %):	0.000
IMS Est: (2012 Initial APQ * IMS %):	0.000
2013 Proposed Initial APQ:	25.000

Basic Class: 9300-B

Total PQ Requested: 47,199,595.000

2013 Initial APQ Worksheets

FDA Est: 4.50%

IMS Est: 00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 50% Invent	preposed MQ
(b)(4),(b)(7)(E)		5.000	5.000	0.000	34,493,652.732	0.000	0.000	0.014	0.000	4.000	6.000	3.343	0.236	5.000
		100.000	100.000	2.232	34,493,652.732	0.000	0.054	120.036	0.000	50.000	0.000	146.692	-141.220	100.000
		112,500.000	0.000	44,830.000	34,493,652.732	0.001	61,343.396	85,128.000	0.000	112,500.000	0.000	57,418.667	103,051.246	103,000.000
		6,800,000.000	3,500,000.000	1,567,867.000	34,493,652.732	0.045	2,145,400.168	998,185.000	0.000	6,000,000.000	0.000	2,777,456.667	5,390,595.210	3,217,500.000
		23,000,000.000	17,000,000.000	20,021,175.000	34,493,652.732	0.580	27,306,094.314	2,767,940.000	225,000.000	2,468,106.000	0.000	13,176,826.667	21,420,263.863	17,200,000.000
		5,000.000	1,007,000.000	277.500	34,493,652.732	0.000	379.719	0.000	0.000	5,000.000	0.000	671,333.333	-749,775.352	5,000.000
		21,313,000.000	12,264,900.000	11,906,432.000	34,493,652.732	0.345	16,292,237.295	6,725,343.000	0.000	17,250,000.000	0.000	12,660,162.000	21,601,278.619	17,000,000.000
		2,700,000.000	1,250,000.000	953,059.000	34,493,652.732	0.028	1,304,137.856	0.000	0.000	2,700,000.000	0.000	833,333.333	3,392,672.009	1,457,000.000
MQ Totals:		53,930,605.000	35,022,005.000											35,982,805.000

2013 Final Initial APQ:	39,000,000.000
2012 Final Revised APQ:	39,000,000.000
FDA Est (2012 Initial APQ * FDA %):	40,755,000.000
IMS Est: (2012 Initial APQ * IMS %):	0.000
2013 Proposed Initial APQ:	41,000,000.000

Basic Class: 9640-0

Total PQ Requested: 2,105,000

2013 Initial APQ Worksheets

FDA Est: 00%

INS Est: 00%

Company	DEA Num	2013 Requested MQ	2013 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2013 Projected Exports	2013 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 80% Invent	proposed MQ
(b)(4),(b)(7)(E)		400,000.000	306,905.000	169,200.000	169,501.260	0.996	2,101.259	69,483.000	653,760.000	653,760.000	0.000	310,366.333	942,917.323	400,000.000
		10.000	5.000	0.000	169,501.260	0.000	0.000	135.434	0.000	1.000	0.000	93.623	-136.184	10.000
		3,500.000	3,000.000	301.000	169,501.260	0.002	3.738	491.000	0.000	3,035.000	0.000	2,327.333	256.673	3,500.000
		3,000.000	1,000.000	0.260	169,501.260	0.000	0.003	0.000	0.000	3,000.000	0.000	666.667	2,250.004	3,000.000
MQ Totals:		406,510.000	401,000.000											406,510.000

2012 Final Initial APQ:	401,000.000
2012 Final Revised APQ:	1,951,000.000
FDA Est (2012 Initial APQ * FDA %):	0.000
INS Est (2012 Initial APQ * INS %):	0.000
2013 Proposed Initial APQ:	407,000.000

Basic Class: 9638-0

Total PQ Requested: 1,243,417,000

2013 Initial APQ Worksheets

FDA Est: 00%

IMS Est: 00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 50% Invent	proposed MQ
(b)(4),(b)(7)(E)		30,000,000	0 000	0 000	509,400 000	0 000	0 000	0 000	0 000	27,000 000	0 000	0 000	27 000 000	27,000 000
		1,000,000 000	681,000 000	509,400 000	509,400 000	1 000	1,243,417 000	457,739 000	0 000	636,000 000	0 000	759,159 333	1,421,782 250	760,000 000
MQ Totals:		1,030,000 000	681,000 000											787 000 000

2012 Final Initial APQ:	1,000 000 000
2012 Final Revised APQ:	1,000 000 000
FDA Est: (2012 Initial APQ * FDA %):	0 000
IMS Est: (2012 Initial APQ * IMS %):	0 000

2013 Proposed Initial APQ: 1,000,000 000

Basic Class: 9330-0

Total PQ Requested: 2,369,005.000

2013 Initial APQ Worksheets

FDA Est: .00%

IMS Est: 00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 50% Invent	proposed MQ
(b)(4),(b)(7)(E)		5.000	5.000	0.000	10,092,742.410	0.000	0.000	0.000	0.000	4.000	0.000	3.333	0.250	5.000
		1,000,000.000	750,000.000	0.000	10,092,742.410	0.000	0.000	0.000	0.000	800,000.000	0.000	500,000.000	337,500.000	1,000,000.000
		2,674,000.000	1,630,000.000	1,977,657.000	10,092,742.410	0.196	464,202.803	326,052.000	0.000	2,674,000.000	0.000	1,304,034.667	1,705,701.504	1,305,000.000
		6,500,000.000	5,236,000.000	6,765,759.000	10,092,742.410	0.670	1,588,083.422	980,957.000	0.000	8,444,444.000	0.000	4,144,638.000	5,521,591.277	5,800,000.000
		5,800,000.000	2,312,000.000	1,143,250.410	10,092,742.410	0.113	268,347.871	484,215.650	0.000	5,800,000.000	0.000	1,864,143.767	3,917,210.189	5,800,000.000
		668,000.000	615,000.000	206,078.000	10,092,742.410	0.020	48,370.904	1,955.000	0.000	668,000.000	0.000	411,303.333	265,258.630	668,000.000
		700,000.000	0.000	0.000	10,092,742.410	0.000	0.000	0.000	0.000	700,000.000	0.000	0.000	700,000.000	700,000.000
MQ Totals:		19,442,005.000	10,543,005.000											18,133,005.000

2012 Final Initial APQ:	9,800,000.000
2012 Final Revised APQ:	15,300,000.000
FDA Est: [2012 Initial APQ * FDA %]:	0.000
IMS Est: [2013 Initial APQ * IMS %]:	0.000
2013 Proposed Initial APQ:	18,200,000.000

BASIC CLASS:	2013 Initial Quota Worksheets			Oripavine			9330											
Company:	(b)(4)																	
Request:	2674.0			1000.0			668.0			8600.0			5800.0			700.0		
Current Year MQ:	1630.0			750.0	(buprenorphine pd)		615.0			5236.0			2312.0			0.0		
Year end inventory	326.1			0.0			113.9	(b)(4)		981.0			484.2			2976.5	(PQ inventory)	
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	346.667	156.000	0.450				182.857	160.000	0.875	0.000	0.000	0.540	5818.182	3200.000	0.550	0.000	0.000	0.540
oripavine	700.000	(b)(4)																
oripavine/buprenorphine derivative				1000.000	700.000	0.700												
oxymorphone (sale)	317.778	143.000	0.450				1224.096	508.000	0.415				0.000	0.000	0.880	0.000	0.000	0.880
oxymorphone (conv)										8444.444	7600.000	0.900	0.000	0.000	0.880	3031.250	2425.000	0.800
total needed	1364.444			1000.000			1406.954			8444.444			5818.182			3031.250		
INITIAL MQs																		
est need	1787.004			1437.500			1798.566			10883.599			7366.511			812.563		
MQ:																		
Total Initial MQs:	1365.000			1000.000			668.000			8600.000			5800.000			700.000		

Total MQs:	18133.000	+ others	0.005	=	18133.005

FURTHER CALCULATIONS

Proposed Initial APQ 18200

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 111955 | Date Submitted: 13-APR-12

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

Schedule/List Number: 0
Drug Code: 9652-B
Quota Year: 2013

Name and Address of Registrant
(b)(4)

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

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

Fax. No
Phone No.: (b)(4),(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 2011	2012	2013	Quota Requested
	75,000.0	50,000.0	0.0	143,000.0
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	10,000.0	10,000.0
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
	0.0	0.0	10,000.0	10,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	133,000.0	133,000.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	133,000.0	133,000.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	143,000.0	143,000.0
	0.0	0.0	143,000.0	143,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2010	2011	2013	% 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

Please see supporting documentation sent in separate email.

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID.112154		Date Submitted	24-APR-12
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	2013
		DEA Registration Number	(b)(4),(b)(7)(E)
Contact Person (b)(6)		Fax. No	(b)(4),(b)(6)
Email Address ----------		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 2011	2012	2013	Quota Requested
	6,100,000.0	7,766,000.0	0.0	7,600,000.0
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...	819,584.0	0.0	1,379,490.0	1,379,490.0
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
	819,584.0	0.0	1,379,490.0	1,379,490.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	7,805,096.0	7,805,096.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	7,805,096.0	7,805,096.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	7,600,000.0	7,600,000.0
	0.0	0.0	7,600,000.0	7,600,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2010	2011	2013	% Yield
NOROXYMORPHONE (FOR SALE)	9668-B	0	0	7,825	63.00
NOROXYMORPHONE (FOR CONVERSION)	9668-A	1,731,048	4,319,604	7,797,271	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. 112151		Date Submitted	24-APR-12
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	2013
		DEA Registration Number	(b)(4),(b)(7)(E)
Contact Person (b)(6)		Fax. No	(b)(4),(b)(6)
Email Address ----------		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			
	2011	2012	2013	Quota Requested
	3,500.0	3,000.0	0.0	3,500.0
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...	491.0	0.0	1,313.0	1,313.0
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
	491.0	0.0	1,313.0	1,313.0
Disposition(Sale)/Utilization				
a.Domestic.....	304.0	0.0	3,025.0	3,025.0
b Exports.....	1.0	0.0	0.0	0.0
	305.0	0.0	3,025.0	3,025.0
Acquisition/Production				
a.Domestic Sources.....	67.0	0.0	3,500.0	3,500.0
	67.0	0.0	3,500.0	3,500.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2010	2011	2013	

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. 112152 | Date Submitted: 24-APR-12

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: 2013

Name and Address of Registrant
(b)(4)

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

Contact Person (b)(6)
Email Address ----------

Fax. No
Phone No.

(b)(4),(b)(6)

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

Quota History	Quotas Previously Issued by DEA 2011	2012	2013	Quota Requested
	4,900,000.0	3,606,000.0	0.0	5,600,000.0
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...	106,262.0	0.0	518,016.0	518,016.0
b.In-Process Material.....	1,456,006.0	0.0	300,000.0	300,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	1,562,268.0	0.0	818,016.0	818,016.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	44,694,166.0	44,694,166.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	44,694,166.0	44,694,166.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	5,600,000.0	5,600,000.0
	0.0	0.0	5,600,000.0	5,600,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2010	2011	2013	% Yield
Nalbuphine (Excepted)	0000-0	0	0	637,000	70.00
Naltrexone (Excepted)	0000-0	0	0	2,690,298	85.00
Naloxone (Excepted)	0000-0	0	0	1,366,868	78.00

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-A

2013 Initial APQ Worksheets

Total PQ Requested: 3,628,230.000

FDA Est: 0C%

IMS Est: .0C%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 50% Invent	proposed MQ
(b)(4) (b)(7)(E)		9,800,000.000	5,005,000.000	4,452,292.000	4,452,296.800	1.000	3,628,225.088	1,671,751.000	0.000	8,163,265.000	0.000	4,584,500.667	7,073,046.611	7,073,046.611
MQ Totals:		9,800,000.000	5,005,000.000											7,073,046.611

2012 Final Initial APQ:	5,600,000.000
2012 Final Revised APQ:	5,600,000.000
FDA Est: (2012 Initial APQ * FDA %):	0.000
IMS Est: (2012 Initial APQ * IMS %):	0.000
2013 Proposed Initial APQ:	8,200,000.000

BASIC CLASS:	2013 Initial Quota Worksheets			Oxycodone (conversion)	9330
Company:	(b)(4)				
Request:	9800.0				
Current Year MQ:	5005.0				
Year end inventory	1871.8				
Calculations	amt needed	substance MQ	yield		
oxymorphone (sale)	8163.265	4000.000	0.490		
total needed	8163.265				
INITIAL MQs					
est need	9583.581				
MQ:					
Total Initial MQs:	8200.000				
Total MQs:	8200.000	+ others		=	8200.000

FURTHER CALCULATIONS

Proposed Initial APQ 8200

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 112157	Date Submitted 24-APR-12
Name of Basic Class or List 1 Chemical (only 1 per DEA-189) OXYCODONE (FOR CONVERSION)	Schedule/List Number 0
	Drug Code 9143-A
Name and Address of Registrant (b)(4)	Quota Year 2013
	DEA Registration Number (b)(4),(b)(7)(E)
Contact Person (b)(6)	Fax. No (b)(4),(b)(6)
Email Address	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 2011	2012	2013	Quota Requested
	5,000,000.0	4,230,000.0	0.0	9,800,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	514,386.0	0.0	695,221.0	695,221.0
b.In-Process Material.....	1,357,365.0	0.0	1,950,000.0	1,950,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	1,871,751.0	0.0	2,645,221.0	2,645,221.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	8,163,265.0	8,163,265.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	8,163,265.0	8,163,265.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	9,800,000.0	9,800,000.0
	0.0	0.0	9,800,000.0	9,800,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2010	2011	2013	% Yield
OXYMORPHONE (FOR SALE)	9652-B	3,815,184	4,167,525	8,163,265	49.00

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. 112158		Date Submitted	24-APR-12
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
OXYMORPHONE (FOR SALE)		Schedule/List Number	0
Name and Address of Registrant		Drug Code	9652-B
(b)(4)		Quota Year	2013
		DEA Registration Number	(b)(4),(b)(7)(E)
Contact Person (b)(6)		Fax. No	(b)(4),(b)(6)
Email Address ----------		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 2011	2012	2013	Quota Requested
	2,200,000.0	1,897,000.0	0.0	4,000,000.0
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...	377,233.0	0.0	878,981.0	878,981.0
b.In-Process Material.....	0.0	0.0	250,000.0	250,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	377,233.0	0.0	1,128,981.0	1,128,981.0
Disposition(Sale)/Utilization				
a.Domestic.....	2,368,152.0	0.0	3,517,725.0	3,517,725.0
b Exports.....	1.0	0.0	0.0	0.0
	2,368,153.0	0.0	3,517,725.0	3,517,725.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	4,000,000.0	4,000,000.0
	0.0	0.0	4,000,000.0	4,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2010	2011	2013	% 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

Basic Class: 9739-0

Total PQ Requested: 2,664.170

2013 Initial APQ Worksheets

FDA Est: 20.30%

IMS Est: .00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 80% Invent	proposed MQ
(b)(4);(b)(7)(E)		910.000	1,820.000	448.000	448.000	1.000	2.664.170	1,168.000	0.000	1,092.000	0.000	1,990.667	1,891.213	910.000
		5.000	0.000	0.000	448.000	0.000	0.000	0.251	0.000	5.000	0.000	0.167	4.749	5.000
MQ Totals:		915.000	1,820.000											915.000

2012 Final Initial APQ: 2,500.000

2012 Final Revised APQ: 2,500.000

FDA Est (2012 Initial APQ * FDA %): 3,007.500

IMS Est (2012 Initial APQ * IMS %): 0.000

2013 Proposed Initial APQ: 2,000.000 note: 2011 imported 0.5kg

Basic Class: 9780-0

Total PQ Requested: 60,603,100.000

2013 Initial APQ Worksheets

FDA Est: 00%

IMS Est: 00%

Company	DEA Num	2013 Requested MQ	2012 Revised MQ	2011 Sales	2011 DEA MQ Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2012 Projected Exports	2012 Projected Sales	2013 Projected Exports	Two Thirds Calc	Calc Using CFR 50% Invent	proposed MQ
(b)(4),(b)(7)(E)		10.000	10.000	0.126	6,325,122.896	0.000	1.207	4.579	0.000	2.000	0.000	9.719	-8.570	10.000
		390,000.000	304.000.000	0.000	6,325,122.896	0.000	0.000	0.000	0.000	390,000.000	0.000	202,666.667	182,000.000	390,000.000
		500,000.000	0.000	0.000	6,325,122.896	0.000	0.000	0.000	0.000	450,000.000	0.000	0.000	450,000.000	250,000.000
		5,000.000	72,000.000	6,195,967.770	6,325,122.896	0.980	59,365,621.907	3,578,914.600	0.000	31,100,000.000	0.000	2,433,943.667	101,674,112.784	5,000.000
		10,000,000.000	3,000,000.000	0.000	6,325,122.896	0.000	0.000	0.000	0.000	9,000,000.000	0.000	2,000,000.000	6,750,000.000	10,000,000.000
MQ Totals:		10,895,010.000	3,376,010.000											10,645,010.000

2012 Final Initial APQ:	5,400,000.000
2012 Final Revised APQ:	5,400,000.000
FDA Est: (2012 Initial APQ * FDA %):	0.000
IMS Est: (2012 Initial APQ * IMS %):	0.000

2013 Proposed Initial APQ: 10,600,000.000 based on continued pd and launch

Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Final Revised	Initial	Proposed Revised	Proposed Initial
Schedule I:	**2010**	**2011**	**2012**	**2012**	**2013**
3,4-Methylenedioxyamphetamine (MDA)	20	22	22	22	30
3,4-Methylenedioxy-N-methylcathinone (methylone)			8	12	15
3,4-Methylenedioxymethamphetamine (MDMA)	20	22	22	22	35
3,4-Methylenedioxypyrovalerone (MDPV)			8	12	15
5-Methoxy-N,N-dimethyltryptamine					10
Bufotenine	3	3	3	2	3
Desomorphine					5
Dihydromorphine	3,608,000	3,608,000	3,608,000	3,608,000	3,300,000
Gamma-hydroxybutyric acid	52,156,000	5,772,000	47,000,000	47,000,000	37,000,000
Heroin	20	20	20	20	25
Lysergic Acid Diethylamide	15	16	16	16	30
Methcathinone	4	4	4	12	14

Controlled Substance	Final Revised	Final Revised	Initial	Proposed Revised	Proposed Initial
Schedule II:	**2010**	**2011**	**2012**	**2012**	**2013**
1-Piperdinocyclohexanecarbonitrile	0	2	2	27	17
Alfentanil	8,000	12,800	15,000	19,550	30,600
Amobarbital	3	40,007	40,007	40,007	7
Amphetamine (for conversion)	7,500,000	8,500,000	8,500,000	8,500,000	14,700,000
Amphetamine (for sale)	18,600,000	25,300,000	25,300,000	29,400,000	30,400,000
Cocaine	247,000	216,000	216,000	216,000	192,000
Dextropropoxyphene	92,000,000	7	7	7	15
Dihydrocodeine	800,000	255,000	400,000	400,000	200,000
Diphenoxylate	827,000	730,000	900,000	900,000	600,000
Ecgonine	83,000	83,000	83,000	83,000	102,000
Fentanyl	1,428,000	1,428,000	1,428,000	1,428,000	1,687,000
Lisdexamfetamine	9,000,000	10,400,000	12,000,000	12,000,000	15,400,000
Methamphetamine	3,130,000	3,130,000	3,130,000	3,130,000	3,130,000
levo-desoxyephedrine	750,000	750,000	750,000	750,000	770,000
methamphetamine (for conversion)	2,331,000	2,331,000	2,331,000	2,331,000	2,311,000
methamphetamine (for sale)	49,000	49,000	49,000	49,000	49,000
Methylphenidate	50,000,000	56,000,000	56,000,000	56,000,000	57,800,000
Morphine (for sale)	39,000,000	39,000,000	39,000,000	39,000,000	41,000,000
Noroxymorphone (for sale)	41,000	401,000	401,000	1,981,000	407,000
Opium (tincture)	1,500,000	1,000,000	1,000,000	1,000,000	1,030,000
Oripavine	15,000,000	8,000,000	9,800,000	15,300,000	18,200,000
Oxycodone (for conversion)	5,600,000	5,600,000	5,600,000	5,600,000	8,200,000
Remifentanil	2,500	2,500	2,500	2,500	2,000
Secobarbital	67,000	336,002	336,002	336,002	172,002
Tapentadol	1,000,000	403,000	5,400,000	5,400,000	10,800,000

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-365]

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 2013

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes initial year 2013 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*. 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-365" on all electronic and written correspondence. DEA encourages that all comments be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to www.regulations.gov will be posted for public review and are part of the official docket record. Written comments submitted via regular or express mail should be sent to the Drug Enforcement Administration,

Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at http://www.regulations.gov and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online or made available in the public docket 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 posted online or made available in the public docket, 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.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the "For Further Information Contact" paragraph.

Background

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 by 28 CFR 0.100.

The proposed year 2013 aggregate production quotas 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 2013 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.

In determining the proposed 2013 aggregate production quotas and assessment of annual needs, DEA has taken into account the criteria that 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). DEA proposes the aggregate production quotas and assessment of annual

needs for 2013 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 pursuant to 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 Administrator finds relevant. Other factors 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 2013 assessment of annual needs, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407, respectively).

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, DEA proposes to include 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 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. DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public affects if an unforeseen

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

The Administrator, therefore, proposes that the year 2013 aggregate production quotas and assessment of annual needs for the following schedule I and II controlled substances and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Proposed 2013 Quotas
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	15 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	15 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	15 g
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	15 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	15 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	15 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	15 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
2,5-Dimethoxyamphetamine	12 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	15 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	15 g
3-Methylfentanyl	2 g

3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	30 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	15 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxymethamphetamine (MDMA)	35 g
3,4-Methylenedioxypyrovalerone (MDPV)	15 g
3,4,5-Trimethoxyamphetamine	12 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g
4-Methoxyamphetamine	88 g
4-Methylaminorex	12 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g
4-Methyl-N-methylcathinone (mephedrone)	15 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
5-Methoxy-N,N-dimethyltryptamine	10 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	12 g
Codeine-N-oxide	602 g
Desomorphine	5 g

Diethyltryptamine	12 g
Difenoxin	50 g
Dihydromorphine	3,300,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	46,250,000 g
Heroin	25 g
Hydromorphinol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	13 g
Methaqualone	10 g
Methcathinone	14 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N-Benzylpiperazine	12 g
N,N-Dimethylamphetamine	12 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	2 g
Psilocyn	4 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Proposed 2013 Quotas
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile	21 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g
Alfentanil	38,250 g
Alphaprodine	3 g

Amobarbital	9 g
Amphetamine (for conversion)	18,375,000 g
Amphetamine (for sale)	38,000,000 g
Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	81,250,000 g
Codeine (for sale)	49,506,250 g
Dextropropoxyphene	19 g
Dihydrocodeine	250,000 g
Diphenoxylate	750,000 g
Ecgonine	127,500 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	78,750,000 g
Hydromorphone	4,535,000 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	6 g
Levorphanol	4,500 g
Lisdexamfetamine	19,250,000 g
Meperidine	6,875,000 g
Meperidine Intermediate-A	6 g
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	6 g
Methadone (for sale)	25,000,000 g
Methadone Intermediate	32,500,000 g
Methamphetamine	3,912,500 g
[962,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,888,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)]	
Methylphenidate	72,250,000 g
Morphine (for conversion)	103,750,000 g
Morphine (for sale)	51,250,000 g
Nabilone	25,628 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	508,750 g
Opium (powder)	91,250 g
Opium (tincture)	1,287,500 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	10,250,000 g

Oxycodone (for sale)	123,375,000 g
Oxymorphone (for conversion)	16,000,000 g
Oxymorphone (for sale)	6,875,000 g
Pentobarbital	42,500,000 g
Phenazocine	6 g
Phencyclidine	30 g
Phenmetrazine	3 g
Phenylacetone	20,000,000 g
Racemethorphan	3 g
Remifentanil	2,500 g
Secobarbital	215,003 g
Sufentanil	6,250 g
Tapentadol	13,500,000 g
Thebaine	145,000,000 g

Basic Class – List I Chemicals	Proposed 2013 Quotas
Ephedrine (for conversion)	12,000,000 g
Ephedrine (for sale)	3,200,000 g
Phenylpropanolamine (for conversion)	25,700,000 g
Phenylpropanolamine (for sale)	4,400,000 g
Pseudoephedrine (for sale)	185,000,000 g

The 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 be established at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2013 aggregate production quotas and assessment of annual needs as needed.

Comments

Pursuant to 21 CFR 1303.11 and 21 CFR 1315.11, any interested person may submit written comments on or objections to these proposed determinations. 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 2013 aggregate production quota for each basic class of controlled substance and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Dated:

Michele M. Leonhart
Administrator

within the vicinity of Los Banos, California. The general project location is south of State Route 152 between U.S. 101 and Interstate 5, approximately two hours southeast from San Francisco.

The RMP/GP area is owned by Reclamation and was built as part of the water storage and delivery system of reservoirs, aqueducts, power plants, and pumping stations operated under the California State Water Project and Central Valley Project. Construction began on San Luis Reservoir in 1963 and was completed in 1967 with planned joint-use by the State Water Project and the Central Valley Project. The California Department of Parks and Recreation was given the responsibility to plan, design, construct, maintain, and operate the recreation areas surrounding the reservoirs.

The new plan will: (1) Enhance natural resources and recreational opportunities without interrupting reservoir operations; (2) provide recreational opportunities to meet the demands of a growing population with diverse interests; (3) ensure diversity of recreational opportunities and quality of the recreational experience; (4) protect natural, cultural, and recreational sources while providing resource education opportunities and stewardship; and (5) provide updated management direction for establishing a new management agreement with the State of California.

The Draft EIS/Revised Draft EIR outlines the formulation and evaluation of alternatives designed to address these issues through a representation of the varied interests at the Plan Area. The No Action/No Project Alternative (Alternative 1) would result in the continuation of current management practices. Action Alternative 2 (Limited New Access and Development) emphasizes resource protection and limited new development. Action Alternative 3 (Moderate New Access and Development) balances natural and cultural resource protection and recreation opportunities. Action Alternative 4 (Maximum New Access and Development) provides the most overall recreation facility development.

The Draft RMP/GP EIS/EIR has been developed within the authorities provided by Congress through the Reclamation Recreation Management Act of 1992 (Pub. L. 102–575, Title 28, 16 U.S.C. 460L) and other applicable agency and Department of the Interior policies.

Copies of the Draft RMP/GP EIS/EIR are available for public review at the following locations:

- Bureau of Reclamation, Mid-Pacific Region, Regional Library, 2800 Cottage Way, Sacramento, CA 95825.
- Bureau of Reclamation, South-Central California Area Office, 1243 N Street, Fresno, CA 93721.
- Four Rivers Sector Office, 31426 Gonzaga Road, Gustine, CA 95322
- Los Banos Library, 1312 South 7th Street, Los Banos, CA 93635.
- California Department of Parks and Recreation, Northern Service Center, One Capitol Mall, Suite 500, Sacramento, CA 95814.
- Bureau of Reclamation, Denver Office Library, Building 67, Room 167, Denver Federal Center, 6th and Kipling, Denver, CO 80225.
- Natural Resources Library, U.S. Department of the Interior, 1849 C Street NW., Main Interior Building, Washington, DC 20240–0001.

Public Meeting

A brief presentation, including a project overview, will open the public meeting. This will be followed by an open house during which individual concerns and questions will be addressed through interaction with the project team.

If special assistance is required at the public meeting, please contact Mr. Dave Woolley at 559–487–5049, (TTY 1–800–735–2929), or by emailing *dwoolley@usbr.gov*. Please notify Mr. Woolley as far in advance as possible to enable Reclamation staff enough time to secure the needed services. If a request cannot be honored, the requestor will be notified.

Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: May 17, 2012.

Pablo R. Arroyave,

Deputy Regional Director, Mid-Pacific Region.

[FR Doc. 2012–19021 Filed 8–2–12; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–365]

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 2013

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes initial year 2013 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before September 4, 2012. 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–365" on all electronic and written correspondence. DEA encourages that all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *http://www.regulations.gov* will be posted for public review and are part of the official docket record. Written comments submitted via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Chief, Liaison and Policy Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307–4654.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online or made available in the public docket 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 posted online or made available in the public docket, 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.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

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 by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The proposed year 2013 aggregate production quotas 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 2013 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.

In determining the proposed 2013 aggregate production quotas and assessment of annual needs, DEA has taken into account the criteria that 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). DEA proposes the aggregate production quotas and assessment of annual needs for 2013 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 pursuant to 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 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 2013 assessment of annual needs, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407, respectively).

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

The Deputy Administrator, therefore, proposes that the year 2013 aggregate production quotas and assessment of annual needs for the following schedule I and II controlled substances and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, be established as follows:

	Proposed 2013 quotas g
Basic Class—Schedule I	
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	5
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-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	15
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	15
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	15
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	15
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	15
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12
2,5-Dimethoxy-4-n-propylthiophenethylamine	12
2,5-Dimethoxyamphetamine	12
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	15
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	15
3-Methylfentanyl	2
3-Methylthiofentanyl	2
3,4-Methylenedioxyamphetamine (MDA)	30
3,4-Methylenedioxy-N-methylcathinone (methylone)	15
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24
3,4-Methylenedioxymethamphetamine (MDMA)	35
3,4-Methylenedioxypyrovalerone (MDPV)	15
3,4,5-Trimethoxyamphetamine	12
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12
4-Methoxyamphetamine	88
4-Methylaminorex	12
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12
4-Methyl-N-methylcathinone (mephedrone)	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	12
5-Methoxy-N,N-diisopropyltryptamine	12
5-Methoxy-N,N-dimethyltryptamine	10
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
Alpha-ethyltryptamine	12
Alphameprodine	2
Alphamethadol	2
Alpha-methylfentanyl	2
Alpha-methylthiofentanyl	2
Alpha-methyltryptamine (AMT)	12
Aminorex	12
Benzylmorphine	2
Betacetylmethadol	2
Beta-hydroxy-3-methylfentanyl	2
Beta-hydroxyfentanyl	2
Betameprodine	2
Betamethadol	2
Betaprodine	2
Bufotenine	3
Cathinone	12
Codeine-N-oxide	602
Desomorphine	5

	Proposed 2013 quotas g
Diethyltryptamine	12
Difenoxin	50
Dihydromorphine	3,300,000
Dimethyltryptamine	18
Gamma-hydroxybutyric acid	46,250,000
Heroin	25
Hydromorphinol	54
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	30
Marihuana	21,000
Mescaline	13
Methaqualone	10
Methcathinone	14
Methyldihydromorphine	2
Morphine-N-oxide	655
N-Benzylpiperazine	12
N,N-Dimethylamphetamine	12
N-Ethylamphetamine	12
N-Hydroxy-3,4-methylenedioxyamphetamine	12
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	18
Para-fluorofentanyl	2
Phenomorphan	2
Pholcodine	2
Properidine	2
Psilocybin	2
Psilocyn	4
Tetrahydrocannabinols	491,000
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
Basic Class—Schedule II	
1-Phenylcyclohexylamine	3
1-Piperdinocyclohexanecarbonitrile	21
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000
Alfentanil	38,250
Alphaprodine	3
Amobarbital	9
Amphetamine (for conversion)	18,375,000
Amphetamine (for sale)	38,000,000
Carfentanil	6
Cocaine	240,000
Codeine (for conversion)	81,250,000
Codeine (for sale)	49,506,250
Dextropropoxyphene	19
Dihydrocodeine	250,000
Diphenoxylate	750,000
Ecgonine	127,500
Ethylmorphine	3
Fentanyl	2,108,750
Glutethimide	3
Hydrocodone (for sale)	78,750,000
Hydromorphone	4,535,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	6
Levorphanol	4,500
Lisdexamfetamine	19,250,000
Meperidine	6,875,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	6
Methadone (for sale)	25,000,000
Methadone Intermediate	32,500,000
Methamphetamine	3,912,500

	Proposed 2013 quotas g
[962,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,888,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)].	
Methylphenidate	72,250,000
Morphine (for conversion)	103,750,000
Morphine (for sale)	51,250,000
Nabilone	25,628
Noroxymorphone (for conversion)	9,000,000
Noroxymorphone (for sale)	508,750
Opium (powder)	91,250
Opium (tincture)	1,287,500
Oripavine	22,750,000
Oxycodone (for conversion)	10,250,000
Oxycodone (for sale)	123,375,000
Oxymorphone (for conversion)	16,000,000
Oxymorphone (for sale)	6,875,000
Pentobarbital	42,500,000
Phenazocine	6
Phencyclidine	30
Phenmetrazine	3
Phenylacetone	20,000,000
Racemethorphan	3
Remifentanil	2,500
Secobarbital	215,003
Sufentanil	6,250
Tapentadol	13,500,000
Thebaine	145,000,000
Basic Class—List I Chemicals	
Ephedrine (for conversion)	12,000,000
Ephedrine (for sale)	3,200,000
Phenylpropanolamine (for conversion)	25,700,000
Phenylpropanolamine (for sale)	4,400,000
Pseudoephedrine (for sale)	185,000,000

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 be established 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 2013 aggregate production quotas and assessment of annual needs as needed.

Comments

Pursuant to 21 CFR 1303.11 and 21 CFR 1315.11, 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. In the event the Deputy Administrator decides in his sole discretion to hold such a hearing, the Deputy 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 Deputy Administrator will publish in the **Federal Register** a final order establishing the 2013 aggregate production quota for each basic class of controlled substance and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Dated: July 31, 2012.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2012–19052 Filed 8–2–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prohibited Transaction Class Exemption for Cross-Trades of Securities by Index and Model-Driven Funds

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, "Prohibited Transaction Class Exemption for Cross-Trades of Securities by Index and Model-Driven Funds," to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before September 4, 2012.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the *RegInfo.gov* Web site, *http://www.reginfo.gov/public/do/PRAMain*, on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov*.

Submit comments about this request to the Office of Information and

Drug	Company	Comment	Amount	Response	Proposed APQ	Establish APQ	Change	APQ w/ 25% buffer
amphetamine (for conversion)	(b)(4)	increase APQ	219,000	increase APQ, based on lisdexamfetamine	14,700,000	18,300,000	3,600,000	22,875,000
amphetamine (for sale)		increase APQ	800,000	increase APQ, based on sales	30,400,000	34,100,000	3,700,000	42,625,000
		increase APQ	1,800,000					
		increase APQ	1,100,000					
codeine (for conversion)		increase APQ	13,500,000	APQ adequate, no change	65,000,000	65,000,000	-	-
codeine (for sale)		decrease APQ	6,588,000	APQ adequate, no change	39,605,000	39,605,000	-	-
gamma hydroxybutyric acid		increase APQ	1,660,000	APQ adequate, no change	37,000,000	37,000,000	-	-
hydrocodone (for sale)		increase APQ	12,832,550	increase APQ, based on sales	63,000,000	79,700,000	16,700,000	99,625,000
		increase APQ	10,000,000					
hydromorphone		increase APQ	-	increase APQ, based on IMS data	3,628,000	4,775,000	1,147,000	5,968,750
levo-methamphetmine		increase APQ	12,800	increase APQ, based on new requests	770,000	790,000	20,000	987,500
lisdexamfetamine		increase APQ	123,500	increase APQ, based on exports	15,400,000	16,800,000	1,400,000	21,000,000
		increase APQ	4,600,000					
meperidine		increase APQ	26,100	APQ adequate, no change	5,500,000	5,500,000	-	-
		increase APQ	93,000					
methylphenidate		increase APQ	951,000	increase APQ, based on exports	57,800,000	64,600,000	6,800,000	80,750,000
		decrease APQ	2,900,000					
		increase APQ	3,000,000					
morphine (for conversion)		increase APQ	1,500,000	APQ adequate, no change	83,000,000	83,000,000	-	-
		decrease APQ	7,796,000					
morphine (for sale)		increase APQ	7,500,000	increase APQ, based on sales	41,000,000	48,200,000	7,200,000	60,250,000
		increase APQ	50					
noroxymorphone (for conversion)		increase APQ	6,400,000	APQ adequate, no change	7,200,000	7,200,000	-	-
oripavine		increase APQ	41,000	APQ adequate, no change	18,200,000	18,200,000	-	-
oxycodone (for sale)		increase APQ	12,000,000	increase APQ, based on sales	98,700,000	105,200,000	6,500,000	131,500,000
oxymorphone (for conversion)		decrease APQ	235,000	increase APQ, based on new requests	12,800,000	14,700,000	1,900,000	18,375,000
oxymorphone (for sale)		decrease APQ	2,077,000	APQ adequate, no change	5,500,000	5,500,000	-	-
remifentanil		increase APQ	1,820	increase APQ, based on new requests	2,000	3,000	1,000	3,750
sufentanil		increase APQ	300	increase APQ, based on new requests	5,000	5,002	2	6,253
tapentadol		increase APQ	-	increase APQ, based on new requests	10,800,000	11,000,000	200,000	13,750,000
thebaine		decrease APQ	3,000,000	APQ adequate, no change	116,000,000	116,000,000	-	-

Number of registrants/entities commenting: 6 (one non-registrant)
Number of drugs commented on: 22 22

CMEA Chemical	Company	Comment	Amount	Response	Proposed APQ	Establish APQ	Change
PPA (for conversion)	(b)(4)	increase APQ	2,200,000		25,700,000	25,700,000	-

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

Additional Considerations:

Drug	Response	Proposed	Revised	Change
3,4-methylenedioxy-N-methylcathione (methylone)	increase APQ, based on new requests	15	35	20
N-Benzylpiperazine	increase APQ, based on new requests	12	15	3
3,4,methylenedioxypyrovalerone	increase APQ, based on new requests	15	25	10
4-methyl-N-methylcathinone (mephedrone)	increase APQ, based on new requests	15	25	10
				-
				-

Drug	Proposed APQ w/ 25% buffer	Establish APQ w/ 25% buffer
amphetamine (for conversion)	18,375,000	22,875,000
amphetamine (for sale)	38,000,000	42,625,000
hydrocodone (for sale)	78,750,000	99,625,000
hydromorphone	4,535,000	5,968,750
levo-methamphetmine	962,500	987,500
lisdexamfetamine	19,250,000	21,000,000
methylphenidate	72,250,000	80,750,000
morphine (for sale)	51,250,000	60,250,000
oxycodone (for sale)	123,375,000	131,500,000
oxymorphone (for conversion)	16,000,000	18,375,000
remifentanil	2,500	3,750
sufentanil	6,250	6,253
tapentadol	13,500,000	13,750,000

CONFIDENTIAL

RECEIVED
ODE

2012 SEP -5 AM 7:41

August 30, 2012

DEA Headquarters
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Docket No. DEA-365

Dear Sirs:

I, (b)(4),(b)(6) manufacturing (b)(4),(b)(7)(E) am submitting this comment on the 2013 Proposed Aggregate Production Quota for various products as published in the August 3, 2012 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) Amphetamine (for conversion) by 219,000 grams as base; (ii) Amphetamine (for sale) by 800,000 grams as base [400,000 grams for D,L-Amphetamine and 400,000 grams for D-Amphetamine]; (iii) Gamma-hydroxybutyric acid by 1,660,000 grams as base; (iv) Lisdexamfetamine by 123,500 grams as base; (v) Meperidine by 26,100 grams as base, (vi) Methamphetamine by 12,800 grams as base; (vii) Remifentanil by 1,820 grams as base; and (viii) Sufentanil by 300 grams as base. These numbers are over and above the volumes identified on our late April 2012 requests for 2013. 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

CONFIDENTIAL

RECEIVED
ODE

2012 SEP -5 AM 7:41

August 30, 2012

DEA Headquarters
Attention: DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, VA 22152

Subject: Docket No. DEA-365

Dear Sirs:

I, (b)(4),(b)(6) manufacturing (b)(4),(b)(7)(E) am submitting this comment on the 2013 Proposed Aggregate Production Quota for various products as published in the August 3, 2012 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) Amphetamine (for sale) by 1,800,000 grams as base [800,000 grams for D,L-Amphetamine and 1,000,000 grams for D-Amphetamine]; (ii) Codeine (for conversion) by 13,500,000 grams as base; (iii) Hydrocodone by 12,832,550 grams as base; (iv) Methylphenidate by 951,000 grams as base; (v) Morphine (for conversion) by 1,500,000 grams as base; and (vi) Morphine (for sale) by 7,500,000 grams as base. The following items' procurement quota should be increased by the identified quantity: (i) Phenylpropanolamine (for conversion) by 2,200,000 grams as base. These numbers are over and above the volumes identified on our late April 2012 requests for 2013. 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 or Form 250 will be submitted shortly pertaining to the items for which we are submitting comments.

Very truly yours

(b)(6)

From: (b)(4),(b)(6)
Sent: Friday, September 07, 2012 1:50 PM
To: (b)(6)
Cc:
Subject: 2013 Updated Quota Sheets

(b)(6)

I completed the updating of the manufacturing and procurement 2013 quota sheets for (b)(7)(E) The updates are:

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

Manufacturing

codeine for conversion, 113370 replaces 112303 d,l-amphetamine for sale, 113342 replaces 112443 d-amphetamine for sale, 113341 replaces 112444 hydrocodone, 113369 replaces 112304 methylphenidate, 113340 replaces 112306 morphine for conversion, 113343 replaces 112302 morphine for sale, 113374 is new oxycodone, 113344 is new

Procurement

CPS AMA, 113382 replaces 112309
CPS AOA, 113372 replaces 113371 and 112307 CPS ATA, 113373 replaces 112308 PPA, 113381 replaces 112447

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

Manufacturing

d,l-amphetamine for sale, 113367 replaces 112448 d-amphetamine, 113366 replaces 112449 d-amphetamine for conversion, 113354 is new GHB, 113346 replaces 112256 hydrocodone, 113365 replaces 112277 methamphetamine, 113350 replaces 112257 lisdexamfetamine, 113362 replaces 112260 meperidine, 113352 replaces 112259 morphine for sale, 113363 replaces 112291 oxycodone, 113345 replaces 112289 remifentanil, 113348 replaces 112264 sufentanil, 113351 replaces 112265

Procurement

CPS AOA, 113378 replaces 112294
morphine for sale, 113377 is new

(b)(6)

 (b)(4) has its main place of business at

(b)(4)

While [(b)(4)] aims to keep its network free from viruses you should note that we are unable to scan certain emails, particularly if any part is encrypted or password-protected, and accordingly you are strongly advised to check this email and any attachments for viruses. The company shall NOT ACCEPT any liability with regard to computer viruses nsferred by way of email.

Please note that your communication may be monitored in accordance with [(b)(4)] internal policy documentation.

PUBLIC SUBMISSION

As of: September 04, 2012
Received: September 04, 2012
Status: Pending_Post
Tracking No. 811009da
Comments Due: September 04, 2012
Submission Type: Web

Docket: DEA-2012-0005
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 2013

Comment On: DEA-2012-0005-0001
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 2013

Document: DEA-2012-0005-DRAFT-0004
Comment on FR Doc # N/A

Submitter Information

Name: (b)(6)
Address:
(b)(4)
Email: (b)(4),(b)(6)
Phone: (b)(4),(b)(6)
Fax: (b)(4),(b)(6)
Organization: (b)(4)

General Comment

The attached document constitutes (b)(4),(b)(7)(E) comments to the Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances for 2013.

Attachments

[Docket No. DEA-365] (b)(4),(b)(7)(E) Comment to the Proposed Aggregate Production Quotas for 2013

(b)(4)

(b)(4)

September 4, 2013

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

Attn: DEA Federal Register Representative [Docket No. DEA-365]

This letter constitutes (b)(4) comments on the Proposed Initial Aggregate Production Quotas for 2013, as published in Federal Register on August 3, 2012, FR Vol. 77, No. 150, pages 46519-46523.

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 proprietary 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").

1100 Amphetamine

(b)(4) requests that the initial aggregate be sufficient to include its request for 1,100,000 grams AA of Amphetamine manufacturing quota for 2013.

1724 Methylphenidate

(b)(4) requests that the initial aggregate be sufficient to include its request for 12,000,000 grams AA of Methylphenidate manufacturing quota for 2013.

9668 Noroxymorphone (for conversion)

(b)(4) requests that the initial aggregate be sufficient to include its request for 6,400,000 grams AA of Noroxymorphone (for conversion) manufacturing quota for 2013.

9652 Oxymorphone (for conversion)

(b)(4) requests that the initial aggregate be sufficient to include its request for 7,800,000 grams AA of Oxymorphone (for conversion) manufacturing quota for 2013.

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

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

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

PUBLIC SUBMISSION

As of: September 04, 2012
Received: August 31, 2012
Status: Pending_Post
Tracking No. 810fda42
Comments Due: September 04, 2012
Submission Type: Web

Docket: DEA-2012-0005
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 2013

Comment On: DEA-2012-0005-0001
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 2013

Document: DEA-2012-0005-DRAFT-0002
Comment on FR Doc # N/A

Submitter Information

Name: (b)(6)
Address:
(b)(4)
Email: (b)(4),(b)(6)
Phone: (b)(4),(b)(6)
Fax: (b)(4),(b)(6)
Organization: (b)(4)

General Comment

See attached file(s)

Attachments

Docket No. DEA 365 (b)(4)

(b)(4)

(b)(4)

August 31, 2012

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
Office of Diversion Control
8701 Morrisette Drive
Springfield, VA 22152

RE: Docket No. DEA-365 (b)(4) **Comment**

Dear Sirs:

(b)(4),(b)(7)(E) have submitted quota correspondence as set forth in the table below for the following manufacturing categories. (b)(4) requests that the correspondence provided to the Quota Unit, which constitutes "CONFIDENTIAL BUSINESS INFORMATION", be considered during the 2013 Aggregate Production Quota review.

Quota Category	Quota Application Ref. #	Material Name	Action Needed
Manufacturing	112416	Codeine - 9050	An aggregate increase on (b)(4) customer demand
Manufacturing	112415 112414	Morphine - 9300 Morphine for Conversion- 9300	An aggregate increase based on (b)(4) customer demand
Manufacturing	112418	Oxycodone for Sale – 9143	An aggregate increase based on (b)(4) customer demand
Manufacturing	112420 112421	Oxymorphone for Conversion -9652 Oxymorphone for Sale -9652	An aggregate increase based on (b)(4) customer demand
Manufacturing	112421	Oxymorphone for Sale -9652	An aggregate increase based on (b)(4) customer demand
Manufacturing	112337	Oripavine- 9330	An aggregate increase based on (b)(4) customer demand
Manufacturing	112338	Hydromorphone - 9150	An aggregate increase based on (b)(4) customer demand
Manufacturing	112330	Hydrocodone for Sale – 9193	An aggregate increase based on (b)(4) customer demand
Manufacturing	112339	Methylphenidate – 1724	An aggregate increase based on (b)(4) customer demand

Thank you in advance for considering these requests. If you have any questions regarding this request, please do not hesitate to contact me at (b)(4),(b)(6)

Best regards,

(b)(6)

Director, Process Engineering and DEA Compliance

Supporting data to APQ comments

(b)(4)

(b)(4)

August 31, 2012

Drug Enforcement Administration
(b)(6) ODEQ
Office of Diversion Control
8701 Morrisette Drive
Springfield, VA 22152

RE: Docket No. DEA-365 (b)(4) Comment

Dear Ms. (b)(6)

(b)(4),(b)(7)(E) have submitted 2013 manufacturing quota requests as set forth in the table below for the following drug classes. (b)(4) requests that the information provided in this correspondence be considered during the 2013 Aggregate Production Quota review.

Site	Quota Category	Quota Application Ref. #	Material Name	2013 April Submission kgs base	Revised 2013 Quota kgs base	Change kgs base
(b)(4)	Manufacturing	112416	Codeine - 9050	21,121	14,533	(6,588)
	Manufacturing	112415	Morphine - 9300 *	21,313	24,500	3,187
	Manufacturing	112414	Morphine for Conversion-9300	12,796	5,000	(7,796)
	Manufacturing	112418	Oxycodone for Sale – 9143*	79,000	91,000**	12,000
	Manufacturing	112420	Oxymorphone for Conversion -9652*	4,285	4,050	(235)
	Manufacturing	112421	Oxymorphone for Sale - 9652	4,027	1,950	(2,077)
	Manufacturing	112423	Tapentadol-9780	10,000	10,000	-
	Manufacturing	112417	Thebaine-9333	15,000	12,000	(3,000)
	Manufacturing	112337	Oripavine- 9330	5,800	5,841	41
	Manufacturing	112338	Hydromorphone - 9150 *	3,200	3,200	-
	Manufacturing	112330	Hydrocodone for Sale – 9193*	35,000	45,000	10,000
	Manufacturing	112339	Methylphenidate - 1724*	30,000	27,100	(2,900)

*** Assumes current quota letters sent in July are denied**
**** Includes 1,225 kgs base needed to support validation/development initiatives**

Site	Quota Category	Quota Application Ref. #	Material Name	2013 April Submission kgs base	Revised 2013 Quota kgs base	Change kgs base
(b)(4)	Procurement	111613	PSC - AMA	36,079	41,087	5,008
	Procurement	111593	PSC - ACA	15,500	5,675	(9,825)
	Procurement	111595	PSC - AOA	9,000	7,495	(1,505)
	Procurement	111594	PSC - ATA	111,000	123,574	12,574
	Procurement	111583	CPS AOA	6,500	7,088	588
	Procurement	111578	CPS-ATA	35,000	50,997	15,997

Quota Calculations:

- For each drug class, quota needs are calculated using the same tables provided in typical (b)(4) quota requests.
- The calculations reflect the fact that (b)(4) has not received any grants for their July requests.
- 2012 and 2013 sales forecasts are used to calculate a yearend allowable limit for each year. For illustration and calculation purposes the 2013 quota grants shown result in a year-end inventory meeting the 50% limit.
- Using 2011 ending inventory and current grants (or production volumes if lesser), the 2012 ending inventory is determined and carried over to 2013 calculations.
- Process losses are calculated using 2012 actual yield information and included in each section.
- If a process step is deferred to 2013, there will not be any input material in the table.
- Some cases where the drug class changes, a molecular weight change (MWC) factor is included

Manufacturing Quotas granted as result of 2012 APQ Final Revised

'fentanil

final APQ		29,002
previously granted		15,000

Company	granted	
(b)(4)	14,002	29,002

Amphetamines

final APQ		33,400,000
previously granted		25,299,535

Company	granted		
(b)(4)	d-amp	1,750,000	27,049,535
	d-amp	920,000	27,969,535
	d,l-amp	755,316	28,724,851
	d-amp	500,000	29,224,851
	d,l-amp	600,000	29,824,851
	d,l-amp	180,000	30,004,851
	d-amp	10,000	30,014,851

Codeine (conv)

final APQ		65,000,000
previously granted		47,684,990

Company	granted	
(b)(4)	6,955,000	54,639,990
	10,000	54,649,990

Codeine (sale)

final APQ		39,605,000
previously granted		32,265,105

Company	granted	
(b)(4)	2,361,000	34,626,105

Dihydromorphine

final APQ		3,750,000
previously granted		3,189,010

Company	granted	
(b)(4)	395,000	3,584,010
	112,500	3,696,510

Hydrocodone (sale)

final APQ		79,700,000
previously granted		58,999,725

Company	granted	
(b)(4)	10,000	59,009,725
	2,785,000	61,794,725
	7,148,000	68,942,725
	10,729,000	79,671,725

Hydromorphone

final APQ		4,207,000
previously granted		3,627,942

Company	granted	
(b)(4)	191,154	3,819,096
	190,438	4,009,534
	39,000	4,048,534
	44,250	4,092,784

Methylphenidate

final APQ		64,600,000
previously granted		55,955,914

Company	granted	
(b)(4)	3,081,000	59,036,914
	393,000	59,429,914
	5,046,000	64,475,914

Manufacturing Quotas granted as result of 2012 APQ Final Revised

'ethadone

	final APQ	23,100,000
	previously granted	19,989,762

Company	granted	
(b)(4)	1,403,000	21,392,762

Methadone Intermediate

	final APQ	29,970,000
	previously granted	20,166,124

Company	granted	
(b)(4)	2,243,880	22,410,004
	1,094	22,411,098
	-	22,411,098

Morphine (conv)

	final APQ	83,000,000
	previously granted	60,457,280

Company	granted	
(b)(4)	20,000	60,477,280
	11,748,000	72,225,280

Morphine (sale)

	final APQ	48,200,000
	previously granted	38,472,005

Company	granted	
(b)(4)	326,000	38,798,005
	1,806,000	40,604,005
	7,571,000	48,175,005

Oxycodone (conv)

	final APQ	7,600,000
	previously granted	5,005,000

Company	granted	
(b)(4)	2,537,000	7,542,000

Oxycodone (sale)

	final APQ	105,200,000
	previously granted	97,999,765

Company	granted	
(b)(4)	3,171,000	101,170,765
	3,310,000	104,480,765
(b)(4)		

Oxymorphone (conv)

	final APQ	12,800,000
	previously granted	10,267,500

Company	granted	
(b)(4)	1,048,500	11,316,000

Oxymorphone (sale)

	final APQ	5,500,000
	previously granted	5,302,981

Company	granted	
(b)(4)	110,000	5,412,981

Manufacturing Quotas granted as result of 2012 APQ Final Revised

ripavine

	final APQ	15,300,000
	previously granted	10,543,005

Company	granted	
(b)(4)	1,064,000	11,607,005
	1,372,000	12,979,005

Noroxymorphone (conv)

	final APQ	7,200,000
	previously granted	4,194,200

Company	granted	
(b)(4)	1,994,000	6,188,200

Noroxymorphone (sale)

	final APQ	1,981,000
	previously granted	401,000

Company	granted	
(b)(4)		401,000

PCC

	final APQ	27
	previously granted	2

Company	granted	
(b)(4)	20	22

Sufentanil

	final APQ	6,730
	previously granted	4,502

Company	granted	
(b)(4)	1,725	6,227

IMS Data 20[illegible] 2012 (est)

Substance	2008	2009	% Change	2010	% Change	2011	% Change	2012*	% Change
Amphetamine	14,342.034	16,603.058	15.77%	18,562.562	11.80%	20,164.553	8.63%	22,142.094	9.81%
Codeine	27,836.519	27,365.950	-1.69%	25,249.876	-7.73%	25,992.290	2.94%	24,020.264	-7.59%
Hydrocodone	54,437.480	59,527.711	9.35%	61,536.902	3.38%	64,858.625	5.40%	64,635.099	-0.34%
Hydromorphone	1,142.810	1,341.428	17.38%	1,458.354	8.72%	1,671.450	14.61%	1,879.161	12.43%
Methylphenidate**	17,760.310	18,091.414	1.86%	18,545.359	2.51%	19,051.768	2.73%	19,899.590	4.45%
Morphine	25,729.607	27,775.560	7.95%	28,926.223	4.14%	30,340.353	4.89%	30,695.325	1.17%
Oxycodone	52,212.385	58,308.543	11.68%	68,128.272	16.84%	70,629.751	3.67%	67,956.168	-3.79%
Oxymorphone	916.257	1,257.880	37.28%	1,645.704	30.83%	2,643.474	60.63%	2,110.595	-20.16%

* 2012 Estimate based on Jan-Jun 2012 data

Both MQ and PQ Inventories = 50%

Substance	2011 exp	est 2012 exp	2012*	w/ c.f.	w/ PQ inv	w/ MQ inv
Amphetamine	509.778	559.772	22,142.094	23,802.751	35,704.126	53,556.189
Codeine	1,216.333	1,124.050	24,020.264	19,216.211	28,824.317	43,236.475
Hydrocodone	30.646	30.540	64,635.099	39,427.410	59,141.115	88,711.673
Hydromorphone	550.175	618.545	1,879.161	2,290.999	3,436.498	5,154.747
Methylphenidate	8,684.280	9,070.739	19,899.590	26,383.382	39,575.073	59,362.609
Morphine	547.128	553.529	30,695.325	27,258.462	40,887.692	61,331.539
Oxycodone	6,061.125	5,831.691	67,956.168	64,953.556	97,430.335	146,145.502
Oxymorphone	18.191	14.524	2,110.595	1,850.742	2,776.113	4,164.169

Proposed Rev. APQ	Final Rev. APQ
33,400.000	33,400.000
39,605.000	39,605.000
63,000.000	86,600.000
3,628.000	4,207.000
56,000.000	64,600.000
39,000.000	48,200.000
98,700.000	105,200.000
3,070.000	5,500.000

Inventories adjusted - PQ =30% and MQ = 50%

Substance	2011 exp	est 2012 exp	2012*	w/ c.f.	w/ PQ inv	w/ MQ inv
Amphetamine	509.778	559.772	22,142.094	23,802.869	30,943.729	46,415.594
Codeine	1,216.333	1,124.050	24,020.264	19,216.211	24,981.075	37,471.612
Hydrocodone	30.646	30.540	64,635.099	39,427.410	51,255.633	76,883.450
Hydromorphone	550.175	618.545	1,879.161	2,290.999	2,978.298	4,467.447
Methylphenidate	8,684.280	9,070.739	19,899.590	26,383.382	34,298.396	51,447.595
Morphine	547.128	553.529	30,695.325	27,258.462	35,436.000	53,154.000
Oxycodone	6,061.125	5,831.691	67,956.168	64,953.556	84,439.623	126,659.435
Oxymorphone	18.191	14.524	2,110.595	1,850.742	2,405.965	3,608.947

2013 Establish Initial 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, established initial year 2013 aggregate production quotas (APQ) for schedules I and II controlled substances for which the United States has medical, scientific, industrial, export and reserve stock requirements. Also attached is a list of the 2011 and 2012 APQs for these substances for comparison.

- The APQ (Controlled Substances) and the AAN (Ephedrine, Pseudoephedrine, and Phenylpropanolamine) have previously been published as separate documents. With this publication, they have been combined into a single document. The CSA does not distinguish between the quotas for controlled substances and the quotas for the three chemicals. The DEA regulations are separate for the APQ and AAN, however, there is no prohibition to combining the two and CC did not have any comments regarding this action. Additionally, the combining of the two documents increases efficiency by providing one document to be tracked, for both industry and DEA personnel, and reduces costs related to publishing.

- In an effort to prevent potential drug shortage issues, DEA has added 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 marijuana). DEA learned through meetings with industry that manufacturers do not always maintain the 50% inventory allowance that is permitted and sometimes do not maintain any inventory at all. If a disaster or some other unforeseen event were to occur, there is a strong likelihood that drugs would become unavailable and, if all or most of the quotas had been issued to manufacturers, DEA would not be able to respond quickly because the DEA regulations require public notice and comment for adjustments to the APQ. As such, DEA has determined that an amount of 25% should be adequate to ensure that DEA could immediately respond to such situations and provide sufficient quota to allow continued manufacturing to alleviate potential shortages. The 25% amount is equivalent to one quarter of the year, which is the longer end of the typical manufacturing cycles as communicated to DEA by industry.

- Expeditious publication of this notice is necessary to ensure that quota is available at the beginning of 2013 for manufacturing. The following points provide brief explanations of the changes from the proposed APQ values:

<u>Schedule I substances</u>

- The APQ for **4-methyl-N-methylcathinone, 3,4-methylenedioxy-N-methylcathinone, 3,4,methylenedioxypyrovalerone,** and **N-benzylpiperazine** were increased due to additional applications received to support the manufacturing of diagnostic kits and / or reference standards.

Schedule II substances

- The APQ for **amphetamine (for conversion), lisdexamfetamine,** and **methylphenidate** were increased to support increased exportation requirements.

- The APQ for **amphetamine (for sale), hydrocodone (for sale), hydromorphone, morphine (for sale),** and **oxycodone (for sale)** were increased to the increasing trend in sales data as provided by the manufacturer and IMS Health data.

- The APQ for **methamphetamine, oxymorphone (for conversion), remifentanil, sufentanil,** and **tapentadol** were increased due to additional applications received to support manufacturing efforts.

List I chemicals

- The AAN for **ephedrine (for conversion), ephedrine (for sale),** and **phenylpropanolamine (for sale)** were increased due to additional applications received to support manufacturing efforts.

Controlled Substance Schedule I:	Final Revised 2010	Final Revised 2011	Final Revised 2012	Proposed Initial 2013	Established 2013
3,4-Methylenedioxy-N-methylcathinone (methylone)			24	15	35
3,4-Methylenedioxypyrovalerone (MDPV)			20	15	25
4-Methyl-N-methylcathinone (mephedrone)				15	25
N-Benzylpiperazine			2	12	15

Controlled Substance Schedule II:	Final Revised 2010	Final Revised 2011	Final Revised 2012	Proposed Initial 2013	Established 2013
Amphetamine (for conversion)	7,500,000	8,500,000	13,300,000	18,375,000	22,875,000
Amphetamine (for sale)	18,600,000	25,300,000	33,400,000	38,000,000	42,625,000
Hydrocodone (for sale)	55,000,000	59,000,000	79,700,000	78,750,000	99,625,000
Hydromorphone	3,455,000	3,455,000	4,207,000	4,535,000	5,968,750
Lisdexamfetamine	9,000,000	10,400,000	12,000,000	19,250,000	21,000,000
Methylphenidate	50,000,000	56,000,000	64,600,000	72,250,000	80,750,000
Morphine (for sale)	39,000,000	39,000,000	48,200,000	51,250,000	60,250,000
Oxycodone (for sale)	105,000,000	98,000,000	105,200,000	123,375,000	131,500,000
Oxymorphone (for conversion)	12,800,000	12,800,000	12,800,000	16,000,000	18,375,000
Remifentanil	2,500	2,500	2,500	2,500	3,750
Sufentanil	7,000	5,000	6,730	6,250	6,255
Tapentadol	1,000,000	403,000	5,400,000	13,500,000	13,750,000

List I Chemical	Final Revised 2010	Final Revised 2011	Final Revised 2012	Proposed Initial 2013	Established 2013
Ephedrine (for conversion)	75,000,000	18,600,000	12,000,000	12,000,000	15,100,000
Ephedrine (for sale)	3,900,000	4,200,000	4,303,000	3,200,000	3,500,000
Phenylpropanolamine (for sale)	7,400,000	5,300,000	5,800,000	4,400,000	6,100,000
Pseudoephedrine (for sale)	404,000,000	299,000,000	278,000,000	185,000,000	225,000,000

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-365]

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 2013

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

ACTION: Notice.

SUMMARY: This notice establishes the initial 2013 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

EFFECTIVE DATE: [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION: 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 the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been

delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The 2013 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 2013 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 August 3, 2012, 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 2013," was published in the Federal Register (77 FR 46519). That notice proposed the 2013 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2013 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 September 4, 2012.

Five comments (four from DEA-registered manufacturers and one from a non-registrant) were received within the published comment period, offering comments on a total of 20 schedule I and II controlled substances and one list I chemical. Commenters stated that the proposed aggregate production quotas for amphetamine (for conversion),

amphetamine (for sale), codeine (for conversion), codeine (for sale), gamma hydroxybutyric acid, hydrocodone (for sale), hydromorphone, lisdexamfetamine, meperidine, methamphetamine, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), remifentanil, and sufentanil 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. One commenter stated that the proposed assessment of annual needs quota for phenylpropanolamine (for conversion) was 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.

In determining the 2013 aggregate production quotas and assessment of annual needs, 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 2012 manufacturing quotas, current 2012 sales and inventories, 2013 export requirements, industrial use, additional applications for quotas, as well as information on research and product development requirements. Based on this information, DEA has determined that adjustments to the proposed aggregate production quotas and assessment of annual needs for 3,4-methylenedioxy-N-methylcathinone (methylone), 3,4,methylenedioxypyrovalerone (MDPV), 4-methyl-N-methylcathinone (mephedrone), N-benzylpiperazine, amphetamine (for conversion), amphetamine (for sale), hydrocodone (for sale), hydromorphone, lisdexamfetamine, methylphenidate, morphine (for sale), oxycodone (for sale), oxymorphone (for conversion), remifentanil, sufentanil, tapentadol, ephedrine (for

conversion), ephedrine (for sale), phenylpropanolamine (for sale), and pseudoephedrine (for sale) are warranted. This notice reflects those adjustments.

Regarding codeine (for conversion), codeine (for sale), gamma hydroxybutyric acid, meperidine, methamphetamine, morphine (for conversion), noroxymorphone (for conversion), oripavine, oxymorphone (for sale), and phenylpropanolamine (for conversion) DEA has determined that the proposed initial 2013 aggregate production quotas and assessment of annual needs are sufficient to meet the current 2013 estimated medical, scientific, research, and industrial needs of the United States. This notice finalizes these aggregate production quotas at the same amounts as proposed.

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, 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 established aggregate production quotas reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation.

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 DEA. 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 2013 aggregate production quotas for the following schedule I and II controlled substances and the 2013 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 – Schedule I	Established 2013 Quotas
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	15 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	15 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	15 g
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	15 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	15 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	15 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	15 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
2,5-Dimethoxyamphetamine	12 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	15 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	15 g
3,4,5-Trimethoxyamphetamine	12 g
3,4-Methylenedioxyamphetamine (MDA)	30 g

3,4-Methylenedioxymethamphetamine (MDMA)	35 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	35 g
3,4-Methylenedioxypyrovalerone (MDPV)	25 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g
4-Methoxyamphetamine	88 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g
4-Methylaminorex	12 g
4-Methyl-N-methylcathinone (mephedrone)	25 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
5-Methoxy-N,N-dimethyltryptamine	10 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	12 g
Codeine-N-oxide	602 g
Desomorphine	5 g
Diethyltryptamine	12 g
Difenoxin	50 g

Dihydromorphine	3,300,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	46,250,000 g
Heroin	25 g
Hydromorphinol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	13 g
Methaqualone	10 g
Methcathinone	14 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N,N-Dimethylamphetamine	12 g
N-Benzylpiperazine	15 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	2 g
Psilocyn	4 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Established 2013 Quotas
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile	21 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g
Alfentanil	38,250 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	22,875,000 g
Amphetamine (for sale)	42,625,000 g

Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	81,250,000 g
Codeine (for sale)	49,506,250 g
Dextropropoxyphene	19 g
Dihydrocodeine	250,000 g
Diphenoxylate	750,000 g
Ecgonine	127,500 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	5,968,750 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	6 g
Levorphanol	4,500 g
Lisdexamfetamine	21,000,000 g
Meperidine	6,875,000 g
Meperidine Intermediate-A	6 g
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	6 g
Methadone (for sale)	25,000,000 g
Methadone Intermediate	32,500,000 g
Methamphetamine	3,912,500 g
[987,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,863,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)]	
Methylphenidate	80,750,000 g
Morphine (for conversion)	103,750,000 g
Morphine (for sale)	60,250,000 g
Nabilone	25,628 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	508,750 g
Opium (powder)	91,250 g
Opium (tincture)	1,287,500 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	10,250,000 g
Oxycodone (for sale)	131,500,000 g
Oxymorphone (for conversion)	18,375,000 g
Oxymorphone (for sale)	6,875,000 g

Pentobarbital	42,500,000 g
Phenazocine	6 g
Phencyclidine	30 g
Phenmetrazine	3 g
Phenylacetone	20,000,000 g
Racemethorphan	3 g
Remifentanil	3,750 g
Secobarbital	215,003 g
Sufentanil	6,255 g
Tapentadol	13,750,000 g
Thebaine	145,000,000 g

Basic Class – List I Chemicals	Established 2013 Quotas
Ephedrine (for conversion)	15,100,000 g
Ephedrine (for sale)	3,500,000 g
Phenylpropanolamine (for conversion)	25,700,000 g
Phenylpropanolamine (for sale)	6,100,000 g
Pseudoephedrine (for sale)	225,000,000 g

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 2013 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) _____: (b)(6) :09-24-12

Webcims # ODE-12-855

2013 APQ /AAN vs MQ / IQ Summary

Data Retrieved Jan 8, 2013

Basic Class – Schedule I	Established 2013 APQ (g)	APQ w/o 25% buffer (g)	MQ's Issued (g)	Remaining APQ (g)
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45		0	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45		0	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	5		5	0
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45		35	10
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45		35	10
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–	45		0	45
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45		0	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2		2	0
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45		35	10
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45		0	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45		0	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45		0	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45		0	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45		0	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45		0	45
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	15		0	15
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	15		0	15
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	15		0	15
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	15		0	15
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	15		0	15
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	15		0	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	15		0	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12		12	0
2,5-Dimethoxy-4-n-propylthiophenethylamine	12		12	0
2,5-Dimethoxyamphetamine	12		12	0
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	15		0	15
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	15		0	15
3,4,5-Trimethoxyamphetamine	12		12	0
3,4-Methylenedioxyamphetamine (MDA)	30		29	1
3,4-Methylenedioxymethamphetamine (MDMA)	35		35	0
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24		23	1
3,4-Methylenedioxy-N-methylcathinone (methylone)	35		22	13
3,4-Methylenedioxypyrovalerone (MDPV)	25		23	2
3-Methylfentanyl	2		2	0
3-Methylthiofentanyl	2		2	0
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12		12	0
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12		12	0
4-Methoxyamphetamine	88		87	1
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12		12	0
4-Methylaminorex	12		12	0
4-Methyl-N-methylcathinone (mephedrone)	25		25	0
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68		50	18
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53		40	13
5-Methoxy-3,4-methylenedioxyamphetamine	12		12	0
5-Methoxy-N,N-diisopropyltryptamine	12		12	0
5-Methoxy-N,N-dimethyltryptamine	10		10	0
Acetyl-alpha-methylfentanyl	2		2	0
Acetyldihydrocodeine	2		2	0
Acetylmethadol	2		2	0
Allylprodine	2		2	0
Alphacetylmethadol	2		2	0
Alpha-ethyltryptamine	12		12	0
Alphameprodine	2		2	0
Alphamethadol	2		2	0

Alpha-methylfentanyl	2		2	0
Alpha-methylthiofentanyl	2		2	0
Alpha-methyltryptamine (AMT)	12		12	0
Aminorex	12		12	0
Benzylmorphine	2		2	0
Betacetylmethadol	2		2	0
Beta-hydroxy-3-methylfentanyl	2		2	0
Beta-hydroxyfentanyl	2		2	0
Betameprodine	2		2	0
Betamethadol	2		2	0
Betaprodine	2		2	0
Bufotenine	3		3	0
Cathinone	12		12	0
Codeine-N-oxide	602		552	50
Desomorphine	5		5	0
Diethyltryptamine	12		12	0
Difenoxin	50		50	0
Dihydromorphine	3,300,000		3,081,897	218,103
Dimethyltryptamine	18		17	1
Gamma-hydroxybutyric acid	46,250,000	37,000,000	23,081,920	13,918,080
Heroin	25		16	9
Hydromorphinol	54		2	52
Hydroxypethidine	2		2	0
Ibogaine	5		5	0
Lysergic acid diethylamide (LSD)	30		27	3
Marihuana	21,000		8,525	12,475
Mescaline	13		12	1
Methaqualone	10		5	5
Methcathinone	14		14	0
Methyldihydromorphine	2		2	0
Morphine-N-oxide	655		575	80
N,N-Dimethylamphetamine	12		12	0
N-Benzylpiperazine	15		0	15
N-Ethylamphetamine	12		0	12
N-Hydroxy-3,4-methylenedioxyamphetamine	12		12	0
Noracymethadol	2		2	0
Norlevorphanol	52		52	0
Normethadone	2		2	0
Normorphine	18		18	0
Para-fluorofentanyl	2		2	0
Phenomorphan	2		2	0
Pholcodine	2		2	0
Properidine	2		0	2
Psilocybin	2		2	0
Psilocyn	4		4	0
Tetrahydrocannabinols	491,000	393,000	363,306	29,694
Thiofentanyl	2		2	0
Tilidine	10		10	0
Trimeperidine	2		2	0

Basic Class – Schedule II	Established 2013 APQ (g)	APQ w/o 25% buffer (g)	MQ's Issued (g)	Remaining APQ (g)
1-Phenylcyclohexylamine	3	2	2	0
1-Piperdinocyclohexanecarbonitrile	21	17	17	0
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000	1,800,000	1,147,653	652,347
Alfentanil	38,250	30,600	17,152	13,448
Alphaprodine	3	2	2	0
Amobarbital	9	7	7	0
Amphetamine (for conversion)	22,875,000	18,300,000	7,836,378	10,463,622
Amphetamine (for sale)	42,625,000	34,100,000	26,676,759	7,423,241

Carfentanil	6	5	5	0
Cocaine	240,000	192,000	137,720	54,280
Codeine (for conversion)	81,250,000	65,000,000	41,080,585	23,919,415
Codeine (for sale)	49,506,250	39,605,000	31,491,664	8,113,336
Dextropropoxyphene	19	15	15	0
Dihydrocodeine	250,000	200,000	80,380	119,620
Diphenoxylate	750,000	600,000	579,302	20,698
Ecgonine	127,500	102,000	78,620	23,380
Ethylmorphine	3	2	2	0
Fentanyl	2,108,750	1,687,000	1,519,110	167,890
Glutethimide	3	2	2	0
Hydrocodone (for sale)	99,625,000	79,700,000	61,332,359	18,367,641
Hydromorphone	5,968,750	4,775,000	3,947,453	827,547
Isomethadone	5	4	2	2
Levo-alphacetylmethadol (LAAM)	4	3	2	1
Levomethorphan	6	5	2	3
Levorphanol	4,500	3,600	3,102	498
Lisdexamfetamine	21,000,000	16,800,000	10,688,363	6,111,637
Meperidine	6,875,000	5,500,000	3,850,507	1,649,493
Meperidine Intermediate-A	6	5	3	2
Meperidine Intermediate-B	11	9	7	2
Meperidine Intermediate-C	6	5	3	2
Metazocine	6	5	5	0
Methadone (for sale)	25,000,000	20,000,000	19,973,928	26,072
Methadone Intermediate	32,500,000	26,000,000	23,914,341	2,085,659
Methamphetamine (dex) (for conversion)	2,863,750	2,291,000	599,500	1,691,500
Methamphetamine (d and d,l) (for sale)	61,250	49,000	35,130	13,870
Methamphetamine (levo)	987,500	790,000	766,010	23,990
Methylphenidate	80,750,000	64,600,000	59,944,983	4,655,017
Morphine (for conversion)	103,750,000	83,000,000	57,964,265	25,035,735
Morphine (for sale)	60,250,000	48,200,000	36,928,242	11,271,758
Nabilone	25,628	20,502	12,919	7,583
Noroxymorphone (for conversion)	9,000,000	7,200,000	6,203,974	996,026
Noroxymorphone (for sale)	508,750	407,000	403,628	3,372
Opium (powder)	91,250	73,000	53,360	19,640
Opium (tincture)	1,287,500	1,030,000	860,054	169,946
Oripavine	22,750,000	18,200,000	15,200,366	2,999,634
Oxycodone (for conversion)	10,250,000	8,200,000	5,840,045	2,359,955
Oxycodone (for sale)	131,500,000	105,200,000	92,912,773	12,287,227
Oxymorphone (for conversion)	18,375,000	14,700,000	11,449,375	3,250,625
Oxymorphone (for sale)	6,875,000	5,500,000	4,475,998	1,024,002
Pentobarbital	42,500,000	34,000,000	27,442,002	6,557,998
Phenazocine	6	5	5	0
Phencyclidine	30	24	13	11
Phenmetrazine	3	2	2	0
Phenylacetone	20,000,000	16,000,000	14,113,875	1,886,125
Racemethorphan	3	2	2	0
Remifentanil	3,750	3,000	1,825	1,175
Secobarbital	215,003	172,002	81,002	91,000
Sufentanil	6,255	5,004	4,933	71
Tapentadol	13,750,000	11,000,000	2,566,510	8,433,490
Thebaine	145,000,000	116,000,000	87,525,910	28,474,090

Basic Class – List I Chemicals	Established 2013 Quota (g)	IQ's Issued (g)	Remaining AAN (g)
Ephedrine (for conversion)	15,100,000	300	15,099,700
Ephedrine (for sale)	3,500,000	2,978,000	522,000
Phenylpropanolamine (for conversion)	25,700,000	2,960,000	22,740,000
Phenylpropanolamine (for sale)	6,100,000	5,650,000	450,000
Pseudoephedrine (for sale)	225,000,000	174,689,000	50,311,000

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–365]

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 2013

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

ACTION: Notice.

SUMMARY: This notice establishes the initial 2013 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: *Effective Date:* October 1, 2012.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307–4654.

SUPPLEMENTARY INFORMATION: 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 the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator pursuant to 28 CFR 0.104.

The 2013 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 2013 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 August 3, 2012, 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 2013," was published in the **Federal Register** (77 FR 46519). That notice proposed the 2013 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2013 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 September 4, 2012.

Five comments (four from DEA-registered manufacturers and one from a non-registrant) were received within the published comment period, offering comments on a total of 20 schedule I and II controlled substances and one list I chemical. Commenters stated that the proposed aggregate production quotas for amphetamine (for conversion), amphetamine (for sale), codeine (for conversion), codeine (for sale), gamma hydroxybutyric acid, hydrocodone (for sale), hydromorphone, lisdexamfetamine, meperidine, methamphetamine, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), remifentanil, and sufentanil 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. One commenter stated that the proposed assessment of annual needs quota for phenylpropanolamine (for conversion) was 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.

In determining the 2013 aggregate production quotas and assessment of annual needs, 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 2012 manufacturing quotas, current 2012 sales and inventories, 2013 export requirements, industrial use, additional applications for quotas, as well as information on research and product development requirements. Based on this information, DEA has determined that adjustments to the proposed aggregate production quotas and assessment of annual needs for 3,4-methylenedioxy-N-methylcathinone (methylone), 3,4,methylenedioxypyrovalerone (MDPV), 4-methyl-N-methylcathinone (mephedrone), N-benzylpiperazine, amphetamine (for conversion), amphetamine (for sale), hydrocodone (for sale), hydromorphone, lisdexamfetamine, methylphenidate, morphine (for sale), oxycodone (for sale), oxymorphone (for conversion), remifentanil, sufentanil, tapentadol, ephedrine (for conversion), ephedrine (for sale), phenylpropanolamine (for sale), and pseudoephedrine (for sale) are warranted. This notice reflects those adjustments.

Regarding codeine (for conversion), codeine (for sale), gamma hydroxybutyric acid, meperidine, methamphetamine, morphine (for conversion), noroxymorphone (for conversion), oripavine, oxymorphone (for sale), and phenylpropanolamine (for conversion), DEA has determined that the proposed initial 2013 aggregate production quotas and assessment of annual needs are sufficient to meet the current 2013 estimated medical, scientific, research, and industrial needs of the United States. This notice finalizes these aggregate production quotas at the same amounts as proposed.

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, 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 established aggregate production quotas reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. 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 DEA. 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 2013 aggregate production quotas for the following schedule I and II controlled substances and the 2013 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 2013 quotas
Schedule I	
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	15 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	15 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	15 g
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	15 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	15 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	15 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	15 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
2,5-Dimethoxyamphetamine	12 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	15 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	15 g
3,4,5-Trimethoxyamphetamine	12 g
3,4-Methylenedioxyamphetamine (MDA)	30 g
3,4-Methylenedioxymethamphetamine (MDMA)	35 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	35 g
3,4-Methylenedioxypyrovalerone (MDPV)	25 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g
4-Methoxyamphetamine	88 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g
4-Methylaminorex	12 g
4-Methyl-N-methylcathinone (mephedrone)	25 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
5-Methoxy-N,N-dimethyltryptamine	10 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g

Basic class	Established 2013 quotas
Betaprodine	2 g
Butotenine	3 g
Cathinone	12 g
Codeine-N-oxide	602 g
Desomorphine	5 g
Diethyltryptamine	12 g
Difenoxin	50 g
Dihydromorphine	3,300,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	46,250,000 g
Heroin	25 g
Hydromorphinol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	13 g
Methaqualone	10 g
Methcathinone	14 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N,N-Dimethylamphetamine	12 g
N-Benzylpiperazine	15 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	2 g
Psilocyn	4 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g
Schedule II	
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile	21 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g
Alfentanil	38,250 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	22,875,000 g
Amphetamine (for sale)	42,625,000 g
Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	81,250,000 g
Codeine (for sale)	49,506,250 g
Dextropropoxyphene	19 g
Dihydrocodeine	250,000 g
Diphenoxylate	750,000 g
Ecgonine	127,500 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	5,968,750 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	6 g
Levorphanol	4,500 g
Lisdexamfetamine	21,000,000 g
Meperidine	6,875,000 g
Meperidine Intermediate-A	6 g
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	6 g

Basic class	Established 2013 quotas
Methadone (for sale)	25,000,000 g
Methadone Intermediate	32,500,000 g
Methamphetamine	3,912,500 g
[987,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,863,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)].	
Methylphenidate	80,750,000 g
Morphine (for conversion)	103,750,000 g
Morphine (for sale)	60,250,000 g
Nabilone	25,628 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	508,750 g
Opium (powder)	91,250 g
Opium (tincture)	1,287,500 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	10,250,000 g
Oxycodone (for sale)	131,500,000 g
Oxymorphone (for conversion)	18,375,000 g
Oxymorphone (for sale)	6,875,000 g
Pentobarbital	42,500,000 g
Phenazocine	6 g
Phencyclidine	30 g
Phenmetrazine	3 g
Phenylacetone	20,000,000 g
Racemethorphan	3 g
Remifentanil	3,750 g
Secobarbital	215,003 g
Sufentanil	6,255 g
Tapentadol	13,750,000 g
Thebaine	145,000,000 g
List I Chemicals	
Ephedrine (for conversion)	15,100,000 g
Ephedrine (for sale)	3,500,000 g
Phenylpropanolamine (for conversion)	25,700,000 g
Phenylpropanolamine (for sale)	6,100,000 g
Pseudoephedrine (for sale)	225,000,000 g

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 2013 aggregate production quotas and assessment of annual needs as needed.

Dated: September 25, 2012.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2012–24089 Filed 9–28–12; 8:45 am]

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DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–81,791]

Fasco, a Division of Regal Beloit Corporation, Including On-Site Leased Workers From Penmac Personnel Services, Eldon, MI; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated August 30, 2012, workers requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for Trade Adjustment Assistance (TAA) applicable to workers and former workers of Fasco, a division of Regal Beloit Corporation, Eldon, Missouri (Fasco). The determination was issued on August 7, 2012. The Department's Notice of determination was published in the **Federal Register** on August 23, 2012 (77 FR 51066).

Fasco is a warehouse and distribution center for electric motors. The subject worker group includes workers engaged in activities related to the supply of warehousing and distribution of electric motors, as well as engineering, customer service and information technology services. The worker group includes on-site leased workers from Penmac Personnel Services.

The initial investigation resulted in a negative determination based on the findings that there were no shifts to/acquisition from a foreign country by Fasco in the supply of services like or directly competitive with those supplied by the subject workers; that there were no increased imports of services like or directly competitive with those supplied by the subject workers; that Fasco is neither a Supplier to nor a Downstream Producer of a firm that employed a worker group eligible to apply for TAA; and that the workers of Fasco have not met the criteria set forth in Section 222(e) of the Trade Act, as amended.

The request for reconsideration states that workers of the Engineering Services Department provide engineering

IMS Data 2010 - 2013 (est)

Substance	2010	2011	% Change	2012	% Change	2013*	% Change
Amphetamine	**8,875.83**	**9,704.33**	**9.33%**	**10,981.49**	**13.16%**	**11,318.45**	**3.07%**
Cocaine	53.89	48.53	-9.96%	44.03	-9.26%	41.18	-6.48%
Codeine	25,351.25	26,124.26	3.05%	23,600.01	-9.66%	25,491.39	8.01%
Dihydrocodeine	112.37	107.21	-4.59%	75.47	-29.60%	61.44	-18.59%
Diphenoxylate	480.24	462.58	-3.68%	418.96	-9.43%	417.79	-0.28%
Ephedrine	1,478.40	1,535.38	3.85%	1,976.57	28.73%	1,701.44	-13.92%
Fentanyl	510.25	539.82	5.80%	588.02	8.93%	578.44	-1.63%
Hydrocodone	**61,719.78**	**65,105.06**	**5.48%**	**65,037.75**	**-0.10%**	**63,756.39**	**-1.97%**
Hydromorphone	1,460.16	1,675.15	14.72%	1,925.44	14.94%	2,120.37	10.12%
Levorphanol	0.14	0.32	136.46%	1.61	399.07%	2.23	38.36%
Lisdexamfetamine	**10,311.46**	**12,337.65**	**19.65%**	**14,031.68**	**13.73%**	**14,371.09**	**2.42%**
Meperidine	2,579.09	2,302.77	-10.71%	1,891.98	-17.84%	1,665.56	-11.97%
Methadone	7,859.04	7,638.93	-2.80%	7,184.37	-5.95%	6,678.61	-7.04%
Methamphetamine	14.86	13.86	-6.74%	14.61	5.36%	14.09	-3.56%
Methylphenidate	**18,704.32**	**19,217.30**	**2.74%**	**19,747.16**	**2.76%**	**19,367.44**	**-1.92%**
Morphine	28,997.24	30,434.73	4.96%	31,003.40	1.87%	29,663.62	-4.32%
Opium	84.35	84.96	0.72%	81.32	-4.28%	80.65	-0.82%
Oxycodone	**68,320.72**	**70,866.67**	**3.73%**	**67,866.14**	**-4.23%**	**65,311.45**	**-3.76%**
Oxymorphone	**1,653.43**	**2,655.67**	**60.62%**	**1,959.43**	**-26.22%**	**1,850.54**	**-5.56%**
Pentazocine	694.40	839.71	20.93%	712.27	-15.18%	617.63	-13.29%
Pentobarbital	85.41	79.08	-7.41%	46.56	-41.12%	34.03	-26.92%
Pseudoephedrine	127,452.77	104,502.78	-18.01%	94,451.20	-9.62%	109,963.75	16.42%
Remifentanil	0.89	1.05	17.99%	1.12	7.56%	1.13	0.74%
Secobarbital	23.20	20.78	-10.43%	15.67	-24.59%	13.20	-15.76%
Sufentanil	0.07	0.05	-22.81%	0.05	-1.44%	0.04	-15.22%

*Estimates based on Jan-Mar 2013 Data

Basic Class: 9250-0

2013 Revised APQ Worksheets

PQ Total(CM+PD): 16,175,370.000

FDA Est: -.064

IMS Est: -.07

Company	DEA Num	2013 MQ Request	2013 MQ	2012 Sales	2012 Total Sales	% of 2012 Sales	Share of 2013 Total PQ	2012 Inventory	2013 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4),(b)(7)(E)		6,421,387.000	6,321,000.000	4,976,800.000	17,835,768.583	0.279	4,513,491.025	3,316,884.000	0.000	2,550,654.332	3,569,179.781
		5,000.000	0.000	0.000	17,835,768.583	0.000	0.000	0.000	0.000	0.000	0.000
		10.000	10.000	2.593	17,835,768.583	0.000	2.343	5.536	0.000	-2.491	-1.962
		390,393.000	223,393.000	26,872.000	17,835,768.583	0.002	24,370.385	62,133.000	0.000	-30,451.500	-24,952.019
		34,700.000	0.000	0.000	17,835,768.583	0.000	0.000	0.000	0.000	0.000	0.000
		67,000.000	0.000	0.000	17,835,768.583	0.000	0.000	0.000	0.000	0.000	0.000
		16,200,000.000	9,904,525.000	9,774,716.000	17,835,768.583	0.548	8,864,751.032	3,635,734.000	13,350.000	7,901,792.341	9,902,233.789
		3,851,000.000	3,551,000.000	3,057,378.000	17,835,768.583	0.171	2,772,755.217	652,225.000	0.000	2,952,356.782	3,578,063.521
MQ Totals:		26,969,490.000	19,999,928.000	17,835,768.583				7,666,981.536	13,350.000	13,374,349.464	

Final Initial APQ:	20,000,000.000		
Proposed Revised:	26,500,000.000	33,125,000.000	with 25% buffer
Final Revised APQ:	0.000		
MQ Need=PQ* 1.6 - Revised MQ - Inventory:	-3,403,854.536	**CFR 50%:**	-2,988,754.890
2012 Initial APQ:	20,000,000.000		
FDA Est = 2012 APQ * (1 + FDA Est):	18,720,000.000		
IMS Est = 2012 APQ * (1 + IMS Est):	18,592,000.000		

Pending

DEA Name	DEA Num	Requested	Previously Granted	Difference
(b)(4),(b)(7)(E)		390,393.00	223,393.000	167,000.000
		16,200,000.00	9,904,525.000	6,295,475.000
Total Pending				6,462,475.00

0

DEA Name	DEA Num	Requested	Granted	ARCOS	2013 Est	30% Inv	Total	Difference
(b)(4);(b)(7)(E)		15,000,000.00	9,904,525.00	4,322,160.566	17,288,642.264	5,186,592.679	22,475,234.943	12,570,709.9432
		6,421,387.00	6,321,000.00	1,422,145.268	5,688,581.072	1,706,574.322	7,395,155.394	1,074,155.3936
		3,851,000.00	3,551,000.00	715,926.952	2,863,707.808	859,112.342	3,722,820.150	171,820.1504
		390,393.00	223,393.00	57,525.770	230,103.080	69,030.924	299,134.004	75,741.0040
		10	10	0.027	0.108	0.032	0.140	-9.8596
TOTALS		25,662,790.00	19,999,928.00	6,517,758.58	26,071,034.33	7,821,310.30	33,892,344.63	13,892,416.63

Est ARCOS sales for PQ
17,910,755.804

Est MQ required to meet PQ ARCOS
26,866,133.706

Current PQ granted
16,621,860.000

Est MQ required to meet granted PQ
24,932,790.000

2012-2013 1st qtr Methadone ARCOS Data
MQ 2013

Request ID	Dea Num	Company	Quota Allotment	ARCOS	2013 Est	30% Inv	Total	Difference
113230	(b)(4);(b)(7)(E)		7,617,869.00	2,547,794.101	10,191,176.404	3,057,352.921	13,248,529.325	5,630,660.325
110954			5,617,134.00	1,221,265.238	4,885,060.952	1,465,518.286	6,350,579.238	733,445.238
113581			2,041,118.00	501,919.432	2,007,677.728	602,303.318	2,609,981.046	568,863.046
113787			546,645.00	0.000	0.000	0.000	0.000	-546,645.000
113912			353,500.00	32,711.786	130,847.144	39,254.143	170,101.287	-183,398.713
111303			189,000.00	4,322,160.566	17,288,642.264	5,186,592.679	22,475,234.943	22,286,234.943
111287			189,000.00	0.000	0.000	0.000	0.000	-189,000.000
114103			15,366.00	0.000	0.000	0.000	0.000	-15,366.000
111074			10,500.00	1,644.720	6,578.880	1,973.664	8,552.544	-1,947.456
113459			8,408.00	4,895.498	19,581.992	5,874.598	25,456.590	17,048.590
114171			7,322.00	2,415.596	9,662.384	2,898.715	12,561.099	5,239.099
112663			6,180.00	161,596.614	646,386.456	193,915.937	840,302.393	834,122.393
110548			3,300.00	670.800	2,683.200	804.960	3,488.160	188.160
114312			2,589.00	646.651	2,586.604	775.981	3,362.585	773.585
112054			2,516.00	275.958	1,103.832	331.150	1,434.982	-1,081.018
115264			2,440.00	0.000	0.000	0.000	0.000	-2,440.000
112793			1,500.00	304.096	1,216.384	364.915	1,581.299	81.299
113825			1,294.00	704.787	2,819.148	845.744	3,664.892	2,370.892
111102			1,245.00	241.488	965.952	289.786	1,255.738	10.738
114184			975	268.320	1,073.280	321.984	1,395.264	420.264
113253			961	1.610	6.440	1.932	8.372	-952.628
112047			869	0.000	0.000	0.000	0.000	-869.000
113892			756	251.818	1,007.272	302.182	1,309.454	553.454
111213			300	30.998	123.992	37.198	161.190	-138.810
111114			300	0.000	0.000	0.000	0.000	-300.000
111152			269	36.721	146.884	44.065	190.949	-78.051
111196			150	9.999	39.996	11.999	51.995	-98.005
111036			100	0.000	0.000	0.000	0.000	-100.000
113877			71	2.147	8.588	2.576	11.164	-59.836
114916			52	0.000	0.000	0.000	0.000	-52.000
111752			25	0.000	0.000	0.000	0.000	-25.000
111270			25	0.000	0.000	0.000	0.000	-25.000
113862			25	0.000	0.000	0.000	0.000	-25.000
111497			10	0.027	0.108	0.032	0.140	-9.860
111992			10	0.000	0.000	0.000	0.000	-10.000
110974			7	0.000	0.000	0.000	0.000	-7.000
113761			5	0.000	0.000	0.000	0.000	-5.000
111548			5	0.000	0.000	0.000	0.000	-5.000
110949			5	0.000	0.000	0.000	0.000	-5.000
114351			3	0.546	2.184	0.655	2.839	-0.161
111185			2	0.000	0.000	0.000	0.000	-2.000
111786			2	0.000	0.000	0.000	0.000	-2.000
113981			2	0.000	0.000	0.000	0.000	-2.000
112574			2	0.000	0.000	0.000	0.000	-2.000
111448			2	0.000	0.000	0.000	0.000	-2.000
111827			1	0.000	0.000	0.000	0.000	-1.000
TOTAL			16,621,860.00	4,477,688.95	17,910,755.80	5,373,226.74	23,283,982.55	6,851,122.55

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

Basic Class: 9254-0

2013 Revised APQ Worksheets

PQ Total(CM+PD): 7,705,055.000

FDA Est:

IMS Est:

Company	DEA Num	2013 MQ Request	2013 MQ	2012 Sales	2012 Total Sales	% of 2012 Sales	Share of 2013 Total PQ	2012 Inventory	2013 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4),(b)(7)(E)		10.000	10.000	0.000	23,904,559.000	0.000	0.000	0.000	0.000	0.000	0.000
		877,000.000	877,000.000	139,508.000	23,904,559.000	0.006	44,987.021	0.000	0.000	58,457.128	91,085.777
		8,600,000.000	8,600,000.000	8,929,140.000	23,904,559.000	0.374	2,878,091.782	522,600.000	0.000	3,218,919.316	5,307,299.727
		150.000.000	0.000	0.000	23,904,559.000	0.000	0.000	0.000	0.000	0.000	0.000
		16,000,000.000	10,791,331.000	10,214,405.000	23,904,559.000	0.427	3,292,365.792	858,064.000	0.000	3,422,011.529	5,810,994.490
		6,080,000.000	4,238,000.000	4,621,506.000	23,904,559.000	0.193	1,489,630.405	803,973.000	0.000	1,132,546.527	2,213,441.507
MQ Totals:		31,707,010.000	24,506,341.000	23,904,559.000				2,184,637.000	0.000	7,831,934.500	

Final Initial APQ:	26,000,000.000		
Proposed Revised:	32,400,000.000	40,500,000.000 with 25% buffer	Increased to match the increase in methadone (9250)
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-15,133,395.500	**CFR 50%:**	-11,083,519.500
2012 Initial APQ:	26,000,000.000		
FDA Est = 2012 APQ * (1 + FDA Est):	26,000,000.000		
IMS Est = 2012 APQ * (1 + IMS Est):	26,000,000.000		

Basic Class: 9300-A

2013 Revised APQ Worksheets

PQ Total(CM+PD): 4,193,200.011

FDA Est:

IMS Est:

Company	DEA Num	2013 MQ Request	2013 MQ	2012 Sales	2012 Total Sales	Sales	Share of 2013 Total PQ	2012 Inventory	2013 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4) (b)(7)(E)		125,000.000	125,000.000	0.000	47,831,774.800	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		159,100.000	158,200.000	82,091.800	47,831,774.800	0.002	7,196.625	54,994.900	0.000	-45,639.288	-25,476.169	0.000
		3,500,000.000	3,500,000.000	1,433,653.000	47,831,774.800	0.030	125,682.014	950.000	3,325,000.000	3,487,436.618	3,839,565.767	0.000
		56,000,000.000	42,285,090.000	34,704,093.000	47,831,774.800	0.726	3,042,354.246	19,670,020.000	0.000	-15,714,959.480	-7,191,053.943	0.000
		1,000.000	1,000.000	0.000	47,831,774.800	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		12,796,000.000	12,796,000.000	11,170,137.000	47,831,774.800	0.234	979,236.476	1,111,683.000	0.000	161,324.419	2,904,896.845	0.000
		2,822,000.000	1,599,975.000	441,800.000	47,831,774.800	0.009	38,730.651	0.000	0.000	50,349.846	156,863.313	0.000
MQ Totals:		75,403,100.000	60,465,265.000	47,831,774.800				20,837,647.900	3,325,000.000	-12,061,487.886		0.000

Final Initial APQ:	83,000,000.000				
Proposed Revised:	73,000,000.000	lowered to reflect trend for past 3 years of MQ granted; will be		91,250,000.000	with 25% buffer
Final Revised APQ:	0.000				
MQ Need=PQ* 1.6 - Revised MQ - Inventory:	-75,013,112.884		CFR 50%:	-64,103,469.186	
2012 Initial APQ:	83,000,000.000				
FDA Est = 2012 APQ * (1 + FDA Est):	83,000,000.000				
IMS Est = 2012 APQ * (1 + IMS Est):	83,000,000.000				

Basic Class: 9668-B

2013 Revised APQ Worksheets

PQ Total(CM+PD): 4,855.000

FDA Est:

IMS Est:

Company	DEA Num	2013 MQ Request	2013 MQ	2012 Sales	2012 Total Sales	% of 2012 Sales	Share of 2013 Total PQ	2012 Inventory	2013 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4),(b)(7)(E)		1,000,000.000	400,000.000	166,804.000	166,807.382	1.000	4,854.902	374,296.000	1,000,000.000	632,015.372	673,473.627
		10.000	10.000	0.242	166,807.382	0.000	0.007	261.541	0.000	-261.532	-261.472
		3,500.000	2,618.000	0.000	166,807.382	0.000	0.000	534.000	0.000	-534.000	-534.000
		3,000.000	1,000.000	3.140	166,807.382	0.000	0.091	0.000	0.000	0.119	0.899
MQ Totals:		1,006,510.000	403,628.000	166,807.382				375,091.541	1,000,000.000	631,219.959	

Final Initial APQ:	407,000.000		
Proposed Revised:	1,010,000.000	1,262,500.000	with 25% buffer
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-771,437.041	**CFR 50%:**	-730,948.946
2012 Initial APQ:	401,000.000		
FDA Est = 2012 APQ * (1 + FDA Est):	401,000.000		
IMS Est = 2012 APQ * (1 + IMS Est):	401,000.000		

Basic Class: 9143-B

2013 Revised APQ Worksheets

PQ Total(CM+PD): 77,119,414.000

FDA Est:

IMS Est: -.038

Company	DEA Num	2013 MQ Request	2013 MQ	2012 Sales	2012 Total Sales	% of 2012 Sales	Share of 2013 Total PQ	2012 Inventory	2013 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4),(b)(7)(E)		5.000	5.000	0.000	78,672,122.708	0.000	0.000	0.020	0.000	-0.020	-0.020
		60.000	60.000	3.998	78,672,122.708	0.000	3.919	803.439	0.000	-798.344	-797.541
		139,000.000	115,835.000	2,936.000	78,672,122.708	0.000	2,878.054	12,187.000	0.000	-8,445.530	-7,855.433
		22,500.000	22,500.000	0.000	78,672,122.708	0.000	0.000	0.000	0.000	0.000	0.000
		3,600,000.000	900,000.000	385,669.000	78,672,122.708	0.005	358,451.991	890,207.000	0.000	-424,219.412	-350,724.762
		1,080,000.000	1,080,000.000	0.000	78,672,122.708	0.000	0.000	0.000	0.000	0.000	0.000
		22,000,000.000	22,000,000.000	18,099,866.000	78,672,122.708	0.230	17,742,638.833	16,073,590.000	0.000	6,991,640.482	10,629,675.041
		65,500,000.000	43,326,873.000	39,262,449.000	78,672,122.708	0.499	38,487,547.493	12,240,264.000	0.000	37,793,547.741	45,684,782.616
		5,000.000	5,000.000	11,190.710	78,672,122.708	0.000	10,969.845	29,325.000	0.000	-15,064.201	-12,815.016
		26,000,000.000	26,000,000.000	20,490,277.000	78,672,122.708	0.260	20,085,871.597	15,657,708.000	5,000,000.000	15,453,925.075	19,572,200.746
		1,078,000.000	565,000.000	439,731.000	78,672,122.708	0.006	431,052.269	140,704.000	0.000	419,663.950	508,044.087
MQ Totals:		119,424,565.000	94,015,273.000	78,672,122.708				45,044,788.459	5,000,000.000	60,210,449.741	76,022,509.718

Final Initial APQ:	105,200,000.000		
Proposed Revised:	123,000,000.000	153,750,000.000	with 25% buffer
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-23,380,940.459	**CFR 50%:**	-22,992,763.282
2012 Initial APQ:	98,000,000.000		
FDA Est = 2012 APQ * (1 + FDA Est):	98,000,000.000		
IMS Est = 2012 APQ * (1 + IMS Est):	94,315,200.000		

Pending

DEA Name	DEA Num	Requested	Previously Granted	Difference	
(b)(4),(b)(7)(E)		3,600,000.00	900,000.000	2,700,000.000	
		65,500,000.00	43,326,873.000	22,173,127.000	Currently approved for remaining APQ, jusitfied for balance 11,000kg
		1,078,000.00	565,000.000	513,000.000	
Total Pending				25,386,127.000	based on this figure APQ could be increased to 119,500,000.000

FDA approved 1 branded and 6 generic oxycodone products for the following companies

(b)(4)

Total oxycodone API granted for this product from the above registants	445.404 kg		
		7,002.000	kg exported in 2012
Total oxycodone API granted for all other pq product development efforts	10,016.589 kg	1,156.000	kg exported 1st qtr 2013
Total oxycodone API granted for previously granted pq commercial efforts	71,463.605 kg		
		There is also – 6,593.000	kg in pending pq requests
Total requirements for granted pq commercial and product development effor	81,925.598 kg		
CFR mandated inventory allowance for bulk manufacturers	50%		
Total APQ required to support MQ without considering manufacturing losses	122,888.397 kg		

Dea Num	Company	Quota Request	Quota Allotment	ARCOS	2013 Est	30% Inv	Total	Difference
(b)(4),(b)(7)(E)		79,000,000.00	43,326,873.00	10,726,042.261	42,904,169.044	12,871,250.713	55,775,419.757	12,448,546.757
		26,000,000.00	26,000,000.00	9,721,752.525	38,887,010.100	11,666,103.030	50,553,113.130	24,553,113.130
		22,000,000.00	22,000,000.00	2,925,518.154	11,702,072.616	3,510,621.785	15,212,694.401	-6,787,305.599
		1,080,000.00	1,080,000.00	0.000	0.000	0.000	0.000	-1,080,000.000
		9,920,000.00	900,000.00	3,530.292	14,121.168	4,236.350	18,357.518	-881,642.482
		644,000.00	565,000.00	161,693.368	646,773.472	194,032.042	840,805.514	275,805.514
		139,000.00	115,835.00	65.963	263.852	79.156	343.008	-115,491.992
		22,500.00	22,500.00	0.000	0.000	0.000	0.000	-22,500.000
		5,000.00	5,000.00	3.139	12.556	3.767	16.323	-4,983.677
		60	60	0.170	0.680	0.204	0.884	-59.116
		5	5	0.000	0.000	0.000	0.000	-5.000

Current Total MQ
94,015,273.00

ARCOS est
94,154,423.488

Possible APQ based on 1st qtr ARCOS sales as year est + 30% inv
122,400,750.534

Difference of est ARCOS total and quota allotment
28,385,477.534

does not consider in process
MQ requests which utilize remaining APQ

Current Total PQ
104,975,452.00

Total PQ ARCOS est
87,260,192.66

Possible MQ required to meet granted PQ
136,468,087.60

Possible MQ required to meet PQ ARCOS est
130,890,289.00

2012-2013 1st qtr Oxycodone ARCOS Data
MQ 2013

Dea Num	Company	Quota Request	Quota Allotment	ARCOS	2013 Est	30% Inv	Total	Difference
(b)(4),(b)(7)(E)		16,417,523.00	16,417,523.00	3,447,926.453	13,791,705.812	4,137,511.744	17,929,217.556	1,511,694.556
		15,500,000.00	12,144,208.00	2,864,129.451	11,456,517.804	3,436,955.341	14,893,473.145	2,749,265.145
		15,662,655.00	10,963,865.00	2,228,885.553	8,915,542.212	2,674,662.664	11,590,204.876	626,339.876
		15,662,665.00	10,963,865.00	3,220,021.200	12,880,084.800	3,864,025.440	16,744,110.240	5,780,245.240
		8,366,327.22	8,366,327.00	2,271,246.406	9,084,985.624	2,725,495.687	11,810,481.311	3,444,154.311
		5,553,000.00	5,099,323.00	1,395,375.323	5,581,501.292	1,674,450.388	7,255,951.680	2,156,628.680
		5,463,000.00	5,099,323.00	1,580,828.092	6,323,312.368	1,896,993.710	8,220,306.078	3,120,983.078
		53,663.00	3,929,359.00	919,751.565	3,679,006.260	1,103,701.878	4,782,708.138	853,349.138
		4,294,000.00	3,314,000.00	5,788.088	23,152.352	6,945.706	30,098.058	-3,283,901.942
		4,294,000.00	3,314,000.00	56,006.060	224,024.240	67,207.272	291,231.512	-3,022,768.488
		3,940,651.00	2,360,865.00	607,815.467	2,431,261.868	729,378.560	3,160,640.428	799,775.428
		2,100,000.00	1,770,024.00	585,642.659	2,342,570.636	702,771.191	3,045,341.827	1,275,317.827
		1,899,797.00	1,701,000.00	7,701.183	30,804.732	9,241.420	40,046.152	-1,660,953.848
		1,659,000.00	1,658,000.00	0.000	0.000	0.000	0.000	-1,658,000.000
		56,137.00	1,384,605.00	1,759.218	7,036.872	2,111.062	9,147.934	-1,375,457.066
		1,323,540.00	1,270,080.00	0.000	0.000	0.000	0.000	-1,270,080.000
		1,311,750.00	1,215,600.00	0.000	0.000	0.000	0.000	-1,215,600.000
		2,361,735.00	1,199,210.00	315,679.031	1,262,716.124	378,814.837	1,641,530.961	442,320.961
		2,419,569.00	1,139,077.00	11,487.751	45,951.004	13,785.301	59,736.305	-1,079,340.695
		1,102,693.00	1,102,693.00	92,169.344	368,677.376	110,603.213	479,280.589	-623,412.411
		2,000,000.00	1,030,887.00	3.139	12.556	3.767	16.323	-1,030,870.677
		963,900.00	963,900.00	858.356	3,433.423	1,030.027	4,463.450	-959,436.550
		1,354,640.40	890,810.00	109,993.285	439,973.142	131,991.942	571,965.084	-318,844.916
		1,265,276.00	736,000.00	66,976.170	267,904.681	80,371.404	348,276.085	-387,723.915
		775,000.00	715,885.00	193,955.577	775,822.307	232,746.692	1,008,568.999	292,683.999
		600,000.00	600,000.00	10,726,042.261	42,904,169.042	12,871,250.713	55,775,419.755	55,175,419.755
		485,230.00	485,230.00	537,353.622	2,149,414.490	644,824.347	2,794,238.837	2,309,008.837
		1,620,000.00	455,000.00	6,675.693	26,702.772	8,010.832	34,713.603	-420,286.397
		369,216.00	369,216.00	45,303.552	181,214.207	54,364.262	235,578.469	-133,637.531
		3,873,380.00	364,000.00	180,230.029	720,920.116	216,276.035	937,196.151	573,196.151
		378,720.00	341,473.00	78,953.796	315,815.185	94,744.555	410,559.740	69,086.740
		315,000.00	315,000.00	933,027.273	3,732,109.093	1,119,632.728	4,851,741.821	4,536,741.821
		417,349.80	298,107.00	45,382.569	181,530.277	54,459.083	235,989.360	-62,117.640
		256,934.00	256,934.00	3,794.625	15,178.500	4,553.550	19,732.050	-237,201.950
		3,873,380.00	244,500.00	282.398	1,129.590	338.877	1,468.467	-243,031.533
		233,122.00	233,122.00	0.000	0.000	0.000	0.000	-233,122.000
		244,235.00	228,757.00	22.861	91.443	27.433	118.876	-228,638.124
		216,670.00	216,670.00	22.377	89.507	26.852	116.359	-216,553.641
		209,500.00	209,500.00	2,925,518.154	11,702,072.618	3,510,621.785	15,212,694.403	15,003,194.403
Snapshot of larger list of registrants		132,356,515.77	104,975,452.00	21,815,048.17	87,260,192.66	26,178,057.80	113,438,250.46	8,462,798.46

(b)(4)

2013 Proposed Adjusted Aggregate Production Quotas

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

- The attached Federal Register notice, prepared for your signature, Proposed Adjustment for calendar year 2013 aggregate production quotas (APQ) for schedules I and II controlled substances and the annual assessment of 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.

- In an effort to prevent potential drug shortage issues, DEA has added 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). DEA learned through meetings with industry that manufacturers do not always maintain the 50% inventory allowance that is permitted and sometimes do not maintain any inventory at all. If a disaster or some other unforeseen event were to occur, there is a strong likelihood that drugs would become unavailable and, if all or most of the quotas had been issued to manufacturers, DEA would not be able to respond quickly because the DEA regulations require public notice and comment for adjustments to the APQ. As such, DEA has determined that an amount of 25% should be adequate to ensure that DEA could immediately respond to such situations and provide sufficient quota to allow continued manufacturing to alleviate potential shortages. The 25% amount is equivalent to one quarter of the year, which is the longer end of the typical manufacturing cycles as communicated to DEA by industry.

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

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

Schedule I substances

- The APQ for the temporarily controlled schedule 1 substances (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), N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48) are proposed in this FR. The manufacturing of these substances will be used for analytical standards, reference, and research material.

- The APQ for 3,4-Methylenedioxymethylamphetamine (MDMA), 4-Methyl-2,5-dimethoxyamphetamine (DOM), psilocybin were increased. 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 tetrahydrocannabinols was increased. This increase is due to a bulk manufacturer changing names and registrations, which requires quota to move physical inventory material to the

new registration plus an allowance to continue manufacturing activities for the remainder of the calendar year.

Schedule II substances

- The APQ for ecgonine was increased due to increased registrant requirements. One DEA registrant was denied legitimate requirements because their requirements exceeded the previously established APQ.

- The APQ for morphine (for conversion) was decreased. The decrease was determined by a review of the requested API quantities and the subsequent granted quotas.

- The APQ for amphetamine (for sale), methadone, methylphenidate, and oxycodone (for sale), were increased due to increased sales. Amphetamine (for sale) manufacturing has high losses due to the isomer isolation, i.e., d-amphetamine from the racemic (d, l-amphetamine) mixture. DEA registered bulk manufacturers of these substances were justified by sales and customer procurement quotas but limited by the current APQ in the quantity of quota they received.

- The APQ for noroxymorphone (for sale) was increased due to increased sales and FDA validation and launch requirements. One DEA registrant is the sole supplier of a product that is under FDA review, the material is required for clinical trials which are being conducted in European countries.

- The APQ for methadone intermediate and phenylacetone were increased due to the increased sales of the controlled substances that utilize them as the starting material. These controlled substances include: amphetamine (for conversion), amphetamine (for sale), lisdexamfetamine, and methadone.

Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Initial	Final Revised	Established	Proposed Revised
Schedule I:	**2011**	**2012**	**2012**	**2013**	**2013**
(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					15
3,4-Methylenedioxymethamphetamine (MDMA)	22	22	30	35	50
4-Methyl-2,5-Dimethoxyamphetamine (DOM)	2	2	12	12	25
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)					15
Psilocybin	2	2	2	2	10
Tetrahydrocannabinols	393,000	393,000	393,000	491,000	705,000

Controlled Substance	Final Revised	Initial	Final Revised	Established	Proposed Revised
Schedule II:	**2011**	**2012**	**2012**	**2013**	**2013**
Amphetamine (for sale)	25,300,000	25,300,000	33,400,000	42,625,000	47,186,000
Ecgonine	83,000	83,000	83,000	127,500	144,000
Methadone (for sale)	20,000,000	20,000,000	23,100,000	25,000,000	33,125,000
Methadone Intermediate	26,000,000	26,000,000	29,970,000	32,500,000	40,500,000
Methylphenidate	56,000,000	56,000,000	64,600,000	80,750,000	82,930,250
Morphine (for conversion)	70,000,000	83,000,000	83,000,000	103,750,000	91,250,000
Noroxymorphone (for sale)	401,000	401,000	1,981,000	508,750	1,262,500
Oxycodone (for sale)	98,000,000	98,000,000	105,200,000	131,500,000	149,375,000
Phenylacetone	8,000,000	16,000,000	16,000,000	20,000,000	29,628,750

Note: 2013 values have a 25% buffer added to the calculated US requirements

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-365]

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 2013

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes to adjust the 2013 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as well as to establish the 2013 aggregate production quotas for three recently temporarily controlled substances.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*. 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-365" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at http://www.regulations.gov for easy reference. Paper comments that duplicate the electronic submission are not necessary and are strongly discouraged as all comments submitted to www.regulations.gov will be posted

for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; Telephone: (202) 307-4654.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

All comments received are considered part of the public record and made available for public inspection online at http://www.regulations.gov and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online or made available in the public docket 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 posted online or made available in the public docket, 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.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

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 through 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104. DEA published the 2013 established aggregate production quotas for controlled substances in schedules I and II and assessment for annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the Federal Register (77 FR 59980) on October 1, 2012. That notice stipulated that, as provided for in 21 CFR 1303.13 and 21 CFR 1315.13, all aggregate production quotas and assessments for annual need are subject to adjustment.

Analysis for Proposed Aggregate Production Quotas for Temporarily Scheduled Substances

On May 16, 2013, the Deputy Administrator issued a final order to temporarily schedule three synthetic cannabinoids in schedule I of the CSA: (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); and N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48). See 78 FR 28735. DEA has received applications for registration and quota for these temporarily scheduled controlled substances. In examining the information provided by the applicants, along with other information, DEA finds that there is a current need for these substances. Aggregate production quotas represent those quantities of schedule I and II controlled substances to be manufactured in the United States in 2013 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. As such, pursuant to 21 U.S.C. 826(a), the Deputy Administrator must determine the total quantity and establish production quotas for each of the three temporarily controlled substances.

In making this determination, the Deputy Administrator has taken into account the criteria that DEA is required to consider in accordance with 21 U.S.C. 826(a) and 21 CFR 1303.11. DEA proposes the aggregate production quotas for these three temporarily controlled substances by considering: (1) total estimated net disposal of each substance by all manufacturers; (2) estimated trends in the national rate of net disposal; (3) total estimated inventories of the basic class and of all substances manufactured from the class; (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 Deputy Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

Analysis for Proposed Revised 2013 Aggregate Production Quotas and Assessment of Annual Needs

DEA proposes to adjust the established 2013 aggregate production quotas for some schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in the United States in 2013 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.

In proposing the adjustment, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine by considering: (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 or individual rates of net disposal are temporary, short term, or long term; (3) whether any increased demand 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 Deputy Administrator finds relevant.

DEA also considered updated information obtained from 2012 year-end inventories, 2012 disposition data submitted by quota applicants, estimates of the medical needs of the United

States, product development, and other information made available to DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors 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 revised 2013 assessment of annual needs, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407, respectively).

As described in the previously published notice establishing the 2013 aggregate production quotas and assessment of annual needs, 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, 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. 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 DEA. DEA does not anticipate utilizing the reserve in the absence

of these circumstances.

The Deputy Administrator, therefore, proposes that the year 2013 aggregate production quotas for the three temporarily scheduled substances be established, and to adjust the 2013 aggregate production quotas for some schedule I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Previously Established 2013 Quotas	Proposed or Proposed Adjusted 2013 Quotas
Temporarily Scheduled Substances		
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	N/A	15 g
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	N/A	15 g
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	N/A	15 g
Schedule I		
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g	No change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g	No change
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g	No change
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g	No change
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g	No change
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g	No change
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g	No change
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g	No change
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g	No change
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g	No change
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g	No change
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g	No change
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g	No change
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g	No change
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g	No change
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	15 g	No change
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	15 g	No change
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	15 g	No change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	15 g	No change

2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	15 g	No change
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	15 g	No change
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	15 g	No change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g	No change
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g	No change
2,5-Dimethoxyamphetamine	12 g	No change
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	15 g	No change
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	15 g	No change
3,4,5-Trimethoxyamphetamine	12 g	No change
3,4-Methylenedioxyamphetamine (MDA)	30 g	No change
3,4-Methylenedioxymethamphetamine (MDMA)	35 g	50 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g	No change
3,4-Methylenedioxy-N-methylcathinone (methylone)	35 g	No change
3,4-Methylenedioxypyrovalerone (MDPV)	25 g	No change
3-Methylfentanyl	2 g	No change
3-Methylthiofentanyl	2 g	No change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g	No change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g	No change
4-Methoxyamphetamine	88 g	No change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g	25 g
4-Methylaminorex	12 g	No change
4-Methyl-N-methylcathinone (mephedrone)	25 g	No change
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g	No change
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g	No change
5-Methoxy-3,4-methylenedioxyamphetamine	12 g	No change
5-Methoxy-N,N-diisopropyltryptamine	12 g	No change
5-Methoxy-N,N-dimethyltryptamine	10 g	No change
Acetyl-alpha-methylfentanyl	2 g	No change
Acetyldihydrocodeine	2 g	No change
Acetylmethadol	2 g	No change
Allylprodine	2 g	No change
Alphacetylmethadol	2 g	No change
Alpha-ethyltryptamine	12 g	No change
Alphameprodine	2 g	No change
Alphamethadol	2 g	No change
Alpha-methylfentanyl	2 g	No change
Alpha-methylthiofentanyl	2 g	No change
Alpha-methyltryptamine (AMT)	12 g	No change
Aminorex	12 g	No change
Benzylmorphine	2 g	No change
Betacetylmethadol	2 g	No change

Beta-hydroxy-3-methylfentanyl	2 g	No change
Beta-hydroxyfentanyl	2 g	No change
Betameprodine	2 g	No change
Betamethadol	2 g	No change
Betaprodine	2 g	No change
Bufotenine	3 g	No change
Cathinone	12 g	No change
Codeine-N-oxide	602 g	No change
Desomorphine	5 g	No change
Diethyltryptamine	12 g	No change
Difenoxin	50 g	No change
Dihydromorphine	3,300,000 g	No change
Dimethyltryptamine	18 g	No change
Gamma-hydroxybutyric acid	46,250,000 g	No change
Heroin	25 g	No change
Hydromorphinol	54 g	No change
Hydroxypethidine	2 g	No change
Ibogaine	5 g	No change
Lysergic acid diethylamide (LSD)	30 g	No change
Marihuana	21,000 g	No change
Mescaline	13 g	No change
Methaqualone	10 g	No change
Methcathinone	14 g	No change
Methyldihydromorphine	2 g	No change
Morphine-N-oxide	655 g	No change
N,N-Dimethylamphetamine	12 g	No change
N-Benzylpiperazine	15 g	No change
N-Ethylamphetamine	12 g	No change
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g	No change
Noracymethadol	2 g	No change
Norlevorphanol	52 g	No change
Normethadone	2 g	No change
Normorphine	18 g	No change
Para-fluorofentanyl	2 g	No change
Phenomorphan	2 g	No change
Pholcodine	2 g	No change
Properidine	2 g	No change
Psilocybin	2 g	10 g
Psilocyn	4 g	No change
Tetrahydrocannabinols	491,000 g	705,000 g
Thiofentanyl	2 g	No change
Tilidine	10 g	No change

Trimeperidine	2 g	No change
Schedule II		
1-Phenylcyclohexylamine	3 g	No change
1-Piperdinocyclohexanecarbonitrile	21 g	No change
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g	No change
Alfentanil	38,250 g	No change
Alphaprodine	3 g	No change
Amobarbital	9 g	No change
Amphetamine (for conversion)	22,875,000 g	No change
Amphetamine (for sale)	42,625,000 g	47,186,000 g
Carfentanil	6 g	No change
Cocaine	240,000 g	No change
Codeine (for conversion)	81,250,000 g	No change
Codeine (for sale)	49,506,250 g	No change
Dextropropoxyphene	19 g	No change
Dihydrocodeine	250,000 g	No change
Diphenoxylate	750,000 g	No change
Ecgonine	127,500 g	144,000 g
Ethylmorphine	3 g	No change
Fentanyl	2,108,750 g	No change
Glutethimide	3 g	No change
Hydrocodone (for sale)	99,625,000 g	No change
Hydromorphone	5,968,750 g	No change
Isomethadone	5 g	No change
Levo-alphacetylmethadol (LAAM)	4 g	No change
Levomethorphan	6 g	No change
Levorphanol	4,500 g	No change
Lisdexamfetamine	21,000,000 g	No change
Meperidine	6,875,000 g	No change
Meperidine Intermediate-A	6 g	No change
Meperidine Intermediate-B	11 g	No change
Meperidine Intermediate-C	6 g	No change
Metazocine	6 g	No change
Methadone (for sale)	25,000,000 g	33,125,000 g
Methadone Intermediate	32,500,000 g	40,500,000 g
Methamphetamine	3,912,500 g	No change
[987,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,863,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)]		
Methylphenidate	80,750,000 g	82,930,250 g
Morphine (for conversion)	103,750,000 g	91,250,000 g

Morphine (for sale)	60,250,000 g	No change
Nabilone	25,628 g	No change
Noroxymorphone (for conversion)	9,000,000 g	No change
Noroxymorphone (for sale)	508,750 g	1,262,500 g
Opium (powder)	91,250 g	No change
Opium (tincture)	1,287,500 g	No change
Oripavine	22,750,000 g	No change
Oxycodone (for conversion)	10,250,000 g	No change
Oxycodone (for sale)	131,500,000 g	153,750,000 g
Oxymorphone (for conversion)	18,375,000 g	No change
Oxymorphone (for sale)	6,875,000 g	No change
Pentobarbital	42,500,000 g	No change
Phenazocine	6 g	No change
Phencyclidine	30 g	No change
Phenmetrazine	3 g	No change
Phenylacetone	20,000,000 g	29,628,750 g
Racemethorphan	3 g	No change
Remifentanil	3,750 g	No change
Secobarbital	215,003 g	No change
Sufentanil	6,255 g	No change
Tapentadol	13,750,000 g	No change
Thebaine	145,000,000 g	No change
List I Chemicals		
Ephedrine (for conversion)	15,100,000 g	No change
Ephedrine (for sale)	3,500,000 g	No change
Phenylpropanolamine (for conversion)	25,700,000 g	No change
Phenylpropanolamine (for sale)	6,100,000 g	No change
Pseudoephedrine (for sale)	225,000,000 g	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 2013 aggregate production quotas and assessment of annual needs as needed.

Comments

Pursuant to 21 CFR 1303.11 and 21 CFR1315.11, 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. In the event the Deputy Administrator decides in his sole discretion to hold such a hearing, the Deputy 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 Deputy Administrator will publish in the Federal Register a Final Order establishing any adjustment of 2013 aggregate production quota for each basic class of controlled substance and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Dated:

Thomas M. Harrigan
Deputy Administrator

OC:_____

OD:_____

OD/D:_____

ODX:_____

ODXS:_____

ODW: _____

ODQ:_____

ODQ: (b)(6) _____ : (b)(6)

Webcims #

(DFN#: 680-03 Drug control files - Manufacturing and Procurement quotas)

INTERNATIONAL TRADE COMMISSION

[USITC SE–13–015]

Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: June 28, 2013 at 11:00 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. 731–TA–1210–1212 (Preliminary) (Welded Stainless Steel Pressure Pipe from Malaysia, Thailand, and Vietnam). The Commission is currently scheduled to transmit its determinations to the Secretary of Commerce on or before July 1, 2013; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on or before July 9, 2013.
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.

Issued: June 18, 2013.

By order of the Commission.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2013–14807 Filed 6–18–13; 11:15 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–365]

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 2013

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes to adjust the 2013 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as well as to establish the 2013 aggregate production quotas for three recently temporarily scheduled substances.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before July 22, 2013. 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–365" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at *http://www.regulations.gov* for easy reference. Paper comments that duplicate the electronic submission are not necessary and are strongly discouraged as all comments submitted to *www.regulations.gov* will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; Telephone: (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

All comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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 posted online or made available in the public docket 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 posted online or made available in the public docket, 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.

Personal identifying information and confidential business information identified and located as set forth above will be redacted, and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

Background

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 through 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104. DEA published the 2013 established 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 in the Federal Register (77 FR 59980) on October 1, 2012. 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.

Analysis for Proposed Aggregate Production Quotas for Temporarily Scheduled Substances

On May 16, 2013, the Deputy Administrator issued a final order to temporarily schedule three synthetic cannabinoids in schedule I of the CSA: (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); and N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48). See 78 FR 28735. DEA has received applications for registration and quota for these temporarily scheduled substances. In examining the information provided by the applicants, along with other information, DEA finds that there is a current need for these substances. Aggregate production quotas represent those quantities of schedule I and II controlled substances to be manufactured in the United States in 2013 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. As such, pursuant to 21 U.S.C. 826(a), the Deputy Administrator must determine the total quantity and establish production quotas for each of the three temporarily scheduled substances.

In making this determination, the Deputy Administrator has taken into account the criteria that DEA is required to consider in accordance with 21 U.S.C. 826(a) and 21 CFR 1303.11. DEA proposes the aggregate production quotas for these three temporarily scheduled substances by considering: (1) Total estimated net disposal of each substance by all manufacturers; (2) estimated trends in the national rate of net disposal; (3) total estimated inventories of the basic class and of all substances manufactured from the class; (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 Deputy Administrator finds relevant. Those quotas do not include imports of controlled substances for use in industrial processes.

Analysis for Proposed Revised 2013 Aggregate Production Quotas and Assessment of Annual Needs

DEA proposes to adjust the established 2013 aggregate production quotas for some schedule I and II controlled substances to be manufactured in the United States in 2013 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. DEA is not proposing to adjust the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine at this time.

In proposing the adjustment, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine by considering: (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 or individual rates of net disposal are temporary, short term, or long term; (3) whether any increased demand 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 Deputy Administrator finds relevant.

DEA also considered updated information obtained from 2012 year-end inventories, 2012 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors 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 revised 2013 assessment of annual needs, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407, respectively).

As described in the previously published notice establishing the 2013 aggregate production quotas and assessment of annual needs, 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, 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. 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 DEA. DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Deputy Administrator, therefore, proposes that the year 2013 aggregate production quotas for the three temporarily scheduled substances be established, and to adjust the 2013 aggregate production quotas for some schedule I and II controlled substances and ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Previously established 2013 quotas	Proposed or proposed adjusted 2013 quotas
Temporarily Scheduled Substances		
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144)	N/A	15 g.
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	N/A	15 g.
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	N/A	15 g.
Schedule I		
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g	No change.
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g	No change.
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g	No change.
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200)	45 g	No change.
1-Butyl-3-(1-naphthoyl)indole (JWH–073)	45 g	No change.
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g	No change.
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g	No change.
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g	No change.
1-Pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678)	45 g	No change.
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g	No change.
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g	No change.
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g	No change.
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g	No change.
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g	No change.
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g	No change.
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	15 g	No change.
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	15 g	No change.
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	15 g	No change.
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	15 g	No change.
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	15 g	No change.
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	15 g	No change.
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	15 g	No change.
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g	No change.
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g	No change.
2,5-Dimethoxyamphetamine	12 g	No change.
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	15 g	No change.
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	15 g	No change.
3,4,5-Trimethoxyamphetamine	12 g	No change.
3,4-Methylenedioxyamphetamine (MDA)	30 g	No change.
3,4-Methylenedioxymethamphetamine (MDMA)	35 g	50 g.
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g	No change.
3,4-Methylenedioxy-N-methylcathinone (methylone)	35 g	No change.
3,4-Methylenedioxypyrovalerone (MDPV)	25 g	No change.
3-Methylfentanyl	2 g	No change.
3-Methylthiofentanyl	2 g	No change.
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g	No change.
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	12 g	No change.
4-Methoxyamphetamine	88 g	No change.
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g	25 g.
4-Methylaminorex	12 g	No change.
4-Methyl-N-methylcathinone (mephedrone)	25 g	No change.
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g	No change.
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47, 497 C8-homolog).	53 g	No change.
5-Methoxy-3,4-methylenedioxyamphetamine	12 g	No change.
5-Methoxy-N,N-diisopropyltryptamine	12 g	No change.
5-Methoxy-N,N-dimethyltryptamine	10 g	No change.
Acetyl-alpha-methylfentanyl	2 g	No change.
Acetyldihydrocodeine	2 g	No change.
Acetylmethadol	2 g	No change.
Allylprodine	2 g	No change.
Alphacetylmethadol	2 g	No change.
Alpha-ethyltryptamine	12 g	No change.
Alphameprodine	2 g	No change.
Alphamethadol	2 g	No change.
Alpha-methylfentanyl	2 g	No change.
Alpha-methylthiofentanyl	2 g	No change.
Alpha-methyltryptamine (AMT)	12 g	No change.
Aminorex	12 g	No change.
Benzylmorphine	2 g	No change.
Betacetylmethadol	2 g	No change.
Beta-hydroxy-3-methylfentanyl	2 g	No change.
Beta-hydroxyfentanyl	2 g	No change.

Basic class	Previously established 2013 quotas	Proposed or proposed adjusted 2013 quotas
Betameprodine	2 g	No change.
Betamethadol	2 g	No change.
Betaprodine	2 g	No change.
Bufotenine	3 g	No change.
Cathinone	12 g	No change.
Codeine-N-oxide	602 g	No change.
Desomorphine	5 g	No change.
Diethyltryptamine	12 g	No change.
Difenoxin	50 g	No change.
Dihydromorphine	3,300,000 g	No change.
Dimethyltryptamine	18 g	No change.
Gamma-hydroxybutyric acid	46,250,000 g	No change.
Heroin	25 g	No change.
Hydromorphinol	54 g	No change.
Hydroxypethidine	2 g	No change.
Ibogaine	5 g	No change.
Lysergic acid diethylamide (LSD)	30 g	No change.
Marihuana	21,000 g	No change.
Mescaline	13 g	No change.
Methaqualone	10 g	No change.
Methcathinone	14 g	No change.
Methyldihydromorphine	2 g	No change.
Morphine-N-oxide	655 g	No change.
N,N-Dimethylamphetamine	12 g	No change.
N-Benzylpiperazine	15 g	No change.
N-Ethylamphetamine	12 g	No change.
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g	No change.
Noracymethadol	2 g	No change.
Norlevorphanol	52 g	No change.
Normethadone	2 g	No change.
Normorphine	18 g	No change.
Para-fluorofentanyl	2 g	No change.
Phenomorphan	2 g	No change.
Pholcodine	2 g	No change.
Properidine	2 g	No change.
Psilocybin	2 g	10 g.
Psilocyn	4 g	No change.
Tetrahydrocannabinols	491,000 g	No change.
Thiofentanyl	2 g	No change.
Tilidine	10 g	No change.
Trimeperidine	2 g	No change.
Schedule II		
1-Phenylcyclohexylamine	3 g	No change.
1-Piperdinocyclohexanecarbonitrile	21 g	No change.
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g	No change.
Alfentanil	38,250 g	No change.
Alphaprodine	3 g	No change.
Amobarbital	9 g	No change.
Amphetamine (for conversion)	22,875,000 g	No change.
Amphetamine (for sale)	42,625,000 g	47,186,000 g.
Carfentanil	6 g	No change.
Cocaine	240,000 g	No change.
Codeine (for conversion)	81,250,000 g	No change.
Codeine (for sale)	49,506,250 g	No change.
Dextropropoxyphene	19 g	No change.
Dihydrocodeine	250,000 g	No change.
Diphenoxylate	750,000 g	No change.
Ecgonine	127,500 g	144,000 g.
Ethylmorphine	3 g	No change.
Fentanyl	2,108,750 g	No change.
Glutethimide	3 g	No change.
Hydrocodone (for sale)	99,625,000 g	No change.
Hydromorphone	5,968,750 g	No change.
Isomethadone	5 g	No change.
Levo-alphacetylmethadol (LAAM)	4 g	No change.
Levomethorphan	6 g	No change.
Levorphanol	4,500 g	No change.
Lisdexamfetamine	21,000,000 g	No change.
Meperidine	6,875,000 g	No change.

Basic class	Previously established 2013 quotas	Proposed or proposed adjusted 2013 quotas
Meperidine Intermediate—A	6 g	No change.
Meperidine Intermediate—B	11 g	No change.
Meperidine Intermediate—C	6 g	No change.
Metazocine	6 g	No change.
Methadone (for sale)	25,000,000 g	33,125,000 g.
Methadone Intermediate	32,500,000 g	40,500,000 g.
Methamphetamine	3,912,500 g	No change.
[987,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,863,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)]		
Methylphenidate	80,750,000 g	96,750,000 g.
Morphine (for conversion)	103,750,000 g	91,250,000 g.
Morphine (for sale)	60,250,000 g	No change.
Nabilone	25,628 g	No change.
Noroxymorphone (for conversion)	9,000,000 g	No change.
Noroxymorphone (for sale)	508,750 g	1,262,500 g.
Opium (powder)	91,250 g	No change.
Opium (tincture)	1,287,500 g	No change.
Oripavine	22,750,000 g	No change.
Oxycodone (for conversion)	10,250,000 g	No change.
Oxycodone (for sale)	131,500,000 g	153,750,000 g.
Oxymorphone (for conversion)	18,375,000 g	No change.
Oxymorphone (for sale)	6,875,000 g	No change.
Pentobarbital	42,500,000 g	No change.
Phenazocine	6 g	No change.
Phencyclidine	30 g	No change.
Phenmetrazine	3 g	No change.
Phenylacetone	20,000,000 g	29,628,750 g.
Racemethorphan	3 g	No change.
Remifentanil	3,750 g	No change.
Secobarbital	215,003 g	No change.
Sufentanil	6,255 g	No change.
Tapentadol	13,750,000 g	No change.
Thebaine	145,000,000 g	No change.
List I Chemicals		
Ephedrine (for conversion)	15,100,000 g	No change.
Ephedrine (for sale)	3,500,000 g	No change.
Phenylpropanolamine (for conversion)	25,700,000 g	No change.
Phenylpropanolamine (for sale)	6,100,000 g	No change.
Pseudoephedrine (for sale)	225,000,000 g	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 2013 aggregate production quotas and assessment of annual needs as needed.

Comments

Pursuant to 21 CFR 1303.11 and 21 CFR 1315.11, 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. In the event the Deputy Administrator decides in his sole discretion to hold such a hearing, the Deputy 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 Deputy Administrator will publish in the **Federal Register** a Final Order establishing any adjustment of 2013 aggregate production quota for each basic class of controlled substance and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Dated: June 14, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013–14723 Filed 6–19–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; Noramco, Inc. (GA)

Pursuant to § 1301.33(a), Title 21 of the Code of Federal Regulations (CFR), this is notice that on March 21, 2012, Noramco, Inc., 1440 Olympic Drive, Athens, Georgia 30601, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of Opium tincture (9630), a basic class of controlled substance listed in schedule II.

The company plans to manufacture the listed controlled substance in bulk for distribution to its customers.

Any other such applicant, and any person who is presently registered with DEA to manufacture such substance,

§ 880.6305 Ingestible event marker.

(a) *Identification.* An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device must be demonstrated to be biocompatible and non-toxic;

(2) Nonclinical, animal, and clinical testing must provide a reasonable assurance of safety and effectiveness, including device performance, durability, compatibility, usability (human factors testing), event recording, and proper excretion of the device;

(3) Appropriate analysis and nonclinical testing must validate electromagnetic compatibility performance, wireless performance, and electrical safety; and

(4) Labeling must include a detailed summary of the nonclinical and clinical testing pertinent to use of the device and the maximum number of daily device ingestions.

Dated: May 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11628 Filed 5–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–373]

Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cannabinoids Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily schedule three synthetic cannabinoids under the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The substances are (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11) and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cannabinoids and their salts, isomers and salts of isomers into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this order, the full effect of the CSA and the Controlled Substances Import and Export Act (CSIEA) and their implementing regulations including criminal, civil and administrative penalties, sanctions and regulatory controls of Schedule I substances will be imposed on the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids.

DATES: *Effective Date:* This Final Order is effective on May 16, 2013.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; telephone (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Background

Section 201 of the CSA (21 U.S.C. 811) provides the Attorney General with the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling up to one year.

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no exemption or approval in effect under section 505 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355) for the substance (21 U.S.C. 811(h)(1)). The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of DEA, who in turn has delegated her authority to the Deputy Administrator of DEA. 28 CFR 0.100, Appendix to Subpart R.

Section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into Schedule I of the CSA.[1] The Deputy Administrator has transmitted notice of his intent to place UR-144, XLR11 and AKB48 in Schedule I on a temporary basis to the Assistant Secretary by letter dated February 14, 2013. The Assistant Secretary responded to this notice by letter dated March 14, 2013 (received by DEA on March 21, 2013), and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for UR-144, XLR11 or AKB48. The Assistant Secretary also stated that HHS has no objection to the temporary placement of UR-144, XLR11 or AKB48 into Schedule I of the CSA. DEA has taken into consideration the Assistant Secretary's comments (21 U.S.C. 811(h)(4)). As UR-144, XLR11 and AKB48 are not currently listed in any schedule under the CSA, and as no exemptions or approvals are in effect for UR-144, XLR11 and AKB48 under Section 505 of the FD&C Act (21 U.S.C. 355), DEA believes that the conditions of 21 U.S.C. 811(h)(1) have been satisfied. On April 12, 2013, a Notice of Intent to temporarily schedule these three synthetic cannabinoids was published in the **Federal Register** (78 FR 21858).

To make a finding that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA (21 U.S.C. 811(h)(3)). These factors are as follows: the substance's history and current pattern of abuse; the scope, duration and significance of abuse, and what, if any, risk there is to the public health. 21 U.S.C. 811(c)(4)–(6). Consideration of these factors includes actual abuse, diversion from legitimate channels and clandestine importation, manufacture or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling (21 U.S.C. 811(h)) may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for

[1] Because the Secretary of the Department of Health and Human Services (HHS) has delegated to the Assistant Secretary for Health of the Department of Health and Human Services the authority to make domestic drug scheduling recommendations, for purposes of this Final Order, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the Controlled Substance Act (CSA), with the concurrence of NIDA. 50 FR 9518.

abuse, no currently accepted medical use in treatment in the United States (U.S.), and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for UR-144, XLR11 and AKB48 indicate that these three synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the U.S., and a lack of accepted safety for use under medical supervision.

Synthetic Cannabinoids

While synthetic cannabinoids have been developed over the last 30 years for research purposes to investigate the cannabinoid system, no scientific literature referring to UR-144, XLR11 or AKB48 was available prior to these drugs' identification in the illicit market. In addition, no legitimate non-research uses have been identified for these synthetic cannabinoids nor have they been approved by FDA for human consumption. Synthetic cannabinoids, of which (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) are representative, are so-termed for their Δ9-tetrahydrocannabinol (THC)-like pharmacological properties. Numerous herbal products have been analyzed, and UR-144, XLR11 and AKB48 have been identified, in varying mixture profiles and amounts, spiked on plant material.

As of April 3, 2013, according to the System to Retrieve Information from Drug Evidence (STRIDE) data, there are 1,510 reports involving 179 total cases for UR-144, 1,194 reports involving 186 total cases for XLR11 and 112 reports involving 40 total cases for AKB48. From January 2010 to March 2013, the National Forensic Laboratory Information System (NFLIS) registered 14,831 reports containing these synthetic cannabinoids (UR-144—5,465 reports; XLR11—8,837 reports; AKB48—529 reports) from at least 32 states. No instances regarding UR-144, XLR11 or AKB48 were reported in NFLIS prior to March of 2010. For the period January 2010 through March 2013, NFLIS and STRIDE reports [2] for the three synthetic cannabinoids UR-144, XLR11 and AKB48 (16,014 total reports) exceeded the number of reports for the five synthetic cannabinoids JWH–018, JWH–073, JWH–200, CP–47,497 and CP–47,497 C8 (7,555 total reports). JWH–018, JWH–200, JWH–073, CP–47,497 and CP–47,497 C8 homologue were temporarily scheduled on March 1, 2011, and later placed in Schedule I by Section 1152 of Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. 112–144, on July 9, 2012. Section 1152 of the FDASIA [3] amended the CSA by placing cannabimimetic agents and 26 specific substances (including 15 synthetic cannabinoids, 2 synthetic cathinones, and 9 phenethylamines of the 2C-series) in Schedule I. UR-144, XLR11 and AKB48 were not included among the 15 specific named synthetic cannabinoids, and do not fall under the definition of cannabimimetic agents, under FDASIA.

Factor 4. History and Current Pattern of Abuse

Synthetic cannabinoids (JWH–018) laced on plant material were first reported in the U.S. in December 2008, when a shipment of "Spice" was seized and analyzed by U.S. Customs and Border Patrol in Dayton, Ohio. Also in December 2008, JWH–018 and cannabicyclohexanol were identified by German forensic laboratories.

Since the initial identification of JWH–018 (December 2008), many additional synthetic cannabinoids with purported psychotropic effects have been found laced on plant material or related products. The popularity of these synthetic cannabinoids and their associated products appears to have increased since January 2010 in the U.S. based on seizure exhibits and media reports. This trend appears to mirror that experienced in Europe since 2008. Synthetic cannabinoids are being encountered in several regions of the U.S. with the substances primarily found as adulterants on plant material products as self-reported on internet discussion boards. Since then, numerous other synthetic cannabinoids including UR-144, XLR11 and AKB48 have been identified as product adulterants.

Data gathered from published studies, supplemented by discussions on Internet Web sites and personal communications with toxicological testing laboratories, demonstrate that products laced with UR-144, XLR11 and/or AKB48 are being abused mainly by smoking for their psychoactive properties. The adulterated products are marketed as 'legal' alternatives to marijuana. This characterization, along with their reputation as potent herbal intoxicants, has increased their popularity. Several synthetic cannabinoids, including UR-144, XLR11 and AKB48, have been shown to display higher potency in scientific studies when compared to THC. Smoking mixtures of these substances for the purpose of achieving intoxication has been identified as a reason for numerous emergency room visits and calls to poison control centers. Abuse of these synthetic cannabinoids and their products has been characterized with both acute and long term public health and safety issues. In addition, numerous states, local jurisdictions, and the international community have controlled these substances.

Factor 5. Scope, Duration and Significance of Abuse

According to forensic laboratory reports, the first appearance of synthetic cannabinoids in the U.S. occurred in December 2008, when U.S. Customs and Border Protection analyzed "Spice" products. NFLIS has reported 14,831 exhibits (January 2010 to March 2013) related to UR-144, XLR11 and AKB48 from various states including Alaska, Alabama, Arkansas, California, Colorado, Florida, Georgia, Iowa, Indiana, Illinois, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, North Dakota, Nebraska, Nevada, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin and Wyoming. STRIDE has reported 2,816 records involving UR-144, XLR11 and/or AKB48 from January 2010 through April 3, 2013. From January 1 through December 31, 2012, the American Association of Poison Control Centers [4] has reported receiving in excess of 5,200 calls relating to products purportedly laced with synthetic cannabinoids. Although the center does not identify specific cannabinoid substances, the data does indicate the magnitude of adverse exposure to synthetic cannabinoids.

Factor 6. What, If Any, Risk There Is to the Public Health

UR-144, XLR11 and AKB48 are pharmacologically similar to Schedule I

[2] National Forensic Laboratory Information System (NFLIS) is a program sponsored by the Drug Enforcement Administration's (DEA), Office of Diversion Control which compiles information on exhibits analyzed in State and local law enforcement forensic laboratories. System to Retrieve Information from Drug Evidence (STRIDE) is a DEA database which compiles information on exhibits analyzed in DEA laboratories.

[3] Subtitle D of Title XI of the Food and Drug Administration Safety and Innovation Act (FDASIA), which includes Sections 1151–1153 of Pub. L. 112–144, is also known as the "Synthetic Drug Abuse Prevention Act of 2012," or "SDAPA."

[4] American Association of Poison Control Centers (AAPCC) is a non-profit, national organization that represents the poison centers of the United States.

substances THC and JWH–018, as well as other synthetic cannabinoids. By sharing pharmacological similarities with the Schedule I substances (THC and JWH–018), synthetic cannabinoids pose a risk to the abuser. In addition, the chronic abuse of products laced with synthetic cannabinoids has also been linked to addiction and withdrawal. Law enforcement, military and public health officials have reported exposure incidents that demonstrate the dangers associated with abuse of synthetic cannabinoids to both the individual abusers and other affected individuals since these substances were never intended for human use. Warnings regarding the dangers associated with abuse of synthetic cannabinoids and their products have been issued by numerous state public health departments, poison control centers and private organizations. In a 2012 report, the Substance Abuse and Mental Health Services Administration (SAMHSA) reported 11,406 emergency department visits involving a synthetic cannabinoid product during 2010. In a 2013 report, SAMHSA reported the number of emergency department visits in 2011 involving a synthetic cannabinoid product had increased 2.5 times to 28,531.

Detailed product analyses have detected variations in the amount and type of synthetic cannabinoid laced on plant material even within samplings of the same product. Since abusers obtain these drugs through unknown sources, purity of these drugs is uncertain, thus posing significant adverse health risk to these users. Submissions to DEA laboratories from January 2012 through February 11, 2013, have documented over 142 distinct packaging examples containing a mixture of UR-144, XLR11 and/or AKB48. These unknown factors present a significant risk of danger to the abuser. Some of the adverse health effects reported in response to the abuse of synthetic cannabinoids include vomiting, anxiety, agitation, irritability, seizures, hallucinations, tachycardia, elevated blood pressure, and loss of consciousness. As mentioned above, there are reported instances of emergency department admissions in association with the abuse of these THC-like substances. There are no recognized therapeutic uses of these substances in the U.S.

In February 2013, the Centers for Disease Control and Prevention published a report by Murphy et al. describing unexplained cases of acute kidney injury in 16 patients, all of whom had reported recent smoking of synthetic cannabinoids. Upon further investigation, it was determined that of the 16 patients, 7 of the subjects had smoked substances that were positive for XLR11 or its metabolite. Cases were reported from Wyoming (4 cases), Rhode Island (1 case), New York (2 cases), Oregon (6 cases), Kansas (1 case) and Oklahoma (2 cases).

Finding of Necessity of Schedule I Scheduling To Avoid Imminent Hazard to Public Safety

Based on the available data and information, the continued uncontrolled manufacture, distribution, importation, exportation and abuse of UR-144, XLR11 and AKB48 pose an imminent hazard to the public safety. DEA is not aware of any currently accepted medical uses for these synthetic cannabinoids in the U.S. A substance meeting the statutory requirements for temporary scheduling (21 U.S.C. 811(h)) may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the U.S., and a lack of accepted safety for use under medical supervision. Available data and information for UR-144, XLR11 and AKB48 indicate that these three synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the U.S., and a lack of accepted safety for use under medical supervision.

Conclusion

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)), the Deputy Administrator has considered available data and information and has set forth herein the grounds for his determination that it is necessary to temporarily schedule three synthetic cannabinoids, (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11) and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) in Schedule I of the CSA and finds that placement of these synthetic cannabinoids into Schedule I of the CSA is warranted in order to avoid an imminent hazard to the public safety.

Because the Deputy Administrator hereby finds that it is necessary to temporarily place these synthetic cannabinoids into Schedule I to avoid an imminent hazard to the public safety, the final order temporarily scheduling these substances will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of up to three years pending completion of the permanent or regular scheduling process.

Regular scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth specific criteria for scheduling a drug or other substance. While temporary scheduling orders are not subject to judicial review (21 U.S.C. 811(h)(6)), the regular scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a permanent scheduling determination. Final decisions which conclude the regular scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877.

Regulatory Requirements

With the issuance of this final order, UR-144, XLR11 and AKB48 become subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, possession, importation and exportation of a Schedule I controlled substance under the CSA and the CSIEA.

1. Registration. Any person who manufactures, distributes, imports, exports, or possesses UR-144, XLR11 or AKB48, or who engages in research or conducts instructional activities with respect to UR-144, XLR11 or AKB48, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with 21 U.S.C. 822 and 957. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration and may not continue their activities until DEA has approved that application. Retail sales of Schedule I controlled substances to the general public are not allowed under the CSA. Possession of any of these substances in a manner not authorized by the CSA on or after May 16, 2013 is unlawful and may subject those in possession of any of these substances to prosecution pursuant to the Controlled Substances Act.

2. Security. UR-144, XLR11 and AKB48 are subject to Schedule I security requirements. Accordingly, appropriately registered DEA registrants must manufacture, distribute and store these substances in accordance with 1301.71; 1301.72(a), (c) and (d); 1301.73; 1301.74; 1301.75(a) and (c); and 1301.76 of Title 21 of the Code of Federal Regulations as of May 16, 2013.

3. Labeling and packaging. All labeling and packaging requirements for controlled substances set forth in Part 1302 of Title 21 of the Code of Federal Regulations shall apply to commercial containers of UR-144, XLR11 and AKB48. Current DEA registrants authorized to handle UR-144, XLR11 and AKB48 shall comply with Part 1302 of Title 21 of the Code of Federal Regulations within thirty (30) calendar days of May 16, 2013.

4. Quotas. Every manufacturer authorized to manufacture UR-144, XLR11 and AKB48 must apply for and be granted a quota to manufacture such substance(s) pursuant to Part 1303 of Title 21 of the Code of Federal Regulations. No authorized manufacturer may manufacture UR-144, XLR11 or AKB48 in excess of a quota assigned to him as of May 16, 2013.

5. Inventory. Every DEA registrant authorized to possess any quantity of UR-144, XLR11 or AKB48 is required to keep inventory of all stocks of these substances on hand pursuant to 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations. Every authorized DEA registrant shall comply with all inventory requirements within thirty (30) calendar days of May 16, 2013.

6. Records. All registrants who are authorized to handle UR-144, XLR11 or AKB48 are required to keep records pursuant to 1304.03, 1304.04, 1304.21, 1304.22 and 1304.23 of Title 21 of the Code of Federal Regulations. Current DEA registrants authorized to handle UR-144, XLR11 or AKB48 shall comply with all recordkeeping requirements within thirty (30) calendar days of May 16, 2013.

7. Reports. All registrants are required to submit reports in accordance with 1304.33 of Title 21 of the Code of Federal Regulations. Registrants who manufacture or distribute UR-144, XLR11 or AKB48 are required to comply with these reporting requirements and shall do so as of May 16, 2013.

8. Order Forms. All registrants involved in the distribution of UR-144, XLR11 or AKB48 must comply with order form requirements of Part 1305 of Title 21 of the Code of Federal Regulations as of May 16, 2013.

9. Importation and Exportation. All importation and exportation of UR-144, XLR11 or AKB48 must be conducted by appropriately registered DEA registrants in compliance with Part 1312 of Title 21 of the Code of Federal Regulations on or after May 16, 2013.

10. Criminal Liability. The manufacture, distribution or possession with the intent to conduct these activities; as well as possession, importation or exportation of UR-144, XLR11 or AKB48 not authorized by, or in violation of the CSA or the Controlled Substances Import and Export Act occurring as of May 16, 2013 is unlawful.

Regulatory Matters

Section 201(h) of the CSA (21 U.S.C. 811(h)) provides for an expedited temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in Schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of a proposed temporary scheduling order is transmitted to the Secretary of HHS. 21 U.S.C. 811(h)(1).

In as much as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) do not apply to this final order. In the alternative, even assuming that this final order might be deemed to be subject to section 553 of the APA, the Deputy Administrator finds that there is good cause to forgo the notice and comment requirements of section 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency of the temporary scheduling action to avoid an imminent hazard to the public safety.

Further, DEA believes that this temporary scheduling action Final Order is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where (as here) the agency is not required by section 553 of the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 "Regulatory Planning and Review," section 3(f), and, accordingly, this action has not been reviewed by the Office of Management and Budget.

This action will not have substantial direct effects on the states, on the relationship between the national government and the states, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 "Federalism" it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act) (5 U.S.C. 801–808), DEA has submitted a copy of this Final Order to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

Under the authority vested in the Attorney General by section 201(h) of the CSA (21 U.S.C. 811(h)), and delegated to the Deputy Administrator of the DEA by Department of Justice regulations (28 CFR 0.100, Appendix to Subpart R), the Deputy Administrator hereby orders that 21 CFR part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Section 1308.11 is amended by adding new paragraphs (h)(9), (10), and (11) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(9) (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers—7144 (Other names: UR–144, 1-pentyl-3-(2,2,3,3-tetramethylcyclopropoyl)indole)

(10) [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts and salts of isomers—7011 (Other names: 5-fluoro-UR-144, 5-F-UR-144, XLR11, 1-(5-fluoro-pentyl)-3-(2,2,3,3-tetramethylcyclopropoyl)indole)

(11) *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts and salts of isomers—7048 (Other names: APINACA, AKB48)

Dated: May 10, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013-11593 Filed 5-15-13; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 5

[Docket No. TTB-2012-0001; T.D. TTB-113; Re: Notice No. 126]

RIN 1513-AB91

Standards of Identity for Pisco and Cognac

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: This final rule amends the Alcohol and Tobacco Tax and Trade Bureau regulations setting forth the standards of identity for distilled spirits to include Pisco as a type of brandy that must be manufactured in accordance with the laws and regulations of either Peru or Chile, as appropriate, governing the manufacture of those products. This final rule also removes "Pisco brandy" from the list of examples of geographical designations in the distilled spirits standards of identity, and it includes a technical correction to remove "Cognac" from the same list of examples. These changes provide greater clarity in distilled spirits labeling.

DATES: *Effective Date:* This final rule is effective July 15, 2013.

FOR FURTHER INFORMATION CONTACT: Karen Welch, Alcohol and Tobacco Tax and Trade Bureau, Regulations and Rulings Division; telephone 202-453-1039, ext. 046; email *ITD@ttb.gov.*

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), codified in the United States Code at 27 U.S.C. 205(e), authorizes the Secretary of the Treasury (Secretary) to prescribe regulations relating to the packaging, marking, branding, labeling, and size and fill of containers of alcohol beverages that will prohibit consumer deception and provide the consumer with adequate information as to the identity and quality of the product. Section 105(e) of the FAA Act also generally requires bottlers and importers of alcohol beverages to obtain certificates of label approval prior to bottling or importing alcohol beverages for sale in interstate commerce. Regulations implementing those provisions of section 105(e) as they relate to distilled spirits are set forth in part 5 of title 27 of the Code of Federal Regulations (27 CFR part 5). The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120-01 (Revised), dated January 21, 2003, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

Certificates of Label Approval

TTB's regulations prohibit the release of bottled distilled spirits from customs custody for consumption unless an approved Certificate of Label Approval (COLA) covering the product has been deposited with the appropriate Customs officer at the port of entry. See 27 CFR 5.51. The TTB regulations also generally prohibit the bottling or removal from a plant of distilled spirits unless the proprietor possesses a COLA covering the labels on the bottle. See 27 CFR 5.55.

Classes and Types of Spirits

The TTB labeling regulations require that the class and type of distilled spirits appear on the product's brand label. See 27 CFR 5.32(a)(2) and 5.35. Those regulations provide that the class and type must be stated in conformity with § 5.22 of the TTB regulations (27 CFR 5.22) if defined therein. Otherwise, the product must be designated in accordance with trade and consumer understanding thereof, or, if no such understanding exists, by a distinctive or fanciful name, and in either case (with limited exceptions), followed by a truthful and adequate statement of composition (see 27 CFR 5.35).

Section 5.22 establishes standards of identity for distilled spirits products and categorizes these products according to various classes and types. As used in § 5.22, the term "class" refers to a general category of spirits, such as "whisky" or "brandy." Currently, there are 12 different classes of distilled spirits recognized in § 5.22, including whisky, rum, and brandy. The term "type" refers to a subcategory within a class of spirits. For example, "Cognac" is a type of brandy, and "Canadian whisky" is a type of whisky.

Brandy and Pisco

Brandy is Class 4 in the standards of identity, where it is defined in § 5.22(d) as "an alcoholic distillate from the fermented juice, mash, or wine of fruit, or from the residue thereof, produced at less than 190° proof in such manner that the distillate possesses the taste, aroma, and characteristics generally attributed to the product, and bottled at not less than 80° proof." "Pisco" is a term recognized by both the governments of Peru and Chile as a designation for a distilled spirits product made from grapes. Generally, Pisco is classified as brandy under the terms of TTB's current labeling regulations. However, Pisco is not currently listed as a type of brandy in Class 4. Rather, "Pisco brandy" has been included in Class 11, at § 5.22(k)(3), as an example of a geographical name that is not a name for a distinctive type of distilled spirits, and that has not become generic.

International Agreements

Pursuant to the United States-Peru Trade Promotion Agreement, the United States recognized Pisco Perú as a distinctive product of Peru (Article 2.12(2) of the Agreement). Accordingly, the United States agreed not to permit the sale of any product as Pisco Perú unless it has been manufactured in Peru in accordance with the laws and regulations of Peru governing Pisco.

In addition, pursuant to the United States-Chile Free Trade Agreement, the United States recognized Pisco Chileno (Chilean Pisco) as a distinctive product of Chile (Article 3.15(2) of the Agreement). Accordingly, the United States agreed not to permit the sale of any product as Pisco Chileno (Chilean Pisco) unless it has been manufactured in Chile in accordance with the laws and regulations of Chile governing the manufacture of Pisco.

In like manner, Peru and Chile agreed, respectively, to recognize Bourbon Whiskey and Tennessee Whiskey (which is defined in both Agreements as a straight Bourbon Whiskey authorized to be produced only in the State of Tennessee), as distinctive products of the United States, and not to permit the sale of any product as Bourbon Whiskey or Tennessee Whiskey unless it has been manufactured in the United States in accordance with the laws and regulations of the United States governing the manufacture of Bourbon Whiskey and Tennessee Whiskey. (TTB notes that there are alternative spellings for the same term—"whisky" in the TTB regulations in 27 CFR part 5 and "whiskey" in the Agreements with Peru and Chile.)

2013 Final Revised APQ AAN Comments and additional applications received during comment period

Comments received as of 7-25-2013:

Drug	Company	Comment	Amount	Response	Proposed APQ	Final APQ	Change
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	(b)(4)	increase APQ	10	APQ adequate, no change	15	15	-
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)		increase APQ	10	APQ adequate, no change	15	15	-
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)		increase APQ	10	APQ adequate, no change	15	15	-
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)		increase APQ	10	APQ adequate, no change	15	15	-
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)		increase APQ	10	APQ adequate, no change	15	15	-
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)		increase APQ	10	APQ adequate, no change	15	15	-
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)		increase APQ	10	APQ adequate, no change	15	15	-
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)		increase APQ	10	APQ adequate, no change	15	15	-
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)		increase APQ	10	APQ adequate, no change	15	15	-
3,4-Methylenedioxymethamphetamine (MDMA)		increase APQ	10	APQ adequate, no change	50	50	-
4-Anilino-N-phenethyl-4-piperidine (ANPP)		increase APQ	267,376	APQ adequate, no change	2,250,000	2,250,000	-
d,l amphetamine		increase APQ	1,852,484	APQ adequate, no change	47,186,000	47,186,000	-
d-amphetamine		increase APQ	42,668				
		increase APQ	1,167,911				
		increase APQ	490,000				
codeine (for conversion)		increase APQ	8,200,132	APQ adequate, no change	81,250,000	81,250,000	-
dihydromorphine		increase APQ	899,110	justified, increase APQ	3,300,000	3,990,000	690,000
diphenoxylate (for sale)		increase APQ	130,000	justified, increase APQ	750,000	887,500	137,500
gamma hydroxybutric acid		increase APQ	19,868,990	justified, increase APQ	46,250,000	67,500,000	21,250,000
hydrocodone		increase APQ	8,126,914	APQ adequate, no change	99,625,000	99,625,000	-
hydromorphone		increase APQ	40,000	justified, increase APQ	5,968,750	6,750,000	781,250
		increase APQ	391,537				
levomethorphan		increase APQ	150	justified, increase APQ	6	195	189
methadone		increase APQ	1,250,000	APQ adequate, no change	33,125,000	33,125,000	-
		increase APQ	3,895,475				
methadone intermediate		increase APQ	800,000	APQ adequate, no change	40,500,000	40,500,000	-
		increase APQ	3,415,010				
methylphenidate		increase APQ	2,421,780	APQ adequate, no change	96,750,000	96,750,000	-
morphine (for conversion)		increase APQ	1,900,000	APQ adequate, no change	91,250,000	91,250,000	-
morphine (for sale)		increase APQ	689,045	justified, increase APQ	60,250,000	61,125,000	875,000
oxycodone (for sale)		increase APQ	22,250,127	APQ adequate, no change	153,750,000	153,750,000	-
		increase APQ	80,000				
		increase APQ	169,000				
oripavine		increase APQ	1,955,556	APQ adequate, no change	22,750,000	22,750,000	-
oxymorphone (for conversion)		increase APQ	700,000	APQ adequate, no change	18,375,000	18,375,000	-
		increase APQ	1,800,000				
oxymorphone (for sale)		increase APQ	180,000	justified, increase APQ	6,875,000	7,000,000	125,000
		increase APQ	538,378				
phenylacetone		increase APQ	10,500,000	justified, increase APQ	29,628,750	42,393,750	12,765,000
sufentanil		increase APQ	469	justified, increase APQ	6,255	6,880	625

Number of Companies commenting: 6

Number of drugs commented on: 31

30 30

Additional Considerations:

Drug	Consideration	Proposed	Revised	Change
gamma hydroxybutric acid	(b)(4) submitted requests on 7/3 & 7/16/13 for establishment of quota 2,454,380g for product development	see comment	see comment	table
heroin	(b)(4) submitted requests on 7/17/13 for the establishment of 8g of quota	25	25	-
hydromophone	(b)(4) submitted request on 7/8/13 for increase of 192,225g to granted quota	see comment	see comment	table
methadone	(b)(4) submitted request on 7/3/13 for increase of 167,000 g to granted quota	see comment	see comment	table
noroxymorphone (for sale)	(b)(4) submitted request on 7/3/13 increase of 48,000 to granted quota	1,262,000	1,262,000	-
psilocybin	(b)(4) submitted requests on 7/16/13 for the establishment of 5g of quota	10	10	-
psilocyn	(b)(4) submitted requests on 7/16/13 for increase of 7g to granted quota	4	12	8

prepared by ODEQ on 7-25-2013

Controlled Substance	Justification
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	(b)(4) just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
3,4-Methylenedioxymethamphetamine (MDMA)	(b)(4) denied previously; reapplication request considered in the proposed revised APQ
4-Anilino-N-phenethyl-4-piperidine (ANPP)	(b)(4) request for 267kg; available in APQ
d,l amphetamine	(b)(4) requests 1853kg - analysis grants 0kg - ARCOS issues to be resolved first; (b)(4) request 43kg; APQ sufficient
d-amphetamine	requests 1168kg - analysis grants 0kg - ARCOS issues to be resolved first; request 490kg - grant same; APQ sufficient
codeine (for conversion)	(b)(4) requests 8200kg; APQ sufficient
dihydromorphine	requests 900kg - grant 700kg; APQ adjusted to provide grant amount
diphenoxylate (for sale)	requests 130kg based on ytd sales - grant same; APQ adjusted to provide grant amount
gamma hydroxybutric acid	(b)(4) requests total APQ; (b)(4) requests product development efforts; APQ adjusted to provide inventory to (b)(4)
heroin	(b)(4) equest based on demands of diagnostic test kits sales
hydrocodone	(b)(4) request 8127kg ; APQ sufficient to consider granting
hydromorphone	(b)(4) - analysis grants 0 - available in APQ
levomethorphan	(b)(4) request based on new customer demand; APQ adjusted to meet new demand
methadone	(b)(4) requests were considered in proposed revised APQ
methadone intermediate	requests were considered in proposed revised APQ
methylphenidate	(b)(4) requests 2422kg; proposed revised APQ sufficient
morphine (for conversion)	(b)(4) requests 1900kg; proposed revised APQ sufficient
morphine (for sale)	requests 689kg; APQ revised to include new request
noroxymorphone (for sale)	(b)(4) request 48kg for clinical trials - already considered in proposed revised APQ
oxycodone (for sale)	(b)(4) requests based on previous limitation of APQ; (b)(4) request 80kg; proposed revised APQ is sufficient
oripavine	(b)(4) request 1956kg; APQ sufficient to consider granting

prepared by ODEQ on 7-25-2013

Controlled Substance	Justification
oxymorphone (for conversion)	(b)(4) request 1064kg- analysis grants same; (b)(4) request 2920kg - analysis grants 1372kg; already considered in proposed revised APQ
oxymorphone (for sale)	request 2995kg - analysis grants 2537kg; increase APQ
psilocybin	(b)(4) just received drug code on bulk manufacturer registration - ref stds; APQ sufficient
psilocyn	just received drug code on bulk manufacturer registration - ref stds; APQ adjusted to meet new demand
phenylacetone	(b)(4) requests 10,500kg to move import to registration and bulk manufacter - no request submitted; APQ adjusted for (b)(4)
sufentanil	(b)(4) request based on sales ytd

2013 Final Revised APQ AAN table of changes

Drug	Proposed APQ	Final APQ	Change
dihydromorphine	3,300,000	3,990,000	690,000
diphenoxylate (for sale)	750,000	887,500	137,500
gamma hydroxybutric acid	46,250,000	67,500,000	21,250,000
hydromorphone	5,968,750	6,750,000	781,250
levomethorphan	6	195	189
morphine (for sale)	60,250,000	61,125,000	875,000
oxymorphone (for sale)	6,875,000	7,000,000	125,000
phenylacetone	29,628,750	42,393,750	12,765,000
psilocyn	4	12	8
sufentanil	6,255	6,880	625

Chemical	Proposed AAN	Final AAN	Change
ephedrine (for sale)	3,500,000	4,200,000	700,000
phenylpropanolamine (for conversion)	25,700,000	44,800,000	19,100,000
pseudoephedrine (for sale)	225,000,000	246,000,000	21,000,000

2012 - 2013 hist[illegible] of MQ v APQ

Drug	2012 Final APQ	2012 Final MQ	Remaining APQ		2013 Final APQ	2013 current MQ	Pending Requests
dihydromorphine	3,750,000	3,742,310	(7,690)		3,990,000	3,742,310	899,110
diphenoxylate (for sale)	900,000	879,000	(21,000)		887,500	579,302	130,000
gamma hydroxybutric acid	37,000,000	26,118,435	(10,881,565)		67,500,000	32,948,209	49,784,300
hydromorphone	4,207,000	4,236,630	29,630		6,750,000	4,455,715	431,537
levomethorphan	10	5	(5)		195	2	150
morphine (for sale)	48,200,000	48,175,305	(24,695)		61,125,000	48,179,273	689,045
oxymorphone (for sale)	5,500,000	5,412,981	(87,019)		7,000,000	4,878,867	718,378
phenylacetone			-		42,393,750		10,500,000
psilocyn	2	2	-		12	4	7
sufentanil	6,730	6,227	(503)		6,880	4,993	469

Proposed Adjustments to the Aggregate Production Quotas for Scheduled I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2013

SUMMARY OF COMMENTS

Document DEA-2013-0005-DRAFT-0002

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

Methadone (for sale)

Rationale: previously denied an increase due to limitations in APQ; approx. 27% manufacturing loss combined with increased sales volumes

Quota Application Reference Numbers provided [copies requested from ODQ on July 17 by e-mail to (b)(6)

Document DEA-2013-0005-DRAFT-0003

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

Methadone Intermediate

Rationale: all methadone intermediate that is produced is consumed in-house to produce methadone hydrochloride; tied directly to methadone (for sale) quota

Document DEA-2013-0005-DRAFT-0004

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

Gamma Hydroxybutyric Acid

Rationale: increase to 48,456,300g to meet demand of (b)(4);(b)(6) – to meet commercial requirements and maintain sufficient inventory levels; some material was destroyed or is planned for destruction based on 2012 material quality issues

Document DEA-2013-0005-DRAFT-0005

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

Oxycodone

Rationale: plans to qualify a new source of thebaine (Tasmanian alkaloids); one full batch will consume 165 kg of thebaine and 157 kg of oxycodone quota; the five batch campaign will require 785 kg of oxycodone quota; request increase of 169,000g

Document DEA-2013-0005-DRAFT-0006

(b)(4),(b)(6),(b)(7)(E)

Thebaine, Oripavine, Oxycodone for Sale, Oxymorphone for Conversion

Rationale: Aggregate increase based on (b)(4) customer demand, in accordance with pending quota requests (PQ Ref. # 116609 (Thebaine) & 116611 (Oripavine); MQ Ref. # 116610 (Oxycodone for Sale) & 116612 (Oxymorphone for Conversion))

Document DEA-2013-0005-DRAFT-0007

(b)(4),(b)(6)

2C-P; 2C-E; 2C-D; 2C-N; 2C-H; 2C-C; 2C-I; 2C-T-2; 2C-T-4; MDMA; Levomethorphan

Rationale: Increase of 2C phenethylamines to provide for initial quota as (b)(4) only recently became registered to handle the substances; increase MDMA to address previous request that was denied due to lack of available APQ; increase levomethorphan to accommodate a new customer's request for bulk synthesis

Document DEA-2013-0005-DRAFT-0008

(b)(4),(b)(6),(b)(7)(E)

Phenylacetone

Rationale: Increase to accommodate domestic production to replace foreign manufacturer that provides imports

Document DEA-2013-0005-DRAFT-0009

(b)(4),(b)(6),(b)(7)(E)

Gamma Hydroxybutyric Acid (Revised)

Rationale: Increase to 49,784,300g to meet demand of (b)(4)

Document DEA-2013-0005-DRAFT-0010

(b)(4),(b)(6)

ANPP; d,l-amphetamine (for sale); d-amphetamine (for sale); codeine (for conversion); dihydromorphine; diphenoxylate; hydrocodone; hydromorphone; methadone intermediate; methadone; methylphenidate; oripavine; oxymorphone (for sale); oxymorphone (for conversion); sufentanil

Rationale: increases to provide for sufficient quantities to include (b)(4) requests

Quota Application Reference Numbers provided [copies requested from ODQ on July 23 by e-mail to (b)(6)

Document DEA-2013-0005-DRAFT-0011

(b)(4),(b)(6)

Amphetamine (for sale) increase by 3,021,395g [D.L-Amphetamine (for sale) by 1,853,484g; D-Amphetamine (for sale) by 1,167,911g]; Morphine (for conversion) by 1,900,000g; Morphine (for sale) by 689,045g

Rationale: Some requests were submitted – increases to cover manufacturing needs

Document DEA-2013-0005-DRAFT-0012

(b)(4),(b)(6)

Hydromorphone by 40,000g; Oxycodone by 80,000g; Oxymorphone by 180,000g

Rationale: Some requests were submitted – increases to cover manufacturing needs

PUBLIC SUBMISSION

As of: July 23, 2013
Received: July 18, 2013
Status: Pending_Post
Tracking No. 1jx-86j2-6qjq
Comments Due: July 22, 2013
Submission Type: Web

Docket: DEA-2013-0005
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 2013

Comment On: DEA-2013-0005-0001
Proposed Adjustments to the 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 2013

Document: DEA-2013-0005-DRAFT-0007
Comment on FR Doc # N/A

Submitter Information

Address:
(b)(4)
Email: (b)(4),(b)(6)
Phone:
Fax: (b)(4),(b)(6)
Organization: (b)(4)

General Comment

See attached file(s)

Attachments

(b)(4) fedreg comment 07182013

CONFIDENTIAL

(b)(4)

18 July 2013

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

Subject: Comment on Proposed Adjustment to 2013 Aggregate Production Quotas
Docket No. DEA-365

Dear Sir/Madam:

(b)(4) is submitting this comment in reference to the Proposed Adjustment to the 2013 Aggregate Production Quotas (APQs) published in the Federal Register under citation Vol. 78, No. 119, pages 37237-37241, dated 30 June 2013. This is Docket No. DEA-365. This comment is CONFIDENTIAL BUSINESS INFORMATION and relates to eleven controlled substances. We request that portions of this comment highlighted below be redacted.

For nine of the substances (all 2 C phenethylamines) (b)(4) only recently became registered as a bulk manufacturer of the substances. Therefore, no manufacturing quota applications were submitted during the annual application period in early 2012. On June 6, 2013, (b)(4) submitted applications for initial quotas for the nine drug classes following approval of it bulk manufacturing application for the substances. However, no response has been received as of this, so it is unclear as to whether there is sufficient APQ to issue in response to our applications. Therefore, (b)(4) is submitting this comment to request that the APQ for these nine substances (listed below) be revised as required to allow for issuance of 10 gram initial quotas to (b)(4) for these drug classes.

Additionally, on February 4, 2013, (b)(4) submitted an application to increase its 2013 manufacturing quota for 3,4-Methylenedioxymethamphetamine (MDMA) by 10 grams. That application was denied on February 27, 2013 due to the limitation of the currently established APQ for MDMA. Therefore, (b)(4) is submitting this comment to request that the APQ for MDMA be revised to allow for a 10 gram increase of (b)(4) MDMA manufacturing quota for 2013. Information regarding why this increase is needed was provided on the February 4th revision application.

Finally, (b)(4) is currently in negotiations with one of its customers to provide a bulk synthesis of Levomethorphan. (b)(4) has a Letter of Intent from the customer indicating their intent to enter into a Purchase Order agreement with (b)(4) for the manufacture of this substance. A copy of that Letter of Intent can be provided upon request. The Purchase Order agreement will be executed at a later date. The Letter of intent is for (b)(4) to deliver a

(b)(4)

(b)(4)

(b)(4)

minimum of 80 grams of Levomethorphan. However, more could be delivered if enough material is produced that meets the customer's specification. Therefore, (b)(4) is submitting this comment to request that the APQ for Levomethorphan be revised to allow for a 150 gram increase to (b)(4) Levomethorphan manufacturing quota for 2013. That quantity will cover both the deliverable quantity for the customer and any non-specification material produced during the synthetic process. The quantity of non-specification material to be produced during this project is unknown at this point due to uncertainty in the production yield for synthesis at this scale.

Also, it should be pointed out that it is unknown when the APQ will be revised (assuming that it will), how long it will take obtain a revised procurement quota necessary to purchase the required quantity of the starting material needed for the synthesis, and how long the actual production time to complete the synthesis will take. Therefore, it is unclear as to whether there ultimately will be sufficient time to produce the final substance in 2013. Because of that, (b)(4) plans to submit a similar comment in response to the proposed initial 2014 APQ for this drug class to cover the eventuality that the final product cannot be obtained in 2013.

Based on this information, (b)(4) requests that the 2013 aggregate production quotas for the following eleven substances be adjusted as needed to ensure that (b)(4) anticipated requirement in the amounts listed below are covered:

2-[2,5-Dimethoxy-4-(n)-propylphenyl]ethanamine [2C-P]	10 g
2-[2,5-Dimethoxy-4-ethylphenyl]ethanamine [2C-E]	10 g
2-[2,5-Dimethoxy-4-methylphenyl]ethanamine [2C-D]	10 g
2-[2,5-Dimethoxy-4-nitro-phenyl]ethanamine [2C-N]	10 g
2-[2,5-Dimethoxyphenyl]ethanamine [2C-H]	10 g
2-[4-Chloro-2,5-dimethoxyphenyl]ethanamine [2C-C]	10 g
2-[4-Iodo-2,5-dimethoxyphenyl]ethanamine [2C-I]	10 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine [2C-T-2]	10 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine [2C-T-4]	10 g
3,4-Methylenedioxymethamphetamine [MDMA]	10 g
Levomethorphan	150 g

Please contact me at (b)(4),(b)(6) if you have any questions regarding this comment.

Sincerely,

(b)(6)

Vice President
Regulatory Affairs

(b)(4)

(b)(4)

PUBLIC SUBMISSION

As of: July 24, 2013
Received: July 24, 2013
Status: DoNotPost
Tracking No. 1jx-86n2-r1s7
Comments Due: July 22, 2013
Submission Type: Unknown

Docket: DEA-2013-0005
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 2013

Comment On: DEA-2013-0005-0001
Proposed Adjustments to the 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 2013

Document: DEA-2013-0005-DRAFT-0012
DEA-2013-0005-0012

Submitter Information

General Comment

Attachments

DEA-2013-0005-0012

CONFIDENTIAL

July 19, 2013

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

Subject: Docket No. DEA-365

Dear Sirs:

I, (b)(4),(b)(6) manufacturing registration (b)(4),(b)(7)(E) am submitting this comment on the Proposed Aggregate 2013 Production Quota for various products as published in the June 20, 2013 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) Hydromorphone by 40,000 grams as base; (ii) Oxycodone by 80,000 grams as base; and (iii) Oxymorphone by 180,000 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 several of the items, quota requests were submitted and we are awaiting a response from the Agency. For the remaining 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: July 24, 2013
Received: July 23, 2013
Status: DoNotPost
Tracking No. 1jx-86n2-j79l
Comments Due: July 22, 2013
Submission Type: Paper

Docket: DEA-2013-0005
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 2013

Comment On: DEA-2013-0005-0001
Proposed Adjustments to the 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 2013

Document: DEA-2013-0005-DRAFT-0011
DEA-2013-0005-0011

Submitter Information

General Comment

Attachments

DEA-2013-0005-0011

CONFIDENTIAL

July 19, 2013

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

Subject: Docket No. DEA-365

Dear Sirs:

I, (b)(4),(b)(6) manufacturing registration (b)(4),(b)(7)(E) am submitting this comment on the Proposed Aggregate 2013 Production Quota for various products as published in the June 20, 2013 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) Amphetamine (for sale) by 3,021,395 grams as base [D,L-Amphetamine (for sale) by 1,853,484 grams as base and D-Amphetamine (for sale) by 1,167,911 grams as base]; (ii) Morphine (for conversion) by 1,900,000 grams as base; and (iii) Morphine (for sale) by 689,045 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 several of the items, quota requests were submitted and we are awaiting a response from the Agency. For the remaining 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: July 23, 2013
Received: July 22, 2013
Status: Pending_Post
Tracking No. 1jx-86lw-lvwu
Comments Due: July 22, 2013
Submission Type: Web

Docket: DEA-2013-0005
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 2013

Comment On: DEA-2013-0005-0001
Proposed Adjustments to the 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 2013

Document: DEA-2013-0005-DRAFT-0010
Comment on FR Doc # N/A

Submitter Information

Name: (b)(6)
Address:
(b)(4)
Email: (b)(4),(b)(6)
Phone: (b)(4),(b)(6)
Fax: (b)(4),(b)(6)
Organization: (b)(4)

General Comment

The attached letter constitutes (b)(4) comments on the Proposed Revised Aggregate Production Quotas for 2013, as published in Federal Register on Thursday June 20, 2013, FR Volume 78, No. 119, pages 37237-37241.

Attachments

(b)(4) Comment to Docket No. DEA-365

(b)(4)

July 22, 2013

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

Attn: DEA Federal Register Representative [Docket No. DEA-365]

This letter constitutes (b)(4) comments on the Proposed Revised Aggregate Production Quotas for 2013, as published in Federal Register on Thursday June 20, 2013, FR Volume 78, No. 119, pages 37237-37241.

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, 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-piperidine (ANPP)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 1,360,000 g AA of ANPP manufacturing quota for 2013, reference DEA online submission 116642.

1100 (A) d,l-Amphetamine (for Sale)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 290,000 g AA of d,l-amphetamine (for sale) manufacturing quota for 2013, reference DEA online submission number 116095. Total Amphetamine is 780,000 g

1100 (B2) d-Amphetamine (for Sale)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 490,000 g AA of d-amphetamine (for sale) manufacturing quota for 2013, reference DEA online submission number 116460.

9050 Codeine (for Conversion)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 30,000,000 g AA of codeine (for conversion) manufacturing quota for 2013, reference DEA online submission number 116637.

(b)(4)

Attn: DEA Federal Register Representative [Docket No. DEA-365]

9145 Dihydromorphine

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 2,800,000 g AA of dihydromorphine manufacturing quota for 2013, reference DEA online submission number 116537.

9170 Diphenoxylate

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 700,000 grams of diphenoxylate manufacturing quota for 2013, reference DEA online submission number 116640.

9193 Hydrocodone

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 27,000,000 g AA of hydrocodone manufacturing quota for 2013, reference DEA online submission number 116638.

9150 Hydromorphone

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 1,380,000 g AA of hydromorphone manufacturing quota for 2013, reference DEA online submission number 116538.

9254 Methadone Intermediate

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 15,700,000 g AA of methadone intermediate manufacturing quota for 2013, reference DEA online submission 116526.

9250 Methadone

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 13,800,000 g AA of methadone manufacturing quota for 2013, reference DEA online submission 116527.

1724 Methylphenidate

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 13,300,000 g AA of methylphenidate manufacturing quota for 2013, reference DEA online submission 116636.

9330 Oripavine

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 10,400,000 g AA of oripavine manufacturing quota for 2013, reference DEA online submission 116643.

(b)(4)

Attn: DEA Federal Register Representative [Docket No. DEA-365]

9652 (B) Oxymorphone (for Sale)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 3,400,000 g AA of oxymorphone (for sale) manufacturing quota for 2013, reference DEA online submission 116641.

9652 (A) Oxymorphone (for Conversion)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 9,400,000 g AA of oxymorphone (for conversion) manufacturing quota for 2013, reference DEA online submission 116644.

9740 Sufentanil

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 2,800 g AA of sufentanil manufacturing quota for 2013, reference DEA online submission 116639.

All of the other (b)(4) quotas remain unchanged at this time.

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

(b)(4),(b)(6)

(b)(4),(b)(6)

supplement to requests

(b)(4)

July 22, 2013

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

RE: **2013 Revised Aggregate Quota Requests for** (b)(4),(b)(7)(E)

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

8333 4-Anilino-N-phenethyl-4-piperidine (ANPP)
(b)(4) requests 267,376 grams AA of additional dihydromorphine manufacturing quota for 2013 (Reference # 116642 on July 22, 2013). With the 1,092,624 grams already granted, the total is 1,360,000 grams.

1100 (A) d,l-Amphetamine
(b)(4) requests 42,668 grams AA of additional d,l-amphetamine manufacturing quota for 2013 (Reference # 116095 on May 2, 2013). With the 247,332 grams already granted the total is 290,000 grams. The original request for 780,000 grams was divided between the two isomers.

1100 (B2) d-Amphetamine
(b)(4) requests 490,000 grams AA of d-amphetamine manufacturing quota for 2013 (Reference # 116460 on June 13, 2013). This is a new quota.

9050 Codeine (for Conversion)
(b)(4) requests 8,200,132 grams AA of additional codeine (for conversion) manufacturing quota for 2013 (Reference # 116637 on July 22, 2013). With the 21,799,868 grams already granted, the total is 30,000,000 grams.

9145 Dihydromorphine
(b)(4) requests 899,110 grams AA of additional dihydromorphine manufacturing quota for 2013 (Reference # 116537 on July 3, 2013). With the 1,900,890 grams already granted, the total is 2,800,000 grams.

(b)(4)

RE: 2013 Revised Aggregate Quota Requests for (b)(4) (b)(7)(E)

9170 Diphenoxylate

(b)(4) requests 130,000 grams AA of additional dihydromorphine manufacturing quota for 2013 (Reference # 116640 on July 22, 2013). With the 470,000 grams already granted, the total is 700,000 grams. math error?

470
+130
600

9193 Hydrocodone

(b)(4) requests 8,126,914 grams AA of additional hydrocodone manufacturing quota for 2013 (Reference # 116638 on July 22, 2013). With the 18,873,086 grams already granted, the total is 27,000,000 grams.

9150 Hydromorphone

(b)(4) requests 391,537 grams AA of additional hydromorphone manufacturing quota for 2013 (Reference # 116538 on July 3, 2013). With the 988,463 grams already granted, the total is 1,380,000 grams.

9254 Methadone Intermediate

(b)(4) requests 3,415,010 grams AA of additional methadone intermediate manufacturing quota for 2013 (Reference # 116526 on July 2, 2013). With the 12,284,990 grams already granted, the total is 15,700,000 grams.

9250 Methadone

(b)(4) requests 3,895,475 grams AA of methadone manufacturing quota for 2013 (Reference # 116527 on July 2, 2013). With the 9,904,525 grams already granted, the total is 13,800,000 grams.

1724 Methylphenidate

(b)(4) requests 2,421,780 grams AA of methylphenidate manufacturing quota for 2013 (Reference # 116636 on July 22, 2013). With the 10,878,220 grams already granted, the total is 13,300,000 grams.

9330 Oripavine

(b)(4) requests 1,955,556 grams AA of additional oripavine manufacturing quota for 2013 (Reference # 116643 on July 22, 2013). With the 8,444,444 grams already granted, the total is 10,400,000 grams.

9652 (B) Oxymorphone (for Sale)

(b)(4) requests 538,378 grams AA of additional oxymorphone (for sale) manufacturing quota for 2013 (Reference # 116641 on July 22, 2013). With the 2,861,622 grams already granted, the total is 3,400,000 grams.

(b)(4)

RE: 2013 Revised Aggregate Quota Requests for (b)(4),(b)(7)(E)

9652 (A) Oxymorphone (for Conversion)

(b)(4) requests 1,800,000 grams AA of additional oxymorphone (for conversion) manufacturing quota for 2013 (Reference # 116644 on July 22, 2013). With the 7,600,000 grams already granted, the total is 9,400,000 grams.

9740 Sufentanil

(b)(4) requests 469 grams AA of additional sufentanil manufacturing quota for 2013 (Reference # 116639 on July 22, 2013). With the 2,331 grams already granted, the total is 2,800 grams.

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

(b)(4),(b)(6)

(b)(4),(b)(6)

No comment - Supplemental request

(b)(4)

July 3, 2013

Christine A. Sannerud, Chief
Quota and UN Reporting Section
DEA Office of Diversion Control
8701 Morrissette Drive
Springfield, VA 22152

Re: Supplemental Information for:

- (b)(4) **Hydromorphone (Ref#116538) and Dihydromorphine (Ref#116537) Manufacturing Quota Requests for** (b)(4) (b)(4),(b)(7)(E)
- **Hydromorphone (Ref#116530) for Procurement Quota Requests for** (b)(4),(b)(7)(E)

Dear Dr. Sannerud:

This packet is submitted for DEA review as supplemental information related to the following previously submitted quota increase requests.

DEA Registration #	Product	Drug Code	Quantity (g)	Date Submitted	DEA Online Reference
(b)(4),(b)(7)(E)	Hydromorphone	9150	1,380,000	07/03/13	116538
	Dihydromorphine	9145	2,800,000	07/03/13	116537
	Hydromorphone	9150	656,284	07/02/13	116530

(b)(4)

(b)(4)

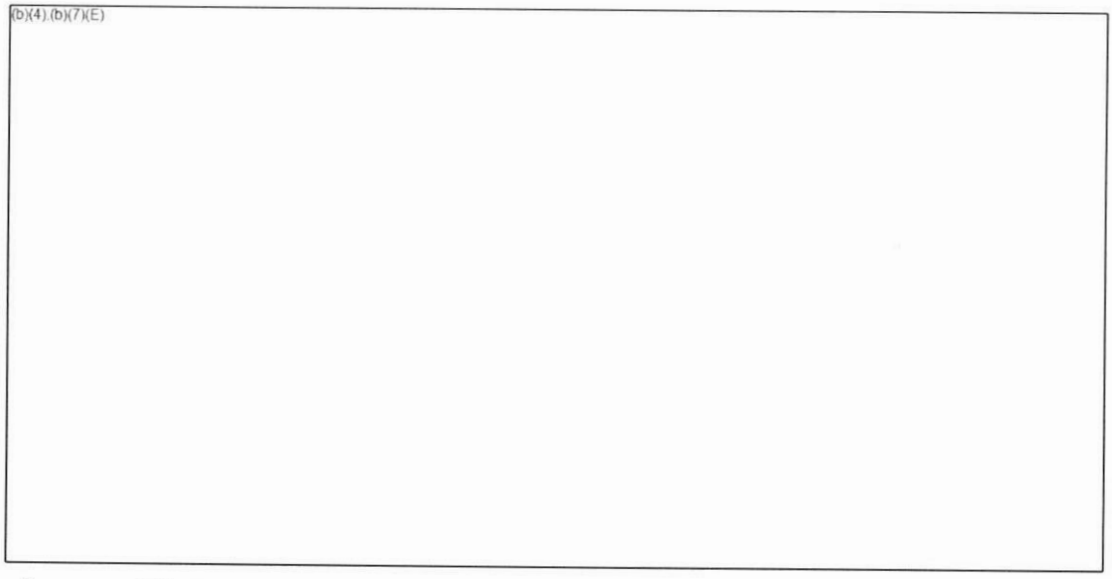
(b)(4) **Request for Hydromorphone MQ is Consistent with DEA's Historical Grants**

(b)(4)

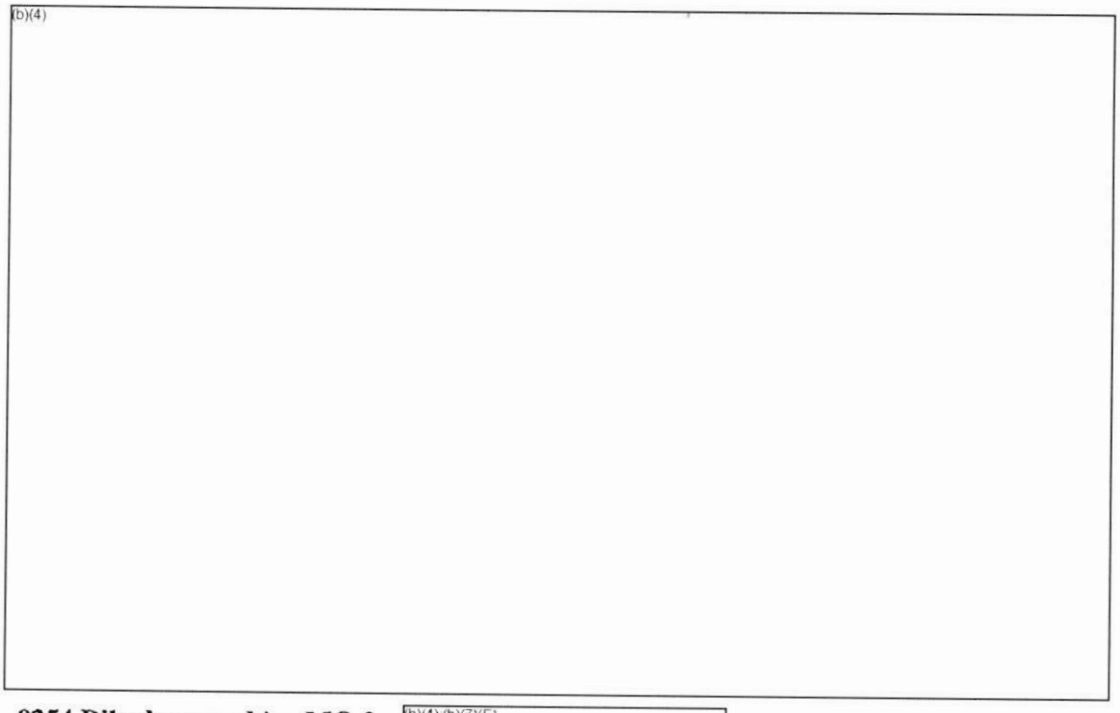
Hydromorphone Bulk Manufacturing Quota for (b)(4),(b)(7)(E)		
Year	Total Annual Quota Amount Requested for (b)(4),(b)(7)(E) (g AA)	Total Quota Amount Granted to (b)(4),(b)(7)(E) (g AA)
2007	1,600,000	1,000,000
2008	1,380,000	1,190,000
2009	1,850,000	1,410,000
2010	1,420,000	1,174,000
2011	1,020,000	1,020,000
2012	1,230,000	1,000,000
2013	1,380,000	988,463

Customer Demand Supports the MQ Request

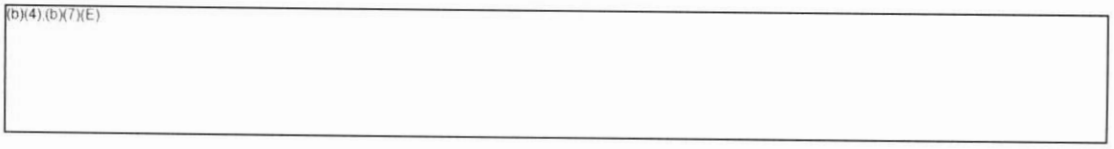
(b)(4),(b)(7)(E)



Improved Hydromorphone Synthesis Process



9254 Dihydromorphine MQ for (b)(4),(b)(7)(E)



9250 Hydromorphone PQ for (b)(4),(b)(7)(E)

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

Conclusion

(b)(4)

Please feel free to contact me if you need additional information or further clarification regarding these requests.

Thank you,

(b)(6)

Supervisor, Controlled Substance Compliance

(b)(4),(b)(6)

PUBLIC SUBMISSION

As of: July 17, 2013
Received: July 16, 2013
Status: Pending_Post
Tracking No. 1jx-86hx-xype
Comments Due: July 22, 2013
Submission Type: Web

Docket: DEA-2013-0005
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 2013

Comment On: DEA-2013-0005-0001
Proposed Adjustments to the 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 2013

Document: DEA-2013-0005-DRAFT-0006
Comment on FR Doc # N/A

Submitter Information

Organization: .

General Comment

See attached file(s)

Attachments

Docket No. DEA-365 (b)(4) Comment

(b)(4)

(b)(4)

July 19, 2013

Drug Enforcement Administration
Attention: DEA Federal Register Representative/ODL
Office of Diversion Control
8701 Morrisette Drive
Springfield, VA 22152

RE: Docket No. DEA-365 (b)(4) Comment

Dear Sirs:

(b)(4),(b)(7)(E) has submitted quota correspondence as set forth in the table below for the following manufacturing categories. (b)(4) requests that the correspondence provided to the Quota Unit, which constitutes "CONFIDENTIAL BUSINESS INFORMATION", be considered during the 2013 Aggregate Production Quota review.

Quota Category	Quota Application Ref. #	Material Name	Action Needed
Procurement	116609	CPS Thebaine – 9670	An aggregate increase based on (b)(4) customer demand
Procurement	116611	CPS Oripavine – 9670	An aggregate increase based on (b)(4) customer demand
Manufacturing	116610	Oxycodone for Sale – 9143	An aggregate increase based on (b)(4) customer demand
Manufacturing	116612	Oxymorphone for Conversion -9652	An aggregate increase based on (b)(4) customer demand

Thank you in advance for considering these requests. If you have any questions regarding this request, please do not hesitate to contact me at (b)(4),(b)(6)

Best regards,

(b)(6)

Director, Controlled Substance Compliance

(b)(4)

(b)(4),(b)(6)

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

June 26, 2013

Subject: Docket No. DEA-365 – Methadone (for sale)

Dear Federal Register Representative,

"PERSONAL IDENTIFYING INFORMATION" to be redacted is (b)(4) (b)(4),(b)(7)(E) **"CONFIDENTIAL BUSINESS INFORMATION"** to be redacted includes increased sales volumes to 3,800 kg (3,382 as base) and a 27% manufacturing loss.

(b)(4) is a registered manufacturer (b)(4),(b)(7)(E) of Methadone (for sale). (b)(4) is providing comment to the proposed final aggregate production quota for 2013 for Methadone (for sale) based on the information provided below.

On April 18, 2013, (b)(4) requested an increase of 300 kg in its 2013 Methadone (for sale) manufacturing quota over its then granted quota of 3,551 kg. On May 21, 2013, (b)(4) was denied the increase "due to the limitations of the currently established aggregate production quota."

Copies of purchase orders were provided to DEA with our quota request Reference # 115658. Since that time (b)(4) customer demands have increased again to ~3,800 kg (3,382 kg as base.) Purchase Orders will again be provided when the actual quota application is submitted.

In your calculations it is important to remember that there is an ~27% manufacturing loss between the point that DEA now requires (b)(4) to count quota as consumed and the final saleable product. Therefore, the additional 1250 kg of quota to be requested will only yield approximately 900 kg (801 kg as base) of saleable product.

(b)(4)

(b)(4)

Granting (b)(4) this additional quota in 2013 will allow the manufacture of the Methadone Intermediate and Methadone Base steps in 2013 so that the Methadone Hydrochloride step can be manufactured in January 2014 to meet our January 2014 customer demand.

(b)(4) respectfully requests that the 2013 aggregate production quota for Methadone (for sale) be increased by at least 1,250,000 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

Xc: (b)(6)

(b)(4)

(b)(4)

(b)(4)

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

(b)(4),(b)(6)

June 26, 2013

Subject: Docket No. DEA-365 – Methadone Intermediate

Dear Federal Register Representative,

"PERSONAL IDENTIFYING INFORMATION" to be redacted is (b)(4) (b)(4),(b)(7)(E) **"CONFIDENTIAL BUSINESS INFORMATION"** to be redacted is "Methadone Hydrochloride sales have increased dramatically from 2,134 kg and 3,100 kg as base in 2011 and 2012 respectively to 3,400 kg as base in 2013."

(b)(4) is a registered manufacturer (b)(4),(b)(7)(E) of Methadone Intermediate. (b)(4) is providing comment to the proposed final aggregate production quota for 2013 for Methadone Intermediate based on the information provided below.

All Methadone Intermediate that (b)(4) manufactures is consumed in house in the manufacture of Methadone Hydrochloride. (b)(4) Methadone Intermediate quota is tied directly to its Methadone (for sale) quota. (b)(4) Methadone Hydrochloride sales have increased dramatically from 2,134 kg and 3,100 kg as base in 2011 and 2012 respectively to 3,400 kg as base in 2013. Additional Methadone Intermediate and Methadone (for sale) quota is required and will be requested to meet this increase. Purchase Orders will be provided with the Methadone (for sale) quota application.

(b)(4) will be requesting an additional 800,000 grams of Methadone Intermediate quota and respectfully requests that the 2013 aggregate production quota for Methadone Intermediate be increased by at least 800,000 grams to allow for (b)(4) request.

(b)(4)

(b)(4)

(b)(4)

If you have any questions or require additional information, please feel free to contact me directly.

Sincerely,

(b)(4),(b)(6)

DEA Compliance Manager

Xc: (b)(6)

(b)(4)

(b)(4)

(b)(4)

JUL 0 8 2013

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

(b)(4),(b)(6)

July 2, 2013

Subject: Docket No. DEA-365 – Oxycodone

Dear Federal Register Representative,

"PERSONAL IDENTIFYING INFORMATION" to be redacted is (b)(4) (b)(4),(b)(7)(E) **"CONFIDENTIAL BUSINESS INFORMATION"** to be redacted is "(b)(4) May 16th quota request was reduced from 513 to only 51 kg being granted (total 616 kg) due to the limitation of the currently established APQ. (b)(4) plans to qualify a new source of Thebaine, Tasmanian Alkaloids. One full size batch will consume ~165 kg of Thebaine and ~157 kg of Oxycodone quota. The five batch campaign will require 785 kg of Oxycodone manufacturing quota. Sales have dramatically increased since our original 2013 quota submission last year."

(b)(4) is a registered manufacturer (b)(4),(b)(7)(E) of Oxycodone. (b)(4) is providing comment to the proposed final aggregate production quota for 2013 for Oxycodone based on the information provided below.

(b)(4) May 16th quota request was reduced from 513 to only 51 kg being granted (total 616 kg) due to the limitation of the currently established APQ. (b)(4) plans to qualify a new source of Thebaine, Tasmanian Alkaloids. One full size batch will consume ~165 kg of Thebaine and ~157 kg of Oxycodone quota. The five batch campaign will require 785 kg of Oxycodone manufacturing quota. Sales have dramatically increased since our original 2013 quota submission last year.

(b)(4)

(b)(4)

(b)(4)

(b)(4) respectfully requests that the 2013 APQ for Oxycodone be increased by at least 169,000 grams (785,000 - 616,000 grams) to allow for (b)(4) 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

Xc: (b)(6)

(b)(4)

(b)(4)

2013 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), 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 2013 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.

- In an effort to prevent potential drug shortage issues, DEA has added 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). DEA learned through meetings with industry that manufacturers do not always maintain the 50% inventory allowance that is permitted and sometimes do not maintain any inventory at all. If a disaster or some other unforeseen event were to occur, there is a strong likelihood that drugs would become unavailable and, if all or most of the quotas had been issued to manufacturers, DEA would not be able to respond quickly because the DEA regulations require public notice and comment for adjustments to the APQ. As such, DEA has determined that an amount of 25% should be adequate to ensure that DEA could immediately respond to such situations and provide sufficient quota to allow continued manufacturing to alleviate potential shortages. The 25% amount is equivalent to one quarter of the year, which is the longer end of the typical manufacturing cycles as communicated to DEA by industry.

- The attached Federal Register seeks to establish the final revised APQ and AAN for 2013. A table summarizing the comments to the FR and any subsequent changes made to the proposed revised values are attached for reference.

<u>List 1 Chemicals:</u>

- OD is recommending an increase in the AAN for **phenylpropanolamine (for conversion)**. The increase is based on bulk manufacturers of amphetamine initiating a new manufacturing process involving the conversion of phenylpropanolamine to amphetamine. Amphetamine is used primarily as the controlled substance for several brand and generic ADHD medications, including Adderall. Historical sales of phenylpropanolamine (for conversion) are not reflective of this new manufacturing process utilizing phenylpropanolamine instead of phenylacetone.

- OD is recommending an increase in the AAN for **ephedrine (for sale) and pseudoephedrine (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 **dihydromorphine and hydromorphone.** The increase is based on increased domestic sales and export requirements of hydromorphone based on registrant and IMS data and the conversion of dihydromorphine to hydromorphone.

- OD is recommending an increase in the APQ for **diphenoxylate (for sale).** The increase is based on increased domestic sales requirements from registrant applications.

- OD is recommending an increase in the APQ for **gamma-hydroxybutyric acid (GHB).** This increase is a result of multiple bulk and dosage-form manufacturers requesting material for FDA validation efforts being granted the necessary quotas and adjustment to the inventory allowance of the bulk manufacturer for the marketed brand.

- OD is recommending an increase in the APQ for **levomethorphan**. The increase is based on customer of established bulk manufacturer for reference standards and exempt preparations.

- OD is recommending an increase in the APQ for **morphine (for sale).** The increase is due to changes in the domestic sales market as reported by registrants and verified by customer IMS and ARCOS data.

- OD is recommending an increase in the APQ for **oxymorphone (for sale).** The increase is due to increased domestic sales and export requirements as reported by registrants and verified by customer ARCOS and IMS data.

- OD is recommending an increase in the APQ for **phenylacetone.** The increase is based on increased domestic sales and import requirements from registrant applications and projected demand for amphetamine products. Amphetamine is used primarily as the controlled substance for several brand and generic ADHD medications, including Adderall.

- OD is recommending an increase in the APQ for **psilocyn.** The increase is based on new drug code added to a bulk manufacturer for reference standards and exempt preparations.

- OD is recommending an increase in the APQ for **sufentanil.** The increase is due to commercial sales & validation efforts with large batch sizes relative to the initial APQ. All validation material will be non-saleable until their customers have also validated the material.

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-365]

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 2013

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

ACTION: Notice.

SUMMARY: This notice establishes final adjusted 2013 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as well as the 2013 aggregate production quotas for three recently temporarily controlled substances.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-7165.

SUPPLEMENTARY INFORMATION:

Background

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 through 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104. DEA published the 2013 established 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 in the Federal Register (77 FR 59980) on October 1, 2012. That notice stated that the Deputy Administrator would adjust, as needed, the established aggregate production quotas in 2013 as provided for in 21 CFR 1303.13 and 21 CFR 1315.13. The 2013 proposed adjusted aggregate production quotas for controlled substances in Schedules I and II and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the Federal Register on June 20, 2013, (78 FR 37237) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before July 22, 2013.

Analysis for Final Adjusted 2013 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the June 20, 2013, notice of proposed adjusted aggregate production quotas and assessment of annual needs, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Six companies submitted timely comments regarding a total of 30 Schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P); 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E); 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D); 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N); 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H); 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C); 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine

(2C–I); 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2); 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4); 3,4-Methylenedioxymethamphetamine (MDMA); 4-Anilino-N-phenethyl-4-piperidine (ANPP); amphetamine (for sale); codeine (for conversion); dihydromorphine; diphenoxylate (for sale); gamma hydroxybutyric acid; hydrocodone; hydromorphone; levomethorphan; methadone; methadone intermediate; methylphenidate; morphine (for conversion); morphine (for sale); oxycodone (for sale); oripavine; oxymorphone (for conversion); oxymorphone (for sale); phenylacetone; and sufentanil 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. One manufacturer commented that the APQ for thebaine was insufficient; however, that commenter was referring to a need for procurement quota for thebaine, which does not directly impact the APQ and, thus, was not considered. DEA did not previously propose adjustments to the 2013 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine and received no comments concerning such.

DEA has taken into consideration the above comments along with the relevant 2012 year-end inventories, initial 2013 manufacturing quotas and import quotas, 2013 export requirements, actual and projected 2013 sales, research and product development requirements, and additional applications received. Based on all of the above, the Deputy Administrator has determined that the proposed adjusted 2013 aggregate production quotas and assessment of annual needs for dihydromorphine; diphenoxylate (for sale); gamma hydroxybutyric acid; hydromorphone; levomethorphan; morphine (for sale); oxymorphone (for sale); phenylacetone; psilocyn; sufentanil; ephedrine (for sale);

phenylpropanolamine (for conversion); and pseudoephedrine (for sale) required additional consideration and hereby further adjusts the 2013 aggregate production quotas for those substances.

Regarding 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P); 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E); 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D); 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N); 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H); 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C); 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I); 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2); 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4); 3,4-Methylenedioxymethamphetamine (MDMA); 4-Anilino-N-phenethyl-4-piperidine (ANPP); amphetamine (for sale); codeine (for conversion); hydrocodone; methadone; methadone intermediate; methylphenidate; morphine (for conversion); oxycodone (for sale); oripavine; and oxymorphone (for conversion), the Deputy Administrator hereby determines that the proposed adjusted 2013 aggregate production quotas and assessment of annual needs for these substances and List I chemicals as published on June 20, 2013, (78 FR 37237) are sufficient to meet the current 2013 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories.

As described in the previously published notice establishing the 2013 aggregate production quotas and assessment of annual needs, 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, 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 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. 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 DEA. DEA does not anticipate utilizing the reserve in the absence of these circumstances.

Pursuant to the above, the Deputy Administrator hereby finalizes the 2013 aggregate production quotas for the following Schedule I and II controlled substances and the 2013 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 2013 Quotas
Temporarily Scheduled Substances	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15 g
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15 g
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15 g
Schedule I	

1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	15 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	15 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	15 g
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	15 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	15 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	15 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	15 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
2,5-Dimethoxyamphetamine	12 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	15 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	15 g
3,4,5-Trimethoxyamphetamine	12 g
3,4-Methylenedioxyamphetamine (MDA)	30 g
3,4-Methylenedioxymethamphetamine (MDMA)	50 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	35 g
3,4-Methylenedioxypyrovalerone (MDPV)	25 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g
4-Methoxyamphetamine	88 g

4-Methyl-2,5-dimethoxyamphetamine (DOM)	25 g
4-Methylaminorex	12 g
4-Methyl-N-methylcathinone (mephedrone)	25 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
5-Methoxy-N,N-dimethyltryptamine	10 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	12 g
Codeine-N-oxide	602 g
Desomorphine	5 g
Diethyltryptamine	12 g
Difenoxin	50 g
Dihydromorphine	3,990,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	67,500,000 g
Heroin	25 g
Hydromorphinol	54 g

Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	13 g
Methaqualone	10 g
Methcathinone	14 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N,N-Dimethylamphetamine	12 g
N-Benzylpiperazine	15 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	10 g
Psilocyn	12 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g
Schedule II	
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile	21 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g
Alfentanil	38,250 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	22,875,000 g
Amphetamine (for sale)	47,186,000 g
Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	81,250,000 g
Codeine (for sale)	49,506,250 g

Dextropropoxyphene	19 g
Dihydrocodeine	250,000 g
Diphenoxylate	887,500 g
Ecgonine	144,000 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	6,750,000 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	195 g
Levorphanol	4,500 g
Lisdexamfetamine	21,000,000 g
Meperidine	6,875,000 g
Meperidine Intermediate-A	6 g
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	6 g
Methadone (for sale)	33,125,000 g
Methadone Intermediate	40,500,000 g
Methamphetamine	3,912,500 g
[987,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,863,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000 g
Morphine (for conversion)	91,250,000 g
Morphine (for sale)	61,125,000 g
Nabilone	25,628 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	1,262,500 g
Opium (powder)	91,250 g
Opium (tincture)	1,287,500 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	10,250,000 g
Oxycodone (for sale)	153,750,000
Oxymorphone (for conversion)	18,375,000 g
Oxymorphone (for sale)	7,000,000 g
Pentobarbital	42,500,000 g
Phenazocine	6 g

Phencyclidine	30 g
Phenmetrazine	3 g
Phenylacetone	42,393,750 g
Racemethorphan	3 g
Remifentanil	3,750 g
Secobarbital	215,003 g
Sufentanil	6,880 g
Tapentadol	13,750,000 g
Thebaine	145,000,000
List I Chemicals	
Ephedrine (for conversion)	15,100,000 g
Ephedrine (for sale)	4,200,000 g
Phenylpropanolamine (for conversion)	44,800,000 g
Phenylpropanolamine (for sale)	6,100,000 g
Pseudoephedrine (for sale)	246,000,000

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

Dated:

Thomas M. Harrigan,
Deputy Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
ODW:_____
ODQ:_____
ODQ (b)(6) _____ (b)(6) 07-30-13
Webcims # ODEQ -
(DFN#: 680-03 Drug control files - Manufacturing and Procurement quotas)

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

Under section 7003(d) of RCRA, a commenter may request an opportunity for a public meeting in the affected area.

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. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $8.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen M. Katz,

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

[FR Doc. 2013–19005 Filed 8–6–13; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–365]

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 2013

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

ACTION: Notice.

SUMMARY: This notice establishes final adjusted 2013 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, as well as the 2013 aggregate production quotas for three recently temporarily controlled substances.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Background

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 through 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104. DEA published the 2013 established 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 in the **Federal Register** (77 FR 59980) on October 1, 2012. That notice stated that the Deputy Administrator would adjust, as needed, the established aggregate production quotas in 2013 as provided for in 21 CFR 1303.13 and 21 CFR 1315.13. The 2013 proposed adjusted aggregate production quotas for controlled substances in Schedules I and II and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the **Federal Register** on June 20, 2013, (78 FR 37237) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before July 22, 2013.

Analysis for Final Adjusted 2013 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the June 20, 2013, notice of proposed adjusted aggregate production quotas and assessment of annual needs, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Six companies submitted timely comments regarding a total of 30 Schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P); 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E); 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D); 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N); 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H); 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C); 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I); 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2); 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4); 3,4-Methylenedioxymethamphetamine (MDMA); 4-Anilino-N-phenethyl-4-piperidine (ANPP); amphetamine (for sale); codeine (for conversion); dihydromorphine; diphenoxylate (for sale); gamma hydroxybutyric acid; hydrocodone; hydromorphone; levomethorphan; methadone; methadone intermediate; methylphenidate; morphine (for conversion); morphine (for sale); oxycodone (for sale); oripavine; oxymorphone (for conversion); oxymorphone (for sale); phenylacetone; and sufentanil 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. One manufacturer commented that the APQ for thebaine was insufficient; however, that commenter was referring to a need for procurement quota for thebaine, which does not directly impact the APQ and, thus, was not considered. DEA did not previously propose adjustments to the 2013 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine and received no comments concerning such.

DEA has taken into consideration the above comments along with the relevant 2012 year-end inventories, initial 2013 manufacturing quotas and import quotas, 2013 export requirements, actual and projected 2013 sales, research and product development requirements, and additional applications received. Based on all of the above, the Deputy Administrator has determined that the proposed adjusted 2013 aggregate production quotas and assessment of annual needs for dihydromorphine; diphenoxylate (for sale); gamma hydroxybutyric acid; hydromorphone; levomethorphan; morphine (for sale); oxymorphone (for sale); phenylacetone; psilocyn; sufentanil; ephedrine (for sale); phenylpropanolamine (for conversion); and pseudoephedrine (for sale) required additional consideration and hereby further adjusts the 2013 aggregate production quotas for those substances.

Regarding 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P); 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E); 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D); 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N); 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C); 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I); 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2); 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4); 3,4-Methylenedioxymethamphetamine (MDMA); 4-Anilino-N-phenethyl-4-piperidine (ANPP); amphetamine (for sale); codeine (for conversion); hydrocodone; methadone; methadone intermediate; methylphenidate; morphine (for conversion); oxycodone (for sale); oripavine; and oxymorphone (for conversion), the Deputy Administrator hereby determines that the proposed adjusted 2013 aggregate production quotas and assessment of annual needs for these substances and List I chemicals as published on June 20, 2013, (78 FR 37237) are sufficient to meet the current 2013 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories.

As described in the previously published notice establishing the 2013 aggregate production quotas and assessment of annual needs, 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, 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 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. 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 DEA. DEA does not anticipate utilizing the reserve in the absence of these circumstances.

Pursuant to the above, the Deputy Administrator hereby finalizes the 2013 aggregate production quotas for the following Schedule I and II controlled substances and the 2013 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 2013 quotas
Temporarily Scheduled Substances	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144)	15 g
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15 g
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15 g
Schedule I	
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH–073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	15 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	15 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	15 g
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	15 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	15 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	15 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	15 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
2,5-Dimethoxyamphetamine	12 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	15 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	15 g
3,4,5-Trimethoxyamphetamine	12 g
3,4-Methylenedioxyamphetamine (MDA)	30 g
3,4-Methylenedioxymethamphetamine (MDMA)	50 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	35 g
3,4-Methylenedioxypyrovalerone (MDPV)	25 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g

Basic class	Final adjusted 2013 quotas
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	12 g
4-Methoxyamphetamine	88 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25 g
4-Methylaminorex	12 g
4-Methyl-N-methylcathinone (mephedrone)	25 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
5-Methoxy-N,N-dimethyltryptamine	10 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	12 g
Codeine-N-oxide	602 g
Desomorphine	5 g
Diethyltryptamine	12 g
Difenoxin	50 g
Dihydromorphine	3,990,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	67,500,000 g
Heroin	25 g
Hydromorphinol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	13 g
Methaqualone	10 g
Methcathinone	14 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N,N-Dimethylamphetamine	12 g
N-Benzylpiperazine	15 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	10 g
Psilocyn	12 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g
Schedule II	
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile	21 g

Basic class	Final adjusted 2013 quotas
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000 g
Alfentanil	38,250 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	22,875,000 g
Amphetamine (for sale)	47,186,000 g
Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	81,250,000 g
Codeine (for sale)	49,506,250 g
Dextropropoxyphene	19 g
Dihydrocodeine	250,000 g
Diphenoxylate	887,500 g
Ecgonine	144,000 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	6,750,000 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	195 g
Levorphanol	4,500 g
Lisdexamfetamine	21,000,000 g
Meperidine	6,875,000 g
Meperidine Intermediate-A	6 g
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	6 g
Methadone (for sale)	33,125,000 g
Methadone Intermediate	40,500,000 g
Methamphetamine	3,912,500 g
[987,500 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,863,750 grams for methamphetamine mostly for conversion to a schedule III product; and 61,250 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000 g
Morphine (for conversion)	91,250,000 g
Morphine (for sale)	61,125,000 g
Nabilone	25,628 g
Noroxymorphone (for conversion)	9,000,000 g
Noroxymorphone (for sale)	1,262,500 g
Opium (powder)	91,250 g
Opium (tincture)	1,287,500 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	10,250,000 g
Oxycodone (for sale)	153,750,000 g
Oxymorphone (for conversion)	18,375,000 g
Oxymorphone (for sale)	7,000,000 g
Pentobarbital	42,500,000 g
Phenazocine	6 g
Phencyclidine	30 g
Phenmetrazine	3 g
Phenylacetone	42,393,750 g
Racemethorphan	3 g
Remifentanil	3,750 g
Secobarbital	215,003 g
Sufentanil	6,880 g
Tapentadol	13,750,000 g
Thebaine	145,000,000 g
List I Chemicals	
Ephedrine (for conversion)	15,100,000 g
Ephedrine (for sale)	4,200,000 g
Phenylpropanolamine (for conversion)	44,800,000 g
Phenylpropanolamine (for sale)	6,100,000 g
Pseudoephedrine (for sale)	246,000,000 g

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: August 1, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013–19046 Filed 8–6–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

Comment Request for Information Collection for Job Corps Placement and Assistance Record, Extension Without Revisions

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (Department), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, ETA is soliciting comments concerning the collection of data about Job Corps Placement Record [OMB Control No. 1205–0035, expires January 2014]: ETA 678 form, Job Corps Placement and Assistance Record. ETA form 678 currently captures information about a student's training and subsequent placement in a job, higher education or the military, as well as the name of the placement provider agency. Data generated from the form ETA 678 is used to evaluate overall placement outcomes. This form is critical to the program's evaluation process. It is the only form which documents a student's post-center placement status. This form is completed by either a Job Corps center records staff or a Career Transition Specialist for each student. Job Corps is not proposing any changes to ETA 678 form, Job Corps Placement Record.

A copy of the proposed Information Collection Request (ICR) can be obtained by contacting the office listed below in the addressee section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee's section below on or before October 7, 2013.

ADDRESSES: Submit written comments to Marcus Gray, Office of Job Corps, Room N–4463, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Telephone number: 202–693–3967 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Server at 877–889–5627 (TTY/TDD). Fax: 202–693–2767; email: *gray.marcus@dol.gov*. A copy of the proposed ICR can be obtained by contacting the person listed above.

SUPPLEMENTARY INFORMATION:

I. Background

Job Corps is the nation's largest residential, educational, and career technical training program for young Americans. Job Corps was established in 1964 by the Economic Opportunity Act, and currently is authorized by Title I–C of the Workforce Investment Act of 1998.

For almost 50 years, Job Corps has helped prepare a total of nearly 3 million at-risk young people ages 16 to 24 for success in our nation's workforce. With 125 centers in 48 states, Puerto Rico, and the District of Columbia, Job Corps assists students across the nation in attaining academic credentials, including a High School Diploma (HSD) and/or High School Equivalency credential, and career technical training, including industry-recognized credentials, state licensures, and pre-apprenticeship credentials.

Job Corps is administered by the Department through the Office of Job Corps and six Regional Offices. The Department awards and administers contracts for the recruiting and screening of new students, center operations, and the placement and transitional support of graduates and former enrollees. Large and small corporations and nonprofit organizations manage and operate 97 Job Corps centers under contractual agreements with the Department. These contract Center Operators are selected through a competitive procurement process that evaluates potential operators' technical expertise, proposed costs, past performance, and other factors, in accordance with the Competition in Contracting Act and the Federal Acquisition Regulations.

The remaining 28 Job Corps centers, called Civilian Conservation Centers, are operated by the U.S. Forest Service, via an interagency agreement. The Department has a direct role in the operation of Job Corps, and does not serve as a pass-through agency for this program.

II. Review Focus

The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the agency's function, including whether the information has practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, by encouraging the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions

Type of Review: Extension

Title: Job Corps Placement Record

OMB Number: Control No. 1205–0035

Affected Public: Individuals or Households (Job Corps students) and Private Sector—(Job Corps centers)

Form(s): ETA 678

Total Annual Respondents: 34,000

Annual Frequency: Once (when placement occurs)

Total Annual Responses: 34,000

Average Time per Response: 7.43 minutes

Estimated Total Annual Burden Hours: 4,210

Total Annual Other Burden Costs for Respondents: $0

Comments submitted in response to this comment request will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: July 31, 2013.

Eric M. Seleznow,

Acting Assistant Secretary.

[FR Doc. 2013–19061 Filed 8–6–13; 8:45 am]

BILLING CODE 4510–FT–P