	(b)(4)	CONFIDENTIAL
(b)(	1)	MAY 19 RECT
May 16, 2014		*****
Ms. Christine A. Sann Drug Enforcement Ad Drug & Chemical Eva 8701 Morrissette Driv Springfield, VA 2215 Subject: (b)(4),(b)(7)(E)	ministration luation (ODE) e	eine (for conversion) Inventory
Dear Dr. Sannerud:		
the DEA allow us to a (for sale).		ufacturing registration (b)(4);(b)(7)(E) requests se of Codeine (for conversion) to Codeine
the production of Code phosphate is produced number (b)(4),(b)(7)(E)	problem we have is the CAT problem. We have is the CAT problem Phosphate due to our DMF in the (b)(4) site. Our has expressed an interest in	site called codeine alkaloid oduced at (b)(4) cannot be used in filings, so all CAT production for codeine customer (manufacturing registration purchasing Codeine Phosphate for a ing we can use the CAT produced for
of this material to be a bitartrate, leaving us very bitartrate this year (or be be) that is in the sale). Once the DEA	or conversion into Hydrocodone as per our contract. (b)(4) with a large inventory. Because next year), we would like to take quota classification as Codeine	a large inventory of material. In 2012 we Bitartrate, and we planned on selling tons backed off on ordering Hydrocodone we are not producing any Hydrocodone two batches of CAT in inventory at (b)(4) (for conversion), and call it Codeine (for eassified CAT will undergo a purification
(b)(4)		

# CONFIDENTIAL

We request the DEA consider the information presented and allow (b)(4) to reclassify up to 694,518 grams of CAT produced as Codeine (for conversion) to Codeine (for sale). This will allow us to avoid production of Codeine (for sale) starting material and reduce our inventory of the recently slow moving Codeine (for conversion) material.
Thank you for your consideration in this matter. Should you have any questions, please contact me at $^{[b)(6)}$
considers this commercial information privileged and confidential. We believe the release of this information will likely cause (b)(4) substantial competitive harm.
Very truly yours, (b)(6)
DEA Materials Control Manager

	2011	2012	9/ Change	2013	% Change	2014*	% Change
Substance			% Change		-0.10%	11,921.39	9.09%
Amphetamine (D,L)	9,703.48	10,938.95		10,928.20	-1.09%	12,584.00	8.51%
Amphetamine (D)	10,597.70	11,725.30	10.64%	11,597.10		37.17	-6.21%
Cocaine	48.53	44.03	-9.28%	39.63	-9.99%		2.40%
Codeine	26,170.71	22,758.28	-13.04%		-4.58%	22,238.38	
Dihydrocodeine	107.21	75.02	-30.03%	36.22	-51.72%	6.76	-81.33%
Diphenoxylate	462.60	413.01	-10.72%	406.20	-1.65%	382.07	-5.94%
Dronabinol	110.82	106.13	-4.24%	110.92	4.52%	115.78	4.38%
Ephedrine	1,535.52	1,973.12	28:50%		5.58%	2,203.60	5.78%
Fentanyl	539.85	575.07	6.53%	548.23	-4.67%	544.38	-0.70%
Hydrocodone	64,933.52	63,163.25		61,575.69	-2.51%	59,479.05	-3.40%
Hydromorphone	1,675.27	1,912.39	14.15%	1,926.07	0.72%	1,857.15	
Levorphanol	0.32	1.54	378.02%	2.33	51.13%	2.53	8.41%
Lisdexamfetamine	12,336.18	14,001.29	13.50%	13,653.65	-2.48%	14,525.01	6.38%
Meperidine	2,303.07	1,885.59	-18.13%	1,537.31	-18.47%	1,364.13	-11.27%
Methadone	7,639.42	6,776.34	-11.30%	5,804.38	-14.34%	5,531.24	
Methamphetamine	13.86	14.40	3.87%	_13.09	-9.11%	12.48	-4.65%
Methylphenidate	19,212.63	19,534.84	1.68%	17,949.13	-8.12%	18,613.58	3.70%
Morphine	30,435.83	28,705.35	-5.69%	26,266.30	-8.50%	25,445.23	3.13%
Na!buphine	61.42	63.60	3.55%	42.02	-33.93%	39.88	-5.08%
Naloxone	391.27	430.32	9.98%	478.98	11.31%	497.20	3.80%
Naltrexone	4.56	0.00	-99.98%	0.00	-100.00%	0.00	0.00%
Opium	84.96	81.02	-4.63%	77.44	-4.42%	77.41	-0.03%
Oxycodone	70,885.82	66,702.94	-5.90%	60,308.91	-9.59%	59,796.79	-0.85%
Oxymorphone	2,655.74	1,958.25	-26.26%	1,865.58	-4.73%	1,951.68	4.62%
Pentazocine	839.71	698.43	-16.82%	563.20	-19.36%	411.38	-26.96%
Pentobarbital	79.12	46.62	-41.07%	24.25	-47.99%	29.66	22.34%
Pseudoephedrine	104,476.73	93,931.68	-10.09%	93,125.29	-0.86%	100,386.58	
Remifentanil	1.05	1.11	·			1.20	3.53%
Secobarbital	20.78	15.67	-24.59%	11.98	-23.55%	10.48	-12.52%
Sufentanil	0.05	0.05	-2.53%	0.05	-7.93%	0.04	-24.36%

<sup>\*</sup>Estimates based on Jan-Mar 2014 Data

IMS Data 2011 - 2014 (est)

Basic Class: 9737-0 Total PQ Requested: 2015 Initial APQ Worksheets

is minuted and anothers

FDA Est:

- Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales :	2013 DÉA MÓ Sales	% of 2013 Sales	Share of 2015 Total PQ 2	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adi Ayad Calc
(b)(4);(b)(7)(E)		2,000	2,000	0.000	5,83G.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	1 500
		12,329.006	14,080,000	5,836.000	5,836.000	1.000	104.000	8,937.000	11,000,000	13,200.000	0.000	8,936,600	17,262,750

MQ Totals: 12,322,000 14,082,000

194,000

2014 Final Initial APQ: 14.100.000
2014 Final Rowlead APQ: 0.000
FDA Est: (2014 Initial APQ \* 1 + FDA Est): 14.100.000
IMS Est: (2014 Initial APQ \* 1 + IMS Est): 14.100.000
2015 Proposed tetrial APQ: 14.100.000
with 25% buffer: 17,625.000

ALFENTANIL

Rasic Cises: 9602-4 Total PQ Requested: 2016 Initial APQ Worksheets

FOA EM: IMS EM:

. Company DEA Num 2015 Requested MQ 2014 Revised MQ 2013 Sales 2013 DEA MQ Seles % of 2013 Sales Share of 2015 Total PQ 2013 Inventory 2014 Projected Exports 20

MQ Totals: 2.000 2.000

0.000

 2014 Final Initial APQ:
 2,000

 2014 Final Revised APQ:
 0,000

 FDA Eat: (2014 Initial APQ\*1+FDA Est):
 2,000

 IMS Est: (2014 Initial APQ\*1+IMS Est):
 2,000

ALLYLPRODINE

Basic Class: Total PG Requested:

FDA Est: (2016 initial APQ \* 1 + FDA Est);

1MS Eat: [2014 Initial APQ \* 1 + IMS Eat]:

5.000

15.000

15 000

#### 2015 Initial APQ Worksheets

PL	•	E	14
(N	s	E	<b>6</b> £

Company	DEA Num	2015 Requested &	4Q 2014 R	rvised IAO 20	13 Sales 201.	OFA MO Sales %	of 2013 Sales	Share of 2015 Total PO	2013 Inventory 20	14 Projected Exports 2014	Projected Sales 2015 P	rejected Exports 2014 Pre	jected forestory 2014 DEA	Projected Inventory Adi /	Avail Calc
(b)(4);(b)(7)(E)		j · 50	00	5.000	0000	0.000	0.000	0.000	0,000	0.000	5 000	0.000	0.000	D 6000	3.750
		5.0	00	5 000	4 00 <b>0</b>	0.000	0.000	0.000	0.000	0.000	1,000	0.000	4.000	4 500	3.750
MQ Totals:		100	<b>0</b> 0	000 07											
2014 Final Initial APO;	15 000														
2014 Final Revised APQ:	0.000														

CARFENTANIL

Basic Class:

Total PG Requested:

2016 Initial APO Workshams

(b)(4)

FOA Est: IMS Est

0.000

3,431,313 128 7,534,825 000

0.000

0.000

0.000

5.000

30,216,718.000

0.600

a 000

1.000

9,750,452,000

5 000

1.624,769.000 24,031,070 250

0.000

2013 Sales 2013 DEA HQ Sales % of 2013 Sales Share of 2015 Total PO 2013 Inventory 2014 Projected Exports 2014 Projected Exports 2014 Projected Inventory 2014 Projected In DEA Num 2015 Requested NO Company 0 000 36,250,765,000 0.000 5.000 0.000 (b)(4);(b)(7)(E) 30,000,000,000 24,506,599.000 29,406,047.000 36,250,765.000 0.811 MQ Totals: 35,500,505,000 24,508,599,000 2014 Final Initial APQ: 55,000,000,000 2014 Final Revised APQ: 0 000 FDA Eat: (2014 Initial APO \* 1 + FOA Eat): 55,000,000 COD IMS Eat (2014 Initial APO 1 1 + IMS Est): 55,000,000 000 letter dated May 15, 2014, stated that they have more API on hand than expected because 2015 Proposed Initial APC: 40,000,000 000 50,000,000,000 with 25% buffer: (b)(4)

4,230,005 000

CODEINE (FOR CONVERSION)



Total PO Requested:

24,230,293.940

2015 Initial APQ Worksheets

FDA Ést INS Est

	Company	DEA NOT	2015 Requested MQ	MO	2013 Sales	2013 DEA MQ Sales W	of 2013 Sales	Share of 2015 Total PO 2	013 Inventory 2	014 Projected Exports 20	14 Projected Sales, 201	3 Projected Exports 2014 P	rojected inventory 201	(4 DEA Projected Inventory A	Adj Avali Calc
(b)(	(4);(b)(7)(E)		5.000	5,000	0.000	26,011,178,528	0.000	0.000	1,600	0.000	5 000	0 000	1.000	1 800	\$ 100
(~)	17,(0)(1)(2)		100,000	100,000	1.039	26,011,178,528	0.000	0.968	43 693	0 000	25 000	0.000 -	104 093	117.893	107,920
			628,000,000	0.000	0 000	26,011,178 528	6,000	0.000	0.000	0 000	558,670.000	0.000	000 3	·558,670.000	0.000
-			222,000,000	146,000,000	106 667 000		0,004	99,363,624	455,397,000	0.000	296,000 000	0.000	234,397 000	308,397 00a	453,797,750
			11,600,000,000	13 145 613 000			0.462	11,199,318,510	5.171.283 000	150,220,000	10,903,400,000	0.000	5,692,152.000	7,263,276.000 1	13,737,672.000
			24,701,000,000	17,231,565,000			0 506	12,268,691,453		0.000	18,717,000,000	0.000	8,596,000,000	3,642,365,000, 1	6,769,523,750
			1,000,000	1,900,000	1.330		0.000	1,239	0.000	0.000	1,000,000	5,000	0.000	0.000	750,000
							0.027	662,917,699	8,000	0,000	3,476,000,000	0.000	147,330 000	-623,086.000	1,916,165,500
- 1			4,935,000 000	2,554,914 000	711,641,000	20,011,178,220	0 027	992,9 11.033	0.500	2,200	2, 11 2,222 222	****			

MQ Totals:

42,287,105.000 33,081,197.000

2014 Final Inffel APQ: 28,900,000,000
2014 Final Revised APQ: 0,000
FDA Est: 2014 Initial APQ \* 1 + FDA E=11: 36,900,000,000
INS Set [2014 Initial APQ \* 1 + (MS Eet): 36,900,000,000

2015 Proposed Initial APO:

36,900,000.000

with 25% buffer:

46,125,000 000

Basic Class:

Total PQ Requested;

2015 Initial APQ Worksheets

FDA Est: MS Est

Сомрату	DEA Num	2016 Requested MQ 2014	Revised MQ 20	13 Sales 20	H3 DEA MO Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory 20:	14 Projected Exports 2014 F	Projected Sales 2	2016 Projected Exports	2014 Projected Inventory	2014 DEA Projected lay	Adj Avad Calc
(b)(4);(b)(7)(E)		5.000	5,000	0.000	1,572,158.507	6 500	0.000	0.006	<b>D</b> DOG	4.000	0.000	0.000	1,000	3.750
		10,000	10.000	0.507	1,572,158,507	0.000	0.000	6.086	D 200	1.000	0.000	14.296	15.086	12.085

MQ Totals: 15,000

90 000

2014 Final Initial APQ: 2014 Final Raylsod APQ: 15,000 0.000 FOA Est: (2014 Initial APQ \* 1 + FDA Extit 15,000 MS Est: (2014 initial APQ \* 1 + MS Est):

15.000

2015 Proposed Initial APC: 15,000 with 25% buffer: 18.750

DEXTROPROPOXYPHENE, BULK (NON

Basic Class: 8120-0

Total PO Requested:

8,113.000

2018 Initial APQ Workshoels

FOA Est IMS Est:

Company	DEA Nutu	2015 Requested MQ 20	14 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 invertory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected inventory	Adj Aveil Calc	MO.
(b)(4);(b)(7)(E)		\$.000	5,000	0.000	7,988,764	0.000	0.000	0.000	0,000	\$,000	0.000	1.000	3.750	1.250
(b)(+),(b)(1)(L)		5,000	5,000	0.764	7,988,764	0.000	0.872	14.945	0.000	3.000	0.000	15.946	14.959	17,817
		80,000,000		7,987,000		1.000	9,110,988	202,423.000	0.000	50,250,000	0.000	164,963.000	211,817.250 2	241,203,968
		1,000.000	250.000	D.200	7,988,784	0,000	-	136,960	0.000	000,000	0,000	0 000	290.220	875.825

241,976,679 81,510,000 60,260.000 MQ Totals:

2018 Final Initial APC: 80,600.000 2014 Final Revised APQ: FDA Est: (2014 Initial APQ \* 1 + FDA Est): 58,600.000 IMS Est: (2014 Institut APQ \* 1 + IMS Eatly 80,600,000

2015 Proposed Initial APQ: 61,100.000 with 25% buffer: 101,375.000

DIHYDROCODEINE

Basic Class:

Tatal PQ Requested:

2015 Initial APQ Workshoots

FDA Est; IMS Est:

Company	DEA Num	2015 Requested MQ 2	014 Revised MQ	2013 Seles	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PO	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Investory	Arti Ave II Cata
(b)(4);(b)(7)(E)		3.000	5.000	0.000	7,988.764	0.000	0.000	0.000	0.000	5.000	0.000	1,000	3.750
		5.000	5.000	0.764	7,988.764	0.000	0.872	14.645	0.000.0	3.000	0.000	15 546	14,959
		60,000,000	000,000,08	7,987,000	7,988,784	1,000	9,110.968	202,423.000	0.000	50,250,000	0.000	164,963,000	211.817.250
		1,000,000	250,000	0.200	7,968.764	9.000	0.228	136.960	0.000	1,000,000	9.000	0,000	290,220
		J											

MQ Totals: 61,010.000 80,260,000

9,113,000

2014 Final Initial APQ: 60,600.000 2014 Final Revised APQ: 0.000 FDA Est (2014 Initial APQ \* 1 + FDA Est); 80,600,000 IMS Est: (2014 Initial APQ \* 1 + IMS Est): BO 600 000

2015 Proposed Initial APQ: 81,100,000 with 25% buffer: 101,375,000

DIHYDROCODEINE

Basic Ciang: brown

Total PG Requested:

2015 Initial APQ Workshoots

FOA Est: IMS Est:

Company	DEA Num	2015 Requested MQ	2014 Revised MQ 2	G13 Sales	2013 DEA MG Sales	% of 2012 Sales	Share of 2015 Total PQ 2	1913 In <del>ye</del> ntory :	2014 Projected Exports	2014 Projected Sales		2014 Projected Inventory	
(b)(4);(b)(7)(E)		2,000	2,000	0.000	702,222,000	0.000	0 000	0,000	0.000	0.500	0.000	1,500	
(b)(4),(b)(1)(L)		27,900,000	0,000	455.000	702,222,000	0,001	0.001	13,489,000	0.000	27,800.000	0.000	13,465.000	
		620,000,000	580,000.000 7	01,757.000	702.222.000	0.969	0.999	285,969,000	18,400.000	579,400,000	0.000	334,783.000	649,476.750

MQ Tatals: 647,902,000 580,002,000

2014 Final Initial APQ: 600,000.000
2014 Final Revised APQ: 0.000
FDA Est: (2014 Initial APQ \*1 + FDA Est): 600,000,000
IMS Est: (2014 Initial APQ \*1 + IMS Est): 600,000,000

2015 Proposed Initial APQ: 1,070,000,000 based on 2014 pending revised APQ and (b)(4) Initial low request value in 2014

1,000

with 25% buffer: 1,337,500.000

DIPHENOXYLATE (FOR SALE)

Basic Class; 91904 Total PQ Requested: 2018 Initial APQ Workshoots

FDA EN: (MS EAT:

Conspany DEA Num 2015 Requested MO 2014 Rentsed MO 2013 Sales 2013 DEA NQ Sales % of 2013 Sales Share of 2015 Total PC 2013 Inventory 2014 Projected Exports 201

MQ Tetals; 2.000 2.000

5.000

 2014 Final Initial APQ:
 2,000

 2014 Final Revised APQ:
 0,000

 FDA Est: (2014 Initial APQ: 1 + FDA Est):
 2,000

 IMS Est: (2014 Initial APQ: 1 + IMS Est):
 2,000

ETHYLMORPHINE

Basic Class: Total PO Requested:

1,002,276,255

1,604,837.000

1,459,029.000

2015 Initial APQ Worksheets

FOA Est: IMS Est:

		DEA.Num	2015 Parameted MO	2014 Revised MO	2013 Sales	2013 DE A MO Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc
0.242.0.25	Company	DESCINA	5.000	r	0.000	998,926,931	0.000	0.000	0.101	0.000	4.000	0.000	1.000	3.826
(b)(4);(b)(7	′)(E)						0.037	37,083,924		0.000	200,000,000	0.000	50,000,000	153,589,000
			200,000.000		36,960.000				1.010	0.000	0.500		1.711	2.258
			2,000		0,538	998,826.931	0.000	0,540					1,000,000	10,690,500
			13,330,000	14,151,000	9,082,000	298,926,935	<b>600</b> ,0	9,112.451		0.600	13,330,000	•	266,183,000	
			475,000,000	461,271.000	245,042.000	998,926,931	0,245	245,863.607	230,549.000	0.000	445,120,000			- 10.00000
			870,000,000	610,000,000	645,039,000	998,926,931	0.646	647,201.765	298,686.000	122,050.000	850,527,000	0.000	388,205.900	,
			33,000,000	-	4,460,000		0.004	4,474,954	17,597,000	0.000	000,000,000	0,000	13,000,000	25,197,750
			17,500,000		0.000		0.000	0.000		0.000	8,500,000	0.000	7,214.900	4,950,000

MQ Totals:

2014 Final Initial APQ: 1,687,000,000 2014 Final Revised APQ: 0.000 FDA Est; (2014 Initia) APQ \* 1 + FDA Est): 1,587,000.000 MIS Est: [2014 Initial APQ \* 1 + IMS Est): 1,687,000,000

2015 Proposed Initial APQ:

1,687,000.000

with 25% buffers

Besic Class: Total PC Requested: 2015 Initial APQ Worksheets

FOA Est; ISIS Est

Company	OEA Num	2015 Requested MO 2014	Revised NO 2	113 Sales 20	11 CEA NO Sales	% of 2013 Sales	Share of 2015 Total PO	2013 Inventory 2	2014 Projected Exports	2014 Projected Sales 20	15 Projected Exports 2014	Projected Investory Ad	j Avail Calc	Na.
(b)(4);(b)(7)(E)		5.000	0.000	0.00	0.000	0.000	0,000	0.000	0,000	4.000	0.000	1,000	0.000	4.000
		101,000,000	0.000	2,000	0.000	0.000	0.000	0.000	0,000	11,000,000	0,000	10,000 000	0.000	91,000,000
MQ Tetals;		101,005.000	0,000											81,004.000
2014 Final British APQ:	0.000													

2014 Final Revised APQ: FDA Est: (2016 initial APQ \* 1 + FDA Est): 0.000 0.000 IMS Est: (2014 feitial APO \* 1 + IMS Est): 0.000 2015 Proposed Initial APQ:

with 25% butter

110,000.000 137,500,000 5.000

HYDROCODONE (FOR CONVERSION)

Besic Class: Total PO Requested:

92,877,262,749

2015 Initial APQ Worksheets

FOA Enti IMS Ect;

(b)(4);(b)(7)(E)	2015 Requested 6tQ 5,000 200,000 000 20,000 366,000,000 26,000,000,000 25,002,000,000 10,000,000,000	\$,000 99,400,000 20,000 175,079,000 15,274,159,000 1,885,919,000	0,000 0,000 3,575 39,742,000 22,852,826,000 148,721,000	45,063,169,355 45,068,169,355 45,068,169,355 45,068,169,355 49,068,169,355 45,068,169,355	0,000 0,000 0,000 0,001 0,507 0,003	0.000 0.000 7.367 81.901.001 47.092.499.004 306.446.809 37.250.155.890	2013 Inventory 0,051 0,000 74,093 12,258,000 7,741,876,000 2,031,879,000 3,655,855,900 2,203,840,000	9 000 0.000 0.000 12,200,000 0.000 0.000	4,000 200,000,000 5,000 385,000,000 23,454,731,000 3,100,000,000 26,002,000,000	0.000 0.000 0.000 0.000 0.000 0.000	69,094 5,000,000 5,102,029,000 6,963,000,000 5,366,000,000	3,758 74,550,000 70,570 440,562,750 20,261,502,750 2,538,410,000 19,960,502,175	0.199 125,450,000 96,450 344,809,001 26,000,000,000 36,706,011 29,002,000,000
	10,000,000,000	2,184,719,000 6,981,532,000	605,442.000 103,852.000	45,068,169.355		1,247,705,343		200.0	6,456,000,000 9,150,000,000	0.000	6,600,000,000	19,960,302,175 3,293,894,250 8,120,275,500	4,167,152.429

2014 Final tritial APQ: 79,700,000 500 2014 Final Revised APQ:

60,790,025,000 53,559,181,000

FDA Est: (2014 Initial APO 1 + FDA Est): 79,700,000.000 IMS Est (2014 Initial APQ \* 1 + IMS Esq: 79,700,000,000

67,796,489.600

Bank Cleve: \$150-0

Basic Clave: #150-0 Total PG Requested; 2015 Initial APQ Wa

2015 Initial APO Worksheets

FDA GAI: IMS EAU

Com	DEA Num	2015 Requested MCI	7014 Revised MQ	2013 Sales	2013 DEA NO Sales	% of 2013 Sales	Share of 2015 Total PG	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	MO
	ally Springer	5.000		0.000		0,000	0.000	0,000	0.000	4,000	0.000	1,000	3.750	5.000
(b)(4);(b)(7)(E)		64,080,000					0.000	0.000	0.000	\$0,000,000	0.000	78,000 000	57,525,000	64,080,000
		30,000		2.021			4.267	49,447	0.000	14,000	0.000	63.848	59,515	30,000
		1				_	0.000	-		112,470,000	0,000,0	0.000	58,500,000	116,000,000
		715,000.000	,				995,004.655					130,000,000	558,912,026	568,344,000
		825,176.000					•			356,000,000		251,600,000		356,000,000
		356,000.000	445,000.000	334,715,000	3,574,775.079	D.D94	491,290,329	•						
		1,160,000,000	1,179,510,000	997.252.000	3,574,775,079	0.279	) 463,753.533	192,659.000	1,760.000	-			1,079,501,750	1,180,000,000
		2 060 000 000	1,674,818,000	1.389.805.400	3.574.775.079	0.389	2,019,938.314	655,997,550	0,000	2,059,000.000	0.000	924,000.000	1,098,111,663	2,060,000,000
		300,000,000				0.012	65,378.169	31,189,000	0.000	133,500,000	0.000	64,000,000	96,575,000	110,750,461

MQ Totals: 4,701,293,000 4,686,072,000

2014 Final Initial APQ: 5,400,000,000
2014 Final Revised APQ: 8,000
FDA Est: (2014 Initial APQ: 1 + FDA Est): 5,400,000,000
MS Ext; (2014 Initial APQ: 1 + MAS Est): 5,400,000,000

2016 Proposed Initial APQ: 5,000,000,000 with 25% buffer 6,250,000,000

HYDROMORPHONE

Bank Class: 9226-0

ask Class: 9226-0 Total PQ Requested:

0.000

2015 Initial APQ Worksheets

FI

FDA Est IMS Est

Company	DEA Num		Revised MQ 2	013 Spius 20	13 DEA MQ SANS %	of 2013 Sales (	Share of 2015 Total PO 2	013 Inventory 2014	Projected Exports 2014 P	Projected Sales 2016 P	rojected Exports 2014 Pro	jected inventory Adj	Avail Calc	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	0.000	0.000	0.000	0,000	8,000	0.500	0.000	1.500	1.500	1.500
MQ Totala;		2.000	2,000			•								1.500
														1.000

 2014 Final Initial APQ:
 4.000

 2014 Final Revised APQ:
 6.000

 FDA Est: (2014 Initial APQ \* 1 + FDA Est):
 4.000

 IMS Est: (2014 Initial APQ \* 1 + IMS Est):
 4.000

ISOMETHADONE

0.003

Basic Class: Total PQ Requested: 2015 Initial APQ Worksheels

FDA Est: INS Est:

Company	DEA Nom	2015 Requested MQ 201-	4 Revised MQ 20	513 Sales 20	113 DEA MQ Sales 16	of 2013 Sales Sha	re of 2015 Total PQ 21	013 Inventory 20	114 Projected Exports 2014 /	Projected Sales 2015 P	rojected Exports 2014	Projected Inventory Adj	Avail Calc	MO
(b)(4);(b)(7)(E)		2,000	2.000	0.000	8,000	0.000	0.000	. 0 000	0.000	0.500	0.000	1.512	1.500	1.500

MQ Totals: 2.000 2.000

2014 Final Initial APQ: 3.000 2014 Final Revised APQ: 0.000 FDA Eat: (2014 tohia) APQ \* 1 + FDA Eat): 3.000 IMS Est: (2014 Initial APQ 1 1 + IMS Est): 3,000

LEVO-ALPHACETYLMETHADOL (LAAM

Basic Class: Total PQ Requested:

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

0.000

2015 Initial APQ Worksheets

FDA Est: IMS Ext:

DFA Num: 2015 Requested MQ 2014 Revised MQ 2013 Spies 2013 DEA MQ Sales % of 2013 Sales Share of 2016 Total PQ 2013 Inventory 2014 Projected Expants 2014 Projected Sales 2015 Projected Expants 2014 Projected Inventory Adj 2.036 0,000 1.536 0.000 1.500 3.927 2.536 2.000 2.000 0.330 0,330 1,000 0.000

MQ Totals; 2.000 2,000 2.538

2014 Final Initial APQ: 150,000 2014 Final Revised APQ: 6.000 FDA Ect: (2014 IARIal APQ \* 1 + FDA Est): 156,000

IMS Est: (2014 Initial APQ \* 1 + IMS Est): 156,000

2015 Proposed Inhial APO: 4.000 with 25% buffer: 5.000

LEVOMETHORPHAN

Basic Class:

9220-0 Total PO Requested:

2015 Initial APQ Worksheets

FDA Est. IMS Est:

Соптралу	DEA Num	2015 Requested MQ 20	14 Revised MQ .	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total FO	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Cafe	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	1,907,000	9.0cg	0.000	0000	0 000	0 500	. 0.000	0 (.500	1.500	2.000
		2,600.000	1.598.006	1.907.000	1,907.900	1.000	4,197.000	42.000	6,000	2,094 900	0.000	1,210,000	1,230.000	2,600,000
NQ Totals:		2,602,000	1,600.000											2,602,000

2014 Final Initial APQ:

1,600,500 2014 Final Revised APG: 0.000 FOA Est: (2014 Initial APQ \* 1 + FDA Est): 1,600,000 MIS Est; (2014 Initial APQ \* 1 + IMS Est): 1,500 000 4,197,000

2015 Proposed Initial APQ: 2,700.000 with 25% buffer: 3,375 000

LEVORPHANOL

Bezig Class: Total PD Requested;

1,692,004.767

#### 2015 Initial APQ Worksheets

FDA Est: MS Est:

-.113

Сопомоч	OEA Num	2015 Requested MG 201	14 Revised MO 20	11 Sales	2013 DEA MQ Sales	% of 2013 Sales	Shore of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Celo	MQ
(b)(4);(b)(7)(E)		5,000	5,000	0.000	2,500,073.540	0.000	0.000	0.000	9.000	4,000	0.000	1.000	3,750	0.250
		5,000	5,000	1.540	2,500,073,540	0.000	1.042	4.791	0.000	1,000	0,000	3.791	7.343	9 533
		130,500,000	0.000	0.000	2,500,073,540	0.000	0.000	0.000	000.0	104,490,000	0.000	52,200.000	0.000	104,400,000
		1,150,000,000	710,000,000 32	9,151,000	2,500,073.546	0,132	272,763,474	93,062,000	9.560	1,000,000,000	9.000	220,000.000	602,311,500	652.87Z.343
MQ Yotals:		1,250,510,000	710,010,000				Ť							757,282,420

2014 Final Initial APQ: 5,000,000,000 2014 Final Revised APQ: FDA Est: (2014 Initial APQ \* 1 + FDA Est): 5,000,000,000 IMS Est: (2014 Initial APQ 11+ IMS Est): 4,436,500,000

(b)(4)

Other considerations:

| \_\_\_\_\_ | has not submitted request as of \$-1-14, left voicemail 5-27-14 requesting update of business plans in 2015
| Only5-30 | \_\_\_\_\_ | submitted 2015 applications, meperiding request # 4,000kg, will leave APQ set from 2014

(b)(4)

MEPERIDINE

Besic Class: 9232-0 Total PG Requested:

\_ 2016 Initial APQ Worksheets 0.000

FDA Est; (MS Est;

2.500

Company	ČEA Nem	2015 Requested MQ	2014 Revised MQ 21	csia2 C10	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory 2	014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Calc	
(b)(4);(b)(7)(E)		3.600	3.000	0.000	0.000	0.000	0.000	0,000	0.000	0.200	0 0.000	2,600	2.250	

MQ Totals: 3 000 3 000 2 2 000

2014 Final Inklat APQ: 5.000
2014 Final Ravised APQ: 0.000
FOA Est: (2014 Inklat APQ \* 1 + FOA Est): 5.000
IMB Est: (2014 Inklat APQ \* 1 + BIS Est): 5.000

MEPERIDINE-INTERMEDIATE-A

Basic Class:

Total PQ Requested:

2016 Initial APQ Workshoots

1.000

TUR	
IMS	Eut;

Company	DEA Num	2015 Requested MQ 2014	Revised NG 21	013 Sales 201	3 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PO	2013 Inventory 201	14 Projected Exports Z014 P	rojected Sales 2015	Projected Exports 2014 Pro	jected inventory Adj	Avail Calc	MO
(b)(4):(b)(7)(E)		5.000	7.000	0.579	0.579	1.000	1.000	7.031	0.000	1,000	0.000	11,531	10,523	14.031
MQ Totals:		6 000	7.000											14.031
2014 Final Initial APO: 2014 Final Revised APO: FDA Est: (2014 Initial APO*1 + FDA Est): USS Est: (2014 Initial APO*1 + MS Est):	9 000 0,000 9,000 9,000													
	•	•												

MEPERIDINE-INTERMEDIATE-9

Rask Class: 9234-0 Total PO Requested:

0.000

2016 Initial APQ Worksheets

FDA Ext: GMS Est:

2.800

| Companie | DEA Num | 2015 Requested MQ 2014 Revised MQ 2013 Sales 2013 DEA MQ Sales % of 2015 Sales | Share of 2015 Total PQ 2013 Invertority | 2014 Projected Exports | 2014 Projected Exports | 2015 Projected Exports | 2015 Projected Exports | 2015 Projected Exports | 2016 Projected Exports | 2015 Projected Exports | 2016 Projected Exports |

MQ Totals: 3,960 2,000 2,600

 2014 Final (wital APQ;
 5,000

 2014 Final Revised APQ;
 0,000

 FDA Ext; (2014 Initial APQ \* 1 + FDA Ext);
 5,000

 IMS Ext; (2014 Initial APQ \* 1 + PM3 Ext);
 5,000

MEPERIDINE-INTERMEDIATE-C

Basic Class: Yotal PO Requested:

5.000

2016 Intilat APQ Workshoets

FDA Ess: IMS Est:

$\begin{picture}(b)(4);(b)(7)(E) \end{picture} \label{eq:decompany} \begin{picture}(b)(4);(b)(7)(E) \end{picture}$ MQ Totals:	2015 Requested MQ 2014 5.000 5.000	5,000 5,000 10,000	3 Sales 2013 DEA MQ Sales 0,000 0,000 0,000 0,000	% of 1013 Sales 0 000 0 000	Share of 2018 Total PC 0,00 0,00	0 C.000	14 Projected Exports 2 0,000 0,000	4,000 1,000	2015 Projected Exports 2 5,000 6,000	.750 0.250 .750 4.000
2014 Final Initial APQ: 15 000 2014 Pinal Revised APQ: 0,000 PDA Est: (2014 Initial APQ * 1 + FDA Est): 15,000 IARS Est: (2014 Initial APQ * 1 + IMS Est): 15,000	0									4250

METAZOCINE

Basic Class: 9250.0

issic Class: 9250 0 Yotal PG Reguested: 2015 Initial APQ We

2015 Initial APQ Workshoots

FOA ENC IMS Est

-.D47

- Company DEA N (b)(4);(b)(7)(E)	2015 Requested MQ 5 000 10 000 526,000,000 15,000,000 000 4,640,000,000	0 900 10,000 339,395,000 10,155,194,000	0,000 1,454 65,918 000	19,975,758.454 19,975,758.454 19,975,758.454 19,975,758.454	B.000 B 000	Share of 2015 Total PQ 0 000 1 235 50:501.126 10,460,399 245 2,961,283.994	0.000 6.841 16,087,000 3,456,715.000	41,830 000	914 Projected \$3164 20 5 000 5 000 481,500 000 14,105,610 000 3,346,400 000	015 Projected Exports 203- 0.000 0.000 10.000 0.000 0.000	0,000 11,349 44,500,000	0 660 12.631 252,111 500 10,208,931,750	80 5,000 13,176 292,493,157 15,000,000,000 3,102,445,742
MO Totals:	Z0,166,015.000	15,026,874 000											18,394,957,075
2014 Final Initial APC: 25,500,01 2014 Final Revised APC: FDA Ext (2014 Initial APC * 1 + FDA Ext): 25,500,01 INS Ext (2014 Initial APC * 1 + IMS Ext): 24,298,91	Q,000 00.006							•					

Other considerations:

2014 MQ	is factibles at the end of 2014 6,376,000,000 6,323,000,000 1/(1) Is not apparent at this time	
sales in 2013 for	1)(4) Is that appeared a storage since	_
ARCOS	5,816,000 000	(b)(4)
HAS	3,100,000.000	(-)(-)
2014 PQ	5,673,785.000	
2013 PO	5 657 134 000	

### ARCOS 2014 top distributors receiving pq

18,334,767 887

	T .	T		T		T	<del></del> _	_
<b>#10</b>	Drive	Del/Maraf &	District for House, as	Cristipular +	(k piu sinykor's	Destributor's	Driamoseor"s	Towl
Fug.	MarMa	Dan No	Heren	Cdy	Man.	Di asian	Critica	GMD1
i	1 METHADONE (92500)	(b)(4):(b)(7)	(F)		147	NEW YORK	*\8\$K*	1,786,320,723
	: METHACONE 1995081	(0)(+),(0)(1)	(L)		FL	LASS A. LAND	TAMPA	530,035.035
	S METHADOVIE:57568:				сн	регяол	COLUMBUS	529,141.798

2,845,497.556

METHADONE

## Mothadone

Measure : Tot Kg (Absolute)

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

Basic Class: Total PQ Requested:

0.000

2015 Initial APQ Worksheets

FDA Est: IMS Est:

Share of 2015 Total PQ 2013 Inventory 2014 Projected Exports Adj Avail Calc 2015 Requested MQ 2014 Revised MQ DEA Num 2013 Sales 2013 DEA MQ Sales % of 2013 Sales 22,287,908,000 0.000 0.000 0.000 0.000 7,500 5.000 (b)(4);(b)(7)(E) 10,000 10.000 0.000 666,946,500 0.009 0.000 66.287.000 0.000 1.025,700.000 822,975.000 194,755,000 22,287,908,000 1,148,000,000 0.484 0.000 2,170,972.000 0.000 10,574,712,750 16,200,000,000 16,200,000.000 11,928,645.000 10,780,205,000 22,287,908,000 0.000 1,258,126,000 0.000 4,746,648,750 4,960,000,000 0,180 4,960,000.000 5,070,739,000 4,002,598.000 22,287,908,000

22,185,705.000 22,308,010,000 17,822,369,000 MQ Totals:

2014 Final Initial APQ: 31,100,000,000 2014 Final Revised APQ: 0.000 FDA Est; (2014 Initial APQ \* 1 + FDA Est): 31,100,000,000 IMS Est: (2014 Initial APQ 11 + IMS Est): 31,100,000,000

2015 Proposed initial APQ: (b)(4)

27,500,000.000

& buffer:

34,375,000,000

Other considerations:

has not requested MQ for 2014 or 2015

in 2013(b)(4) MQ was 9,000kg

bustomers, so add 50% of their 2013 quota to proposed APQ not clear who has picked up (b)(4)

Basic Class: Total PG Requested:

2015 Initial APQ Worksheets

FDA Est. IMS Est.

38,324,780,910

	Company	DEA Nam	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA MO Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Aygii Calc	MO
- 1	(b)(4);(b)(7)(E)		5,000	0,000	0.000	47,603,753.601	0.000	0.000	0.000	0.000	5.000	000,0	0,000	0.000	\$.000
	(b)(+),(b)(1)(L)		749,000,000	0,000	4.000	47,800,753,801	0.000	0.000	0,000	0.000	749,000.000	0.000	0.000	0.000	749,000,000
			4,800,000,000	5,350,000,000	3,335,263,000	47,803,753,801	0,070	74,636.697	24,303.000	3,840,000 990	3,849,000.000	0.000	1,944,301,000	4,030,727.250	3,738,492,871
			17,000,000,000	44,000,000,000	36,564,556.000	47,803,753.801	0.765	519,243,621	12,904,910,000	0.400	37,123,902.000	0000	9,983,206.000	42,678,682,500	20,599,251,621
			22,001,000,000	19,430,762,000	7,417,794,000	47,603,753.601	0.165	178,289,102	2,451,207,000	9 000	20,263,000,000	0,000	4,168,000.000	9,661,476,750	10,209,083,628
			2,000,000	2,675,000	160,000		0.000	3,560	69.210	0.000	2,000 000	0.000	0,000	2,206.156	947,790
			4,500,900,000	1,960,000,000	0.660	47,603,753 801	0.000	0,000	0.000	0.000	4,500,000 000	000,0	0.00.0	1,470,000,000	3,030,000,000

MG Totals:

73,000,000,000

1,069,755.000

69,052,005,000 61,743,637,000

2014 Final Initial APO: 2014 Final Revised APQ: 0.000

FDA Ext (2014 Initial APQ \* 1 + FDA Est): 73,000,000,000 (MS Est (2014 Initial APQ 1 1 + 845 Est): 73,000,000,000

MORPHINE (FOR CONVERSION)

Barkio Claus: \$300-B

Total PQ Requested;

42,541,348.397

2015 Initial APQ Worksheets

1

oranggas FC

FDA Ext: .034

2015 Requested MQ 2014 Revised MQ 2013 Sales 2013 DEA MQ Sales % of 2013 Sales Share of 2015 Total PQ 2013 Inventory 2014 Projected Exports 2016 Projected Sales 2018 Projected Exports 2014 Projected Exports 2016 Projected Sales 2018 Project DEA Num 0.000 1,000 0,026 0.000 4.000 3.770 0.224 5,000 5.000 35,757,656.635 0.000 0.000 2.630 130,576 20.000 0.000 203.576 172,934 213,206 35,757,656.635 0.000 100,000 100.000 2.165 0.000 0.000 216 000,000 0.000 0.000 216,000,000 218,000,000 35,757,656,835 0.000 0.000 0.000 3,9(0,338,102 71,326,000 13,636,395,500 4,779,867,000 3,271,287,000 35,757,656,635 0.091 71,327,000 D,**00**0 4,700,000.000 0.000 5,842,945.377 4,700,000,000 6,502,250,000 14,582,598,500 17,592,397,039 13,299,750.000 0.000 13,800,000,000 14,744,006.000 12,819,984,000 15,757,656,631 0.361 15,468,586,031 5,199,458,000 839,250 000 0.000 750,000 0.000 1,000.000 0.000 1,000.000 35,757,656,635 9,090 0.431 0,000 1,000,000 0.360 5,553,000,000 19,547,553,750 23,965,652,115 21,183,000,000 0.000 0.000 28,002,000.000 19,333,576,000 16,047,146,000 35,757,656,635 0.448 19,226,130,492 6,729,629,000 8,200,000,000 3,150,000,000 3,850,000,000 D 000 7,000,000,000 0.000 0,000 0.000 0.000 7,000,000,000 4,200,000.000 0.000 25,757.656,635 0.000 0.000 0,000 450,000,000 000.0 450,000.000 450,000 000 0.000 0.000 35,757,656,635 0.000 0.000 0,000

MQ Totals: 54,169,105.000 42,558.554.000 52,037,458.502

2914 Final Initial APQ: 50,000,000,000
2914 Final Revised APQ: 9 000
FOA East (2014 Initial APQ \* 1 + IUS Ear): 50,000,000,000
UKS Est: (2014 Initial APQ \* 1 + IUS Ear): 48,43,000,000

MORPHINE (FOR SALE)

Basic Class: 9630-0 Total PQ Requested:

1,130.003.000

2016 Initial APQ Worksheets

FOA Est:

Company	DEA Num	2015 Requested MQ	2014 Revised WO 2	013 Sales	2013 DEA MO Sales	% of 2013 Sales	Share of 2015 Total PO	2013 inventory	291 4 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory		MQ
(b)(4);(b)(7)(E)		53,450,009	35,000,000	21,054.000	388,654,000	0.054	61,530.786	14,352 000	0.000	38,000.000	0.000	19,000,000	37,014,000	74,311.485
(5)(1),(5)(1)(2)		450,000,000	430,000,000 36	65,600 000	386,654,000	0.948	1,068,474,212	173,167,000	0,000	440,000.000	0.000	203,914,000	452,390.250 1	1,278,905.765
		40,000.000	9.000	0.000	386,654,000	Q.000	0.000	0,000	0.000	40,000,000	5.000	0.000	0.000	40,000,000
										-				

MQ Totals: 543,450,000 465,000.000 1,394,217,250

2014 Final Initial APQ: 500,000,000
2014 Final Revised APQ: 0.000
FUA Est: (2014 Initial APQ \* 1 + FUA Est): 500,000,000
BUS Est: (2014 Initial APQ \* 1 + RKS Est): 500,000,000

2015 Proposed Initial APQ: 550,000,000 with 25% buffer: 667,500,000

68,124,000

Basic Class: 8619-0 Total PQ Requested: 2016 Initial APQ Worksheets

FOA ÉRO IMS Ext:

Comp	eny DEA Num	_2016 Requested MQ 201	14 Revised MQ 2013 Sales 2	613 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory 20	014 Projected Exports	2014 Projected Sales	2015 Projected Exports 2	914 Projected Inventory	Adj Avail Celc 6	AC
(b)(4);(b)(7)(E)		56,000,000	58,271,900 51,184,000	51,164,000	1.000	68,124,000	93.000	0.000	17,000,000	0.000	19,000,000	43,773,000 58,35	SR 746
(6)(1),(6)(1)(2)		7-02:042	-,27-105 21,12-1.000	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,								,	,
		J											
MQ Totals:		56,000.000	58,271,000									58,39	\$8.750

2014 Final Minial APQ: 50,000,000
2014 Final Revised APQ: 0,000
FDA Est; (2014 Initial APQ 1 + FDA Est): 90,000,000

IMS Eat: (2014 Intitial APQ \* 1 + IMS Est): 00,000,000

OPIUM, POWDERED

Basic Class: 9330-0 Total PO Requested: Worksheets

FDA Est: BAS Est:

0.000

3,167,000

253,484,004

68,262,000

151,100,000

324,254,000

0.000

0.000

0.000

0.000

0.000

0.000

0.000

5,000

1,200,000 000

1,131,000 000

18,777,778.000

2,892,000,000

1,000,000,000

1,403,000 000

Share of 2015 Total PC

0.000

152,622 346

2,424,597 830

612,227.915

0,000

42,651.751

Inventory 2014 Projected Exports 2014 Projected Sales 2015 Projected Exports 2014 Projected Inventory Adj Avail Calc

0.000

0.000

0.000

0 000

0 000

0.000

D 000

0.000

0.000

0 000

316,179.000

1,339,000.000

1,400,000,000

23,000 000

Company	CEA Num	₩0	MQ	2013 Sales	Sales	% of 2013 Sales	:
(b)(4);(b)(7)(E)		5.000	5 000	0,000	13,621,761 493	0.000	
(D)(4),(D)(1)(L)		1,200,009,000	1,100,000,000	839,490 000	13,621,781,483	- 0047	
		1,131,000,000	1,674,318,000	178,502,000	13 621 761 483	0.013	
		19,000,000,000	10,732,298,000	10.140,513 000	13,621,761,460	0.745	
		5,151,000,000	3,263,650.000	2,565,244,480	13,621,761.480	D.168	
		1,000,000,000	612,500,000	0.000	13,821,761,460	0.000	
		1,000,000,000	430,000 000	0.000	13,621,761 460	D 000	
MQ Totali:		28,482,005,000	17,832,771.000				

3,251,005,000

27,297,005.00a

3 750

-90,633,000 827,375,250 1,200,000,000

796,602.000 1,445,651.500 1,127,000.000

542,750,000 7,578,082,530 3,970,000,000

63,230,000 702,573,000 1,000,000,000

-973,000 000 372,500 000 1,000,000.000

-7,978,198,000 6,101,185,000 19,000 000 000

0.000

2014 Final Initial APQ:	18,200,000.00
2014 Final Revised APQ;	0.90
Est):	18,200,000.00
IMS Eat: (2014 Initial APQ * 1 + IMS EAT):	18,200,000,00

2016 Proposed Initial APQ: 27,300,000,000 with 25% buffer: 34,125,000,000

OR PAVINE

BASIC CLASS:	2015 Initial Quota Worksheets	Oripavine	9330				
Company:	(b)(4)					·	
Request:	1200.0	1131.0	19000.0	5151.0	1000.0	1000.0	
Current Year MQ:	1100.0	1674.0 (buprenorphine pd)	10732.0	3284.0	612.5	430.0	
Year end inventory	3.2	253.5	1579.8	1007.0	324.0 (PQ inventory)	327.0	
Esleviations hydromotphone oripavine oripavine/buptenorphine derivati oxymorphone (sale) oxymorphone (conv) losses	amt needed subtance MQ yield	ami needed aubtance MQ yield 257.778 116.000 0.49 500.000 (fee (b)(4) 368.889 166.000 0.450		2893.258 2060,000 D.712 1.000 (ref stds)	amt needed substance MQ, yield	ami needed subt 428.571 1666.667	ance MQ yield 300,000 0,700 700,000 0,429
total needed	1290,000	1126.667	21948.052	3965.258	1000,000	2095.238	
initial MQs est need MQ: Total Initial MQs:	1771.833	1573.349 1127.600	· 26538.303	4770.573 3970.000	1079.125	2399.531	

27297,005

Total MQs: 2
FURTHER CALCULATIONS

Proposed Initial APQ 27300

27297.000 + others

pripavin

laquest ID. 119726				'A	
	honderl (onle	1 new 105-1001	·	Date Submitted	01-MAY-14
Name of Basic Class or List 1 C PRIPAVINE	nemical (only	T_DOL DEW-IRAL	Schedul	e/List Number	2
ame and Address of Registrant			Drug Co		9330-0
0)(4)			Quota Y	ear istration Number	2015 b)(4):(b)(7)(E)
			new Ked	TRUESCION NUMBER	~,(~,,(~,(, /,(_)
ontact Person (b)(6)			Pax. No		b)(6)
mail Addrags (D)(4):(D)(6)			Phone N		<u> </u>
NOTE: All Quantities	ate to pe Exbreues	d in Grame of Anhy	Quotae Previous	Alkaloid(not as Salts	
icta Kistory		2013	2014	2015	Quota Requeste
		1,000,000.0	1,100,000.0	0.0 Estimate for	1,200,000.0
roduction Data	'	2nd Preceding Year	lst Preceding Year	Current Year	Requested
nventory as of Dec 31					
a.Bulk Controlled Substance/List 1	Chemical	3,167.0	6.c	0.0	
b.In-Process Material		9.0	0.0	0.0	
c. Contained in FINISHED Dosage Fo	erms	3,167.0	0.0	0.0	
isposition(Sale)/Utilization	· ·	640,094.0	0.0	1,200,000.0	1,200,000
a.Domestic		0.0	0.0	0.0	
b Exports		640.094.0	0.0	1,200,000.0	1,200,000
equisition/Production	<u> </u>	731,560.0	0.0	1,200,000.0	1,200,000
a.Domeatic Sources	······	731,568.0	0.0	1,200,000.0	1,200,00
the Purpose is to Manufacture Anothe	r Substance(e), Pu	rnish the Following	Information:	··	
Name of New Substance	Drug		Amount Deed for th		% Yield
		2012	2013	2015	
Date of Destruction			plenetics		
		•			
ckaging Froduct Nama	Strength 0	Inits/Pkg # of	Fkgs	Purpose	Total Quanti
schaging Froduct Name	Strength 0	hits/Pkg s of	Pkga	Purpose	Total Quanti
ckaging Product Nama	Streugth 0	inita/Pkg 4 of	7kga	Purpose	Total Quanti
schaging Froduct Nama	Streagth 0	inits/Pkg 6 of	7kga	Purpose	Total Quanti
schaging Froduct Nama	Streagth 0	inits/Pkg 6 of	7kga	Purpose	Total Quanti
schaging Product Name	Streagth 0	inite/Pkg 4 of	7kga	Purpose	Total Quanti
emarks				· · · · .	
marks ipavine mig quota is requested to ug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
marks ipavine mig quota is requested to ug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific
emarks ripavine mig quota is requested to rug code the the Intermediate quota effects modest growth for the produ	convert oripavin	e to a Burrenorph	ine Intermediats fo	r (b)(4) As there	is no specific

APPLICAT	ION F	OR INDI	VIDUAL MA	NUFACTUR	ING QUOT	ra			
Request ID. 118650						Date St	bmitted	26-MAR-1	4
Name of Basic Class or List 1 Chemical	(only	1 per I	BA-189)		anhedu?	o/List N	umbas	2	
ORIPAVINE Name and Address of Registrant					Drug Co		under	9330-0	
(b)(4)					Quota Y			2015	
					DEA Reg	1stratio	n Number	(b)(4);(b)(7)(E)	
Contact Person (b)(6)					Fax. No	ı		(b)(6)	
Email Address (h)(4)(h)(6)			-		Phone N	o		,,,,	
NOTE: All Quantities are to be	Express:	sed in Gra	ms of Anhyo	troug Acid.	Base, or	Alkaloid(n	ot es Salta	r).	
nota History		20:	13	201			15	Quota Reque	sted
-	-	1,467	039.0	1,674,	318.0	0	. 0	1,131,000	.0
Production Data		2nd Preced	ding Year	lat Precedi	ing Year	Estima		Satimate for	Year
Inventory as of Dec 31				25		Curren	t Year	Requested	
a.Bulk Controlled Substance/List 1 Chemical.	🗔		253,484.0	46-	9 0.0	•	0.0		0.
b.In-Process Material		<del></del>	0.0	<u>(2_(</u>	0.0		0.0		0. D.
c. Contained in FINISHED Dosage Forms	├		253,484.0		0.0		0.0		0
Disposition(Sale)/Utilization	-		154,943.0		0.0		.131,000.G	1,131,	000
a.Domestic.,,i	$\vdash$	<del>.</del>	0.0		0.0		0.0	1.131/	0.
b Exports	Ŀ		154,943.0		0.0	1	,131,000.0	1,131,	000
Acquiaition/Production	一口		151 200 -				131 000 1	1,131,	000
a.Domestic Sources	⊢		154,690.0 154,690.0	-	0.0		,131,000.0 ,131,000.0		
				1-f	<del></del>				
If the Purpose is to Manufacture Another Substance		urnien Che	raileving			ia Purpose		\$ ¥1	n) d
Nome of Now Substance	Drug		2012	A DOUBLE US	2013	- A FAIRAGE	2015	/	
TYDRONORPHONE 209, 218 10 1	9150-		0		0		116,00		
AYTHOROPHONE (FOR SALE)  The (072-101)	9652-1	B	35,053		17,237		166,00	90 L 45.	00
= CAMPE C= (171)									
Product Davelopment Dosage Form Strength	Unite	/Batch	d of Bate	hes Bat	ch Purpos	Ret.	Gnewerth	Mat. Completion	a Tim
Date of Destruction			Ray	plenation					
eckaging Product Name Strength	h	Unite/Pkg	# of	Pkgs		Purpose		Total Quar	atity
<u>-</u>			_						
•									
•									
Remarks									_
Quota is for supply of 506 Kg to $(b)(4)(b)(7)(E)$			(b	)(4); will a	lso use (	ripavine	for intere	nal conversion	to
Dxymorphone and Hydromorphone. See supporting	4 docu	mentation	SUDMITTED	via email	for sale	es breakdo	wn.		
•									
•									
,									
•								1	

APPLICATI	TON 901	INDIVIDO	AT. MARITE	ACTURING QUOT	'A	
Request ID, 119506	CON FUL	- TMDIATDO	AL FAIRNUT	WOTOWTHO MODI	Date Submitted	29-AFR-14
Raquest ID. 119506 Rame of Basic Class or List I Chemical (	(only 1	per DEA-1	(B9)		Paca Summaccau	27-N1X-13
RIPAVINE					e/List_Number	2
Name and Address of Registrant				Drug Co		9330-0 2015
b)(4);(b)(7)(E)				Quota Y DEA Reg	ear Istration Number	
				<u> </u>	·	(1)(0)
contact Person (h)(6)				Pax. No		(b)(6)
MAIL ACQUEUB_(D)(4),(D)(O)  NOTE: All Quantities are to be E	xpre###	in Grane of	Anhydrous	Acid, Base, or	Alkaloid(not as Salte	a).
<u> </u>	<u>-</u>	2013		Quotas Previous	Ty Issued by DEA	Quota Reguested
ucta History	<u> </u>	10,400,000.		10,732,298.0	0.0	19,000,000.0
roduction Data	21	nd Preceding Y		Proceding Year	Retimate for	Estimate for Year
····					Current Year	Requested
nventory as of Dec 31 a, Bulk Controlled Substance/List 1 Chemical		69,	282.C	0.0	316,179.0	<del></del>
b.In-Process Material		<del>-</del>	0.0	0.0	0.0	
c. Contained in FINISHED Donage Forms	├─	69,2	282.d	0.0	316,179.0	
isposition(Sale)/Utilization			o, d	0.0	18,777,776.0	18,777,778
a.Domestic.,			0.0	0.0	0.0	0
b Exports	ļ_		a. c	0.0	19,777,776.0	18,777,778
equisition/Production	<b>—</b>		ō.a	0.0	19,000,000.0	19,000,000
a.Domestic Sources			0.d	0.0	19,000,000.0	
the Purpose is to Manufacture Another Substance(	(s), Fur	nish the Poll	owing Info	ormation:		
Name of New Substance	Drug		λm	sount Deed for th		4 Yield
KYMORFHONE (FOR CONVERSION)	9652-A	3,530		7,854,77	2015	
	7634-A	1,530	, , , , ,	1,000,000	•	
(679.762(inv)					110.90	න,හො
			Batches	Batch Purpose		Est. Completion Ti
Product Development Dosage Form Strength	Units/E	LECK WO	. BECCHEU	Paccel Fairpos	not, denterly	
					•	•
<u> </u>				<u> </u>		
Date of Destruction			Emplane	ation		
						•
•						•
•	.•					_
ackaging Product Name Strength	- De	lts/Pkg	f of Pkgs		Ригрове	Total Quantit
					-	
,						
елатки					<u> </u>	<del></del>
				•		
					•	
						,
				•		
				•		
				•		
				·		

	TORMTON G	OR THREUTHER W	ANUFACTURING QUO	m	
	ICATION P	OR INDIVIDUAL M	MULACIUKING DOD		
Request ID. 119630	<del></del>			Date Submitted	01-MAY-14
Name of Basic Class or List 1 Chemic ORIPAVINE	cal lonly	1 Der DEA-1891	Schadul	e/List Number	2
Name and Address of Registrant			Drug Co		9330-0
(b)(4)			Quota )		2015
				istration Number	
					// \ / (A)
Contact_Person(D)(6)  Rmail_Address_(b)(4):(b)(6)			Fax, No		(b)(6)
NOTE: All Quantities are to	n he Fynrass	ed in Greme of know	Phone to		1
WOLE ALL GUARICIES SEE C			Quotas Praviou	aly Issued by DEA	
Queta History		2013	2014	2015	Quota Requested
		3,126,000.0	3,283,650.0	0.0	5,151,000.0
Production Data		2nd Preceding Year	lot Preceding Year	Estimate for Current Year	Setimate for Year Requested
Inventory as of Dec 31	-				
a.Bulk Controlled Substance/List 1 Chem	ical	0.0	0.0		1,339,000.
b.In-Process Material.,		151,100,0	0.0	0,0	0.0
c. Contained in FINISHED Dosage Forms		151,100.0	70.0	1,339,000.0	1,339,000.0
Disposition(Sale)/Utilization					
a.Domestic	⊢	4,676,705	0.0	2,892,000.0	2,892,000.
b Exports	⊢	4,676.78	0.0	2,892,000.0	2,892,000.0
Acquisition/Production		1,010,10			
a.Domestic Sources	□	2,003,510.0	0.0		5,151,000.0
	<u></u>	2,003,510.0	0.0	5,151,000.0	5,151,000.0
If the Purpose is to Manufacture Another Subs	stance(a), Po	rnish the Following	Information:	<u></u>	
Name of New Substance	Drug		Amount Used for th		k Yiold
		2012	2013	2015	71.20
HYDROMORPHONE	9150-0	1,146,220	1,965,400	.34 2,060,0	UO A 71.20
855.998(10V)					
Product Development Dosage Form Strongth	h Unite	Batch '# of Batc	has Batch Purpos	e Est. Quantity	Est. Completion Time
				•	
Transfor Registrent		Exclenati	lon of Transfer		
				·	
· ·					
<b> </b> •					
<u></u>		·			<u> </u>
Date of Destruction		<u>P</u> x	planation		
,				,	,
· ·					
Packaging Product Name Str					
	rength	mits/Pkg # of	Pkge	Purpose	Total Quantity
<u> </u>	rength	mits/Pkg # of	Pkg●	Purpose	Total Quantity
	rength	mits/Pkg # of	Pkg≠	Putpose	Total Quantity
	rength	Units/Pkg # of	Pkge	Putpose	Total Quantity
	rength	Units/Pkg # of	Pkge	Purpose	Total quantity
,	rength	Units/Pkg # of	Pkge	Purpose	Total Quantity
	rength	Znits/Pkg # of	Pkge	Purpose	Total Quantity
Remarks			. (		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2.892,000 grams for conversion to hydromo: reference standards/conversion to hydromo:	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		
Remarks 2,892,000 grams for conversion to bydromo	rphone, los	a on production e	ctimated at 1,071,0		

	APPLICAT	ION FO	R INDI	VIDUAL MA	NUPACTUR	ING OUOT	A		
Request ID. 119606			2110/2				Date Submitte	d 30	0-APR-14
Name of Basic Class or List 1	Chemical	(only	1 per	DBA-189)					
ORIPAVINE							/List Number		2
Name and Address of Registran	<u> </u>					Orug Coc Quota Ye		<del>- </del> -	<u>9330-0.</u> 2015
(b)(4)							stration Number	er (b)(4);(	
(b)(6)						Fax, No		(b)(6)	
Contact Parson (b)(6)  Rmail Address (h)(4)(h)(6)		1	_			Phone No		(6)(6)	
NOTE: All Quentitie	es exe to be:	Expresse	ed in Gr	ans of Anhye	rous Acid,	Base, or	lkeloid(not se 8s	lts).	
Quota History		-	20	13			ly Issued by DEA 2015	Qua	ta Requested
•			700,	000.0	612,	00.0	0.0	1,	0.000,000
Production Data	_		and Prece	ding Year	1st Proced	ing Year	Estimate for		mate for Year
Inventory as of Dec 31					•		Current Year		sequenced.
a.Bulk Controlled Substance/List	1 Chemical.	🗀		324,264.0		0.0	1,400,000		1,400,000.
b.In-Process Material				0.0		0.0		0.0	
c. Contained in FINISHED Dosage	Forms	⊏	·	324,264.0		0.0	1,400,000	0.0	1,400,000
Disposition(Sale)/Utilization		$\neg \vdash$		-67.0		0.0	1,000,000	1.0[	1,000,000.
a.Domestic				0.0		0.0		1.0	0.
b Exports				67.0		₫.页_	1,000,000	. q	1,000,000.
Acquisition/Production				327,581.0	·-··	0.0	1,000,000		1,000,000
a.Domestic Sources	*********	$\sqsubset$		327,581.0		0.0	1,000,000	0.0	1,000,000.
If the Purpose is to Manufacture Anot	her Substance	(a), Fu	rnish <b>t</b> h	a Following	Informatio	on :			
Name of New Substance	i	Drug		4014	Amount U	and for thi		15	* Yield
Supremorphine base		0000-0	<u> </u>	2012		2013	500	,000	50.00
Buprenorphine HCl		0000-0		ō		0		,000	50.00
•									
Product Development Dosage Form	Strength (	Units/	Batch	# of Batc	bes Bar	tch Purpose	Est. Quantity	Est. C	oppletion Tim
<del></del>							<del>_</del>		
						٠.	-		•
Date of Destruction				Exp	lanation				
r				-					
•	•					•			
_ ·				<del> </del>	,—			· · · ·	- Connected
Packaging Product Name	Strengt	P 1	in1ts/Pkg	# of	kga		Putpose	T	otal Quantity
					`				
			_			,			
Remarks Multistep conversion of intermedia	ce purchases	d from a	a CMO ac	mainst proc	uzement o	uota to Bu	premorphine base	and Bup	renorphine
HCl against manufacturing quota,			,	,	•			-	
			•		•		_		
		•							
		,							
I									
	~								7
	-	-							

	APPLICATION	FOR INDIVIDUAL	MANUFACTUE	ING QUOT	A	
Request ID. 118690				-	Data Submitted	27-MAR-14
Name of Basic Class or List 1 C	hemical (only	v 1 per DRA-189	<u> </u>	Schedule	/List Number	
Name and Address of Registrant				Drug Coc		9330-0
(b)(4)			<u> </u>	Quota Ye		2015
				PEA Regi	lstration Number	(b)(4);(b)(7)(E)
Contact Ferson (b)(6)				Fax. No		(b)(6)
mail Address (b)(4) (b)(6)				Phone No		
NOTE: All Quantities	are to be Empre	seed in Orans of An	nydrous Acid, Onot-	Base, or A	llkaloid(not se Salta ly Isaued by DEA	.)
uota Bistory		2013	20:	14	2015	Quota Requestes
		0.0		0.00	0.0	1,000,000.0
reduction Data		2nd Preceding Year	let Preced	ling Year	Estimate for Current Year	Recioate for Year Requested
nventory as of Dec 31			<u> </u>			· · · · · · · · · · · · · · · · · · ·
a, Bulk Controlled Substance/List 1	Chemical	0		0.0	23,000.0	23,000
b.In-Process Material			d	0.0	. 0.0	<del>-</del>
c. Contained in FINISHED Dosage For	cms			828 0.0	23,000.0	23,000
isposition(Sale)/Utilization			<del></del>	0.0	1,403,000.0	1,403,000
a,Domestic				0.0	0.0	٥
b Exports	······	0	.d	0,0	1,403,000.0	1,403,000
equisition/Production			d	a. of	1,000,000.0	1,000,000
a.Domestic Sources		0		0.0	1,000,000.6	
the Purpose is to Manufacture Another	Substance (s)	Furnish the Followi	ng Informati	3011	<u> </u>	
Name of New Substance	Drug			sed for thi		4 Yield
		2012		2013	2015	
	•					
Product Development Dosage Form   St.	rength Unit	se/Batch   Wof Ba	tches Ba	tah Purpose	Est, Quantity	Est. Completion Ti
•						
renefor Registrant		Explana	tion of Tran	4147		
•						
						<u> </u>
Date of Destruction			Explanation			· .
		Harattan Har	6 Thee		Purposo	Total Quantit
seckaging Product Nama	Strength	Unite/Pkg # 0	f Pkga			
(1, 1)			0, W	$L_{A}I$		
~ ~ ~ (")		<i>√</i> √	Y) 413	Wing.		
They be,		aD <sup>o</sup>	May be		•	
15 m		1,511	<b>~</b> ``			
	<u> </u>			_		
emaț¥o 03,000g is planned for use in Hydro		/			роле	·
us, uoug 18 planned for use in Hydro	musphone and 1	'100'nond to hrum	101 196	ers mediumph		
	-					
					•	
•						

Basic Class; 8143-Total PO Requested; 2016 Initial APQ Worksheets

MILE APQ HORENEELS

FDA Est:

2015 Requested MQ 2014 Revised MQ 2014 Revised MQ 2014 Sales 7013 DEA MQ Sales % of 2013 Sales State of 2015 Total PQ 2013 Inventory 2014 Projected Exports 2014 Projected Exports 2014 Projected Exports 2014 Projected Exports DEA Num Сотрепу 5.000 0.000 0,000 5,624,322,000 0.000 0.000 4.000 0.000 4.000 0.000 1.000 0.000 4.000 (b)(4);(b)(7)(E) 1,101,720,000 5,347,588,500 \$72,879.000 0.000 1,403,509,000 0.000 1,600,000,000 6,157,639,000 5,624,322,000 5,624,322,000 1.000 · \$000 000,000,000,1

MG Totalis: 1,600,004.000 6,157,633.000 1.600,005.000 6,157,633.000 1.600,004.000

2014 Final Initial APQ: 7,400,000,000
2014 Final Revised APQ: 0.000
FDA Est; C2014 Milal APQ\*1\*FDA Ext; 7,400,000,000
(M2 Est; (2014 Milal APQ\*1\*HIS Ext; 7,400,000,000

2015 Proposed Initial APCI: 6,660,000 000 with 25% burler: 6,250,000,000

Other considerations:

booked at historical APQ, requested MQ, granted MQ to determine avg

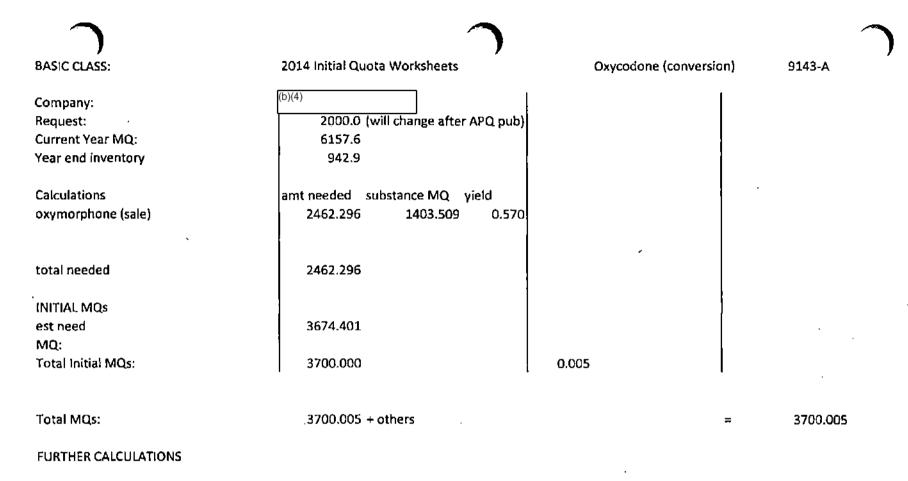
Requested MQ Granted MQ 2010 5,600,000,000 5,600,000,000 5,600,000,000 5,120.000.000 5,200,000.000 5,120,000.000 2011 7,600,000,000 8,000,000.000 7,542,000,000 2012 5,840,045,000 8,200,000,000 9,800,000,000 2013 7,400,000,000 7,400,000,000 6,157,639,000 2014

5.000

6,800,000,000 7,184,000,000 6,051,936,800

6,678,645,600

OXYCODONE (FOR CONVERSION)



Proposed Initial APQ 6680 used historical avg

APPLYCA	TION	FOR INDIVIDUAL	IANUFACTI	URING QUOT	'A	<del></del>
Request ID, 119514					Date Submitted	29-APR-14
Name of Basic Class or List 1 Chemical	_(onl	y 1 per DEA-189				
OXYCODONE (FOR CONVERSION)					e/List Number	0
Name and Address of Registrant				Drug Co		9143-A
(b)(4)				Quota Y	ear letration Number	2015 (b)(4)·(b)(7)(E)
				DEA Reg	recrection Number	(D)(4),(D)(1)(E)
Contact Person (h)(6)				Pax. No		(b)(6)
Smail Address (b)(4):(b)(6) NOTE: All Quantities are to be	N North	and in Grame of Ani	vdrous Aci	<u>Phone N</u>	Alkaloidinat ma Salta	11,
			Que	Stas Previous	TA ISSUED DA DEN	Quota Requested
hota History	ļ	2013 5,840,045.0		7,639.0	2015	1,600,000.0
Production Data		2nd Preceding Year	· .	eding Year	Ratinata for	Estimate for Year
·			l		Current Year	Requested
Inventory as of Dec 31 a,Bulk Controlled Substance/List 1 Chemical	, t	856,366		0.0	1,101,720.0	
b.In-Process Material		116.513		0.0	0.0	
c. Contained in FINISHED Dosage Forms		972,879		0.0	1,101,720.0	
Disposition(Sale)/Utilization						
a.Domestic.,	- [	0		9.0	1,403,509.0	
b Exports	}		4	0.0	1,403,509.0	
Acquisition/Production						
a.Domestic Sources	ļ	0		0.0	1,600,000.0	
					1,800,000.0	1,000,000
If the Purpose is to Manufacture Another Substan						1
Walto of New Substance	Drug	2012	Inount	Used for th	1s Purpose 2015	# Yield
DXYMORPHONE (FOR SALE)	9552			5,937,600		57,00
and the same	3-20					
	11-4-	s/Batch # of Sa	aban I	Batch Purpose	Fet. Quantity	Est. Completion Ti
Product Development Desage Form Strength	Lux	B/Batta 1 OL 24	.04.46		, set. Quantity	
		·				
Promotine Dogistrant I		Femles	tion of Tr	ansfer		<del></del>
Fremsfer Registrant			vr 11.			
				1		
•						
Date of Dastruction		<del></del>	aplanation	· · · · · · · · · · · · · · · · · · ·	<del> </del>	
					•	
Packaging Product Name Strong	th	Units/Pkg 6 o	Pkgn		Purpose	Total Quantity
<del></del>					· -	
		•		1		
				•		
					•	
Remarks	_			<del>-</del>		
						•
•						

Basic Class: 9143 B Total PG Requested:

70,213,784,830

2015 Initial APQ Worksheets

FDA Est: (MS Ext:

-.009

Company	DEA Num	2015 Requested NQ 2	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2016 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2018 Projected Exports	2014 Projected Inventory	Adj Avel  Calc	40
(b)(4);(b)(7)(E)		10,000	5.000	1.520						5,000		1 000		0.947
(5)(1),(5)(1)(2)		60,000	60.000	9.624	78,591,255.584	0.000	6.777	810,606	. 9,000	20,000	0.000	830.608	653,105	859,563
		6,425,000.000	1,335,520,000	46,062,000	76,591,255.584	0.001	41,152.000	23,138,000	0.000	6,425,000.000	0.000	25,000.000	1,018,993,500	5,451,662,000
		2,700,000 000	1,365,000,000	297,405,000	16,591,255.584	0,004	261,215,956	786,049,000	9.000	2,750,000.000	0,000	795,721,000	1,615,536,750	1,293,745,944
		15,900,000,000	24,000,000.000	14,639,041.000	78,591,255,584	0,189	13,257,266,653	14,301,862,000	0.000	15,570,002.000	0.000	8,997,335,000	26,726,396,500	25,689,126,653
		69,002,000,000	64,131,406,000	45,700,030,000	78,591,255.584	0.561	40,625,614,447	23,161,550.000	0.000	64,901,000,000	0,000	15,782,000.000	65,469,717,000	48,676,563,559
		2,500,000	1,000,000	866,355,240	78,591,255,584	0.011	774,005,708	92,406,000	0,000	2,000 mm	D.000	0.000	70,054,500	876.354.135
		11,336,000,000	24.000,000,000	15.656.566.000	78,591,255,584	0.212	14,681,321,554	11,182,045,000	4,800,000.000	10,800,000.000	0,000	6,537,000.000	26,388,513,740	5,019,606,943
		1,900,000.000	784,639.000	190,483,000	76,591,255,584	0.002	170,176,378	537,901,000	0,000	1,250,000.000	0.000	402,792,000	991,905,000	346,342,722

MQ Tobals: (07,265,070,000 (19,67,50) (19,67,50,000 (19,67

2014 Final Initial APQ: 119,500,000,000
2014 Final Revised APQ: 0,000
PDA Est: (2014 Initial APQ\*1 = FDA Est): 119,500,000,000
GMS Est: (2014 Initial APQ\*1 = RMS Est): 119,404,250,000

2016 Proposed Initial APQ: 110,000,000,000 with 25% buffer: \$37,500,000,000

OXYCODONE (FOR SALE)

6,226,005.000

17,252,005.000 13,907,509.000

Basic Class: \$652.4 Total PO Requested;

MQ Totals:

2015 Initial APQ Worksheets

FDA Est IMS Est

Company DEA Num	2015 Requested KQ	2014 Revised MO	2012 Sains	2013 OEA MO Sales	% of 2013 Sales	Share of 2015 Total PQ	2015 Inventory	2014 Projected Exports	2014 Projected Sales	2016 Projected Export	3 2014 Projected Invatabry	Adj Avell Calc	MQ
(b)(4);(b)(7)(E)	5 000	0.000	0,000	7,793,786,005	0.000	0.000	0.000	0.000	4.000	0.00	1.000	0.000	4.000
(-)(-)(-)(-)	16 900 000 000	11,300,000,000	6,300,568,000	7,793,788,000	5.858.G	5,033,159,477	1,579,752.000	0.000	16,832,103.000	0.00	0 1,737,633,000	9,659,821,500	13,068.790.347
	451,000,000	2,507,509,000	1,493,218,000	7,793,788,000	0.192	1,192,845.523	269,680,000	0.000	513,000 000	0.00	624,886,000	2,157,891,750	3,557,034,523
	1,009,000		0.000	7,743,756,000	0.000	0,000	0.000	0.000	(,000.000	. 0.00	0.000	9,000	1,000.000
	1,007.000											•	,

16,626,628,669

2014 Final Initial RPQ:	20,000,000,000
2014 Fami Revised APQ:	0,000
FOA Est: (2014 Inklai APQ * 1 • FOA Est):	20,000,000,000
IMS Est: (2014 kritish APQ * 1 + IMS Est):	20,000,000,000

2015 Proposed Initial APQ: 17,500,000,000 with 25% Suffer: 21,875,000,000

OXYMORPHONE (FOR CONVERSION)

BASIC CLASS:	2015 Initial Que	ota Worksheets			Oxymorphone (conversio	n) 9	652-A
Company:	(b)(4)						
Request:	16900.0			451.0		1.0	
Current Year MQ:	11300.0			2607.5		0,0	
2013 Year end inventory	1579.0			269.7		0.0	,
Calculations	amt needed is	ubstance MQ	yield	amt needed	substance MQ yield	amt needed s	ubstance MQ yi
noroxymorphone (conv)	16825.397	10600.000	0.630	451.000	(for (b)(4) nal-drugs)	1.000 r	ef stds
noroxymorphone (sale)	10.645	6.707	0.630				
total needed	16836.043			451.000		1.000	
NITIAL MQs	1					•	
est need	22291.054			945.947		1.250	
MQ:							
Total Initial MQs:	16900.000			451.000		1.000	

Total MQs:

17352.000 + others

17352.000

**FURTHER CALCULATIONS** 

Established Initial APQ

17500

oxymorphone (conversion)

DRA Registration Number   D(4)(D(4)(C)(F)   EAX, RG.	Request ID.119507				MUFACTUR	ING QUOT	A Date Submitted	29	-APR-14
DELTA CODE   9652-A   2015   OUNTER YEAR   2015   OUNTER STATE   OUNTER YEAR   2015   OUNTER STATE   OUNTER S	Name of Basic Class or List 1 Chemical	_(only_	l_Der_I	KA-1891	·	Schedul	/List Number	1	0
								9	
DRA Registration Number   D(4)(D(4)(C)(F)   EAX, RG.	(b)(4)					Quota Ye	ar	1	2015
Disports   Disports   Disports   Disposition   Dispositi						DEA Regi	letration Number		))(7)(E)
MOTEN AII Quantities are to be Expression in Gresse of Anthritgon Arity, Base, or Pairied Species of State (Content of State of State Species)   1913   2014   2010   20	Contact Person (b)(6)  Small Address (b)(4) (b)(6)	1				Phone No	·	1 / / /	
2013   2014   2015   Queba Requester   9,400,000.0	NOTE; All Quantities are to be	Express	ed in Gre	me of Anby	rous Acid,	Beac, or J	lkaloid (not as Sale	to <u>l.</u>	
1,300,00.0   11,300,00.0   10,300,00.0   16,300,00.0   1	Note History	-+	20	13				Quot	a Requested
New Function   Set   New Function	· · · · · · · ·		9,400	0.000,	11,300	0,000.0	**		
A.Bulk Controlled Substance/List 1 Chemical.   1,979,42.1   0.4   1,000,000.1   1,000,	Production Data	7	2nd Prece	iing Year	1st Preced	ing Year	'		
A.Bulk Controlled Substance/List 1 Chesical.  0. d	Inventory as of Dec 31	F	i.	579.762.0		0.0	737,633.	ol —	737,633.
1,579,762.0				0.0					1,000,000
Separation   Sale			<del></del> ,						1.7 <b>37</b> .633
a.Demostic. 0.0 0.0 0.0 16.932,103.0 16.832,103.0 16.832,103.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0									
Description	-								16,832,103
C.d   O.d   16,900,000.0   16,900.00   1		<b>⊢</b>							
A.Donnestic Sources.    0.0	<u> </u>			0.9		0.0			
Name of New Substance									16,900.000 16,900,000
PROXYMORPHONE (FOR SALE)  PROXYMORPHONE (FOR CONVERSION)  PROXYMORPHONE (FOR CONVERSION)  Product Development Dossys Form Strength Units/Setch & of Batches Satch Furpose Zet. Quantity Zet. Completion Temmsfor Registrant  Explanation of Transfet  Explanation of Transfet  Explanation  Explanation  Explanation  Explanation  Explanation  Explanation  Total Quantity	If the Purpose is to Manufacture Another Substanc	e(s), Fu	rniah the	Following					
PROMUTE PROMUTE FOR CONVERSION)  968-B  1,126,952  4,133,919  16,825,396  63.00  Product Development Desage Form Strangth Units/Setch & of Satches Satch Furpose Ret. Cuentity Est. Completion Temperature Explanation of Transfer  Explanation of Transfer  Explanation  Explanation  Explanation  Explanation  Explanation  Explanation  Explanation	Name of New Substance	Drug		2012	Amount U		Purpose 201	5	# Yield
Product Development Dossys Form   Etrangth   Units/Setch   6 of Batches   Batch Furpose   Est. Quantity   Est. Completion T  ransfor Registrant   Explanation of Transfer    Date of Destruction   Explanation    Strength   Units/Pkg   6 of Pkgs   Purpose   Total Quantity    Total Quantity   Total	NOROXYMORPHONE (FOR SALE)	9668-B	1						63.00
Explanation of Transfer  Explanation of Transfer  Explanation  Explanation  Explanation  Explanation  Explanation  Explanation  Total Quanti	TOROXYMORPHONE (FOR CONVERSION)	966a-A		3,328,952		4,133,919	16,825	. 396	63.00
Explanation of Transfer  Explanation of Transfer  Explanation  Explanation  Explanation  Explanation  Explanation  Explanation  Total Quanti		<del></del>				· ·	1		-
Strength Units/Pkg 4 of Pkgs Durpose Total Quanti	Product Development Dossye Form   Strangth	Units/	Batch	d of Batc	bos Su	tch Purpose	Zat. Quantity	Est. Co	mpletion Ti
Strength Units/Pkg 4 of Pkgs Durpose Total Quanti	•					•			
schaging Product Name Strangth Units/Pkg & of Pkgs Purpose Total Quanti	Transfer Registrant			Explanati	on of Tran	Jior_			
schaging Product Name Strangth Units/Pkg & of Pkgs Purpose Total Quanti									
schaging Product Name Strangth Units/Pkg & of Pkgs Purpose Total Quanti							•		
schaging Product Name Strangth Units/Pkg & of Pkgs Purpose Total Quanti						_			
schaging Froduct Name Strangth Units/Pkg 4 of Pkgs Durposa Total Quanti	Date of Destruction			<u> </u>	planation				
							•		
smarkg	Packaging Froduct Name Strengt	Lh U	hits/Pkg	f of	Pkgs		Purpose	To	tal Quantity
smarke									
emarks									
emarko							-		
stoar   Ke	•								
emarke							<del>-</del>		
	Remarks						_ <del></del>		
						-			
			-						
	1								
				-		•			
			•						

	APPLICATI	ON FOR IND	INIDUAL MAI	NUFACTURI	NG QUOT		04 444	-14
Request ID. 119708			DES 1001			Date Submitted	01-MAY-	-14
Name of Basic Class or List 1	Chemical (	oniv 1 per	DRY-1831	Ic	chedu?	e/List Number	0	
XYMORPHONE (FOR CONVERSION)  Name and Address of Registrant	<del></del>				rug Co		9652-	·A
(b)(4)			<del></del>		uota Y	gar	2015	;
				į.	EA Reg	istration Number	(b)(4);(b)(7)(E	E)
Contact Pergon (b)(6)	1				oN_, xa		(b)(6)	
mail Address (h)(4):(h)(6)		· <del>-</del>		b	hone No	e,		
NOTE: All Quancitie	s ire to be E	epro <u>ceed in Gr</u>	rems of Anhydi	rous Acid, B	Prayions	Alkaloid(not as Salts		
uota History			013	2014		2015	Quota Requ	ueste
,	•	3,03	0,649.0	2,607,5	09.0	0.0	451,000	0.0
reduction Data		2nd Prec	eding Year	int Precodin	ng Yeaz	Sotimate for Current Year	Estimate for Requeste	
inventory as of Dec 31								
a.Bulk Controlled Substance/List	1 Chemical		269,680.0	_	0.0	624,000.0		14,000
b.In-Process Material			0.0		0.0	0.0		
c. Contained in FINISHED Dosage B	Forms,		269,680.0		0.0	624,000.0		24,000
isposition(Sale)/Utilization			72 A) 2 d		0.d	513,000.0	- 51	13,000
a.Domestic		<del> </del>	77,017.0		0.0	0.0		(3,000
b Exporte			1,493,218.0		0.0	513,000.0	51	13,000
equisition/Production			110 660 1			451.000.0		51,000
a.Domestic Sources			1,317,098.0		0.q	451,000.0		51,000 51,000
t the Purpose is to Manufacture Anoth			ne Pollowing			f - Duma	· · · · · · · · · · · · · · · · · · ·	Yield
Name of New Substance	1	Drug	2012	Amount Use	d for th	1s Purpose 2015		
		— <u>—</u> -						
		Unite/Batch	# of Batch	an Bate	h Purpos	Est. Quantity	Est. Complet.	log T
Product Davelopment Cosage Form	Strength		, or acce		.,			
					-			
					_			
ransfer Registrant		<del> </del>	Explanation	on of Transf				
Date of Destruction			Exp	lenati <u>on</u>				
							•	
ackeging Product Name	Strongth	toits/Pk	g fof P	egr		Ригрово	Total Q	uant 1
	<u> </u>							
				•				
		_						
		-						
Remarks			<del></del>			<u>-</u>		
Production loss estimated at 2,000	orame 1 000	grame to eur	port refere	nce standar	d busin	285	-	
- FORESTON 1088 SACISMEN SC 7,000	3emm 1,000	2 CO 4ul						
·								
	-							



20 J4 Q=sta	Current	Fleat [	De#a
PSC-AGA	5,232	6,1(4)	1/48
Magazine Sq Converses	13,720	15,500	1,780
Oversor there Conversion Commercial	2,608	2,095	-513
Charmaphore Consension Development	- 5	671	671
Ossessorphone Sale Commercial	IZI I	975	- 94
Oxymerphoge Sale Development	- 0	0	9

	Wet	
	Current	Additions
2014 OMH Inventory Culculations	Quee	Grand
2013 Endag Liverery	316	3(8
Non saleable material	7	7
3013 Available End. 12v.	J11	314
2014 API Quota	831	975
2014 Development Quota (not wasteded in preentary)		- 0
2014 Derpositions:	1	
Sila	592	592
Processing Losson	(484)	(531)
2014 Ending Jeremen	115	.161
Converted to % Years 4	24.0%	J3.4%

	kgs, tang
2013 Disposition	335
2014 Est Dispositions	592
ለ <b>ሚ</b> ነም •	481
50% Inventory Allowarms	240

Current Quota	Additional Grant
112_	272
] ]	-
249	169
1	
2.60%	2,095
	671
1.568	RBS,s
(13	((0)
(2)	(11)
1,199	619
77,814	45.97+
	Current Quota 272 3 249 2,608 1,588 (13) (23) 1,199

	Kgs, brees
2011 Dispositions	1.416
2014 Est. Dispunit neur	1,588
AVERN	1,302
50% (aventory Alternation	751

	ACTUAL YEAR TO DAYE				ESTIMATE ON REMAINING QUOTA			WITH ENCREASE		
Description	CTS-AOA Input	Process Yield	MWC	Net setput of step	CPS-AOA Input	MWC	Nel autpul of step	Input to Step	MWC	Net output of step
CPS-AOA to Coule Occurrenthme for Conversion	ā	694%	((013)	0	1,708	1.01133	2,606	174174	10133	(5)3)
CPS-AOA to Crede Occurrenteme for Sale TOTAL CPS-AUA	419	71 6W	1.0139	304	79\$ 4,503	10131	\$77	110	(0)33	94

	ACTUAL YEAR TO DATE				ESTIN	ATE ON RE QUOTA		WITH INCREASE			
Description	Laper to Step	Practical Vield	MWC	Net output of step	Lass by rtep	Input to Step	Output of Step	Lass by sup	Input so Step	Output of Step	Loss by ptep
Отушагравна Рас Съргодия		I					I				
COM to COMA	u	99,5%_	1 0000	n l	0	2,600	2,194	1150	1813)	65165_	,
Total					- 4			[83]			
Osymerphone Fer Sair											
CONLin COM I	198	91.5%	1.12(3	203	•	577	591	15	41	97	2
COMPLIE FOM	201	65.0%	0 8920	tik .	1951		343	(240)	vı	\$6	
POM to OMH	\$KO_	77.2%	1.1213	446	(104)	343	283	gaD .		16	((0)
ONG! FG	٥	91 2%	1 0000	0		281	276		46	45	
Total					(141)			(304)			(110)

1015 Quota	Apr-15
PSC-AGA	5,119
PSC-AGA Merphane for Conversant	22,000
Otergraphicse Convertion	450
Observation Conservation Development	
Oncyrroup home. Sale:	3,500
Cheencephane Sale Development	•

2015 ONB! Investory Calculations	With Carrent Quota
2014 Ending Inventors	1(5
Development material	
2014 Aveilable End. lav.	- 613
2015 API Quota	3,500
	<del> </del>
2015 Dispositions	
Seles	1,277
Propositivity Locates	(1,951)
Validation Inventory	334
2015 Ending Laventury	237
Converted to % Yeares	41.4%

	kgs, base
2014 Ed Dispositions	592
2015 Est Desponsions	1,277
Average	934
50% Investory Allowance	467

	) With
•	Cagrent
1015 COMA Inventory Calculations	Quota
2014 Ending Inventory	689
Non satisfale material	1 0
7814 Available End. lav.	483
2015 API Quera	450
2015 Phageatilianta	ᆣᆖ
Sales	5),3
Processing I cetted	
Validation Interdity	0
2015 Fading Intrology	624
Converted to % Vestrand	59.4%

	figs. hans
2014 E.s. Dispeniums	1.518
2011 Est Dispositions	513
Average	1.050
50% Inventory Alforence	525

	l	20	IS Qualit C	ak	_					
•	CPS-ADA	Process		Met aut plut						
Description	Lapet	Yield	MWC	ed Herp						
CPS-AOA is Crude Oromorphone for Conversion	640	69,4%	10(3)	450						
CPS-AOA w Crade Ovymorphous for Sale	4,827	71.6%	1 0133	3,500						
TOTAL CPS-AUA	5,467			T						
	2015 Questa Cale									
Description	Lapot to Step	Process Yield	MWC	Net output of step	Last by ptep					
Description				1						
Onymorphone For Conversion COM to COM	450	99 5%	Linnac	448	- (2)					
Daymorphone For Conversion		99 5%	I nnac	463	(2)					
Onymorphone For Conversion	450				(2)					
Drymorphone For Conversion OM to COMd Total OTymorphone For Sale	450	FI 524	1.1212	3,590	- (2)					
Drymorphone For Conversion COM to COMd Total Crymorphone For Sale COM to COMD COMSTO POM	7,30n 7,30n	91 5% 65 0%	1.1212 0.8920	3,590 2,001	(2) 40					
Drymorphana Foe Correction OM to COA/d Total	450	FI 524	1.1212	3,590	- (2)					

(b)(4) Confidentia

4/30/2014



2014 CPS-Origovine Inventory Calculations	Current Quote	Additional Great
1013 Ending Inventory	75R	757
Non salroble material	- u	
2003 Available End. Inv.	758	7,41
2014 API Quesa	5,232	& LIIO
2014 Demostrant	+	
Morphism for Connection		1,190
Chemorphone for the exercise	3,041	3,041
Ostymorphone for Sale	1,145	1,215
2014 Ending Imvalery	1,404	1,413
Converted to % Yeatered	42%	17%

	With
	Curred
2015 CPS-Oripavine Inventory Cokulations	. Queta
2014 Ending becausey	1.504
Neg polesyste more rate	0
2014 Available End. lav.	1,6114
2015 API Quota	5,139
2015 Dispentions;	7-7-
Morphine for Currention	<del></del>
Охутиврение Гот Солуствой	540
Osstorphum Gr Sale	4,627
2015 Epiting Inventory	1,376
Converted to 1/4 Yearend	26%

(b)(4) Confidentia

<del></del>	APDI.TCAT	MOTS	FOR INDIV	IDUAL MAN	UFACTUR	ING DUOT	A			
Roquest ID. 119780	77. 1 11. 17.							ubmitted	02-MA	Y-14
lame of Basic Class or List 1	Chemical	ionl	v 1 per D	EA-189)			4.2			
XYMORPHONE (FOR CONVERSION)	<u>-</u>					Schedul		Mumber	965	
<u>ame and Address of Registrant</u>						Drug Co Quota Y	<u> </u>	<del></del> -	20	
b)(4)						DEA Reg	istrati	on Number	b)(4);(b)(7)	(E)
ontact Person (b)(6)						Fax. No		(	b)(6)	
mail Address (b)(4);(b)(6) NOTE: All Quantities				a of Ankwir		Phone N		not se Sells	1.	
	s are to be	Expedi			<u>Queta</u>	<u>a_Previouc</u>	ly Induced	S by DEA		
uota History	_		201		201			015	Quota R	
			<u> </u>		C.			D.O	Estimate	00.0
reduction Data			2nd Precedi	ing Year	lar Precedi	ing Year		nt Assi	yedne Refimete	
nventory as of Dec 31		- 1	-	0.0		0.0		0.0		
a.Bulk Controlled Substance/List b.In-Process Material				0.0		Q.D		0.0		
c. Contained in FINISHED Dosage F				0.0		0.0		0.0		
				<u> </u>		0.9				
isposition(Sale)/Utilization		ì		0,0		0.0		1,000.0		1,000
a.Domesticb Exports		}		0.0		0.0		1,000.0		1,00
equisition/Production						0.0		1,000.0		1,000
a.Domestic Sources		ŀ		0.0		0.0		1,000.0		1,000
f the Purpose is to Manufacture Anoth	er Substance	e (a),	Furnish the	Following						
Name of New Substance		Drug	J	2012	Amount Us	ed for th	is Furgos	2015		* Yield
				<u> </u>						
								_		
Product Davelopment Dosage Form	Strongth	Unit	a/Batch	0 of Batch	Bat	ch Purpos	Bet.	Quantity	Est. Compl	etion T
ransfer Registrent				Explanatio	D OF TEADS					
			•							
						,				
				•						
Date of Destruction				Exp	anation					
-		_								
	•									
-										
ckaging Product Name	Strongt	25	Units/Pkg	f of Pi	ige		Purpose	<del></del>	Total	Quenti
		•								
•										
							<u> </u>			
omatke										
support reference standards bus:	iness									
									,	

Basic Clase: 8652-B Total PG Requested:

3,948,441,070

2015 Initial APQ Worksheets

FDA Est: ,0

Company DEA Num	2016 Requested NO 2	2014 Revised MQ	2013 Jakes	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PO	2013 inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avail Celc	MQ
(b)(4);(b)(7)(E)	5.000	5,000	0,000	3,604,592,071	0,000	0.000	9,007	0.000	4.000	0.000	1.000	3.755	0243
(D)(4),(D)(1)(L)	60,000	60,000	4,211	3,604,592,071	0.000	3,909	215.668	0,000	10:000	0.000	258.268	206 901	209.777
	166,000,000	(43,000,000	6,820,000	3,604,592,071	0.002	8,166.336	23,682.000	0.000	155,000,000	0.000	25,000.000	125,011.500	45,303.420
	715,000,000	611,638,000	413,633 000	3,604,592,071	0,115	364,009,739	211,214,000	0 000	623,000.000	0.000	295,541,000	617,142,000	433,065.673
	600,000,000	2,810,598,000	2.602.150.000	3,604,592.071	0.377	2,601,487,700	1,132,591,000	0.000	946,061,000	0.000	423,694,000	2,957,391,750	951,356,125
	3,000,000	3,000,000	41,930,860	3,604,592,071	0.012	38,927.687	34,990.290	0.000	3,000,000	9.000	0,000	26,482,716	14,419 568
	3,501,000,000	880,564,000				306,825,854	310,739,000	0.000	1,277,000.000	0.000	367,000.000	693,477,250	689,370 318
	1,620,000,000	219,000.000	7,559 000			7,017,645	295,828.000	9.000	616,250,000	0.000	275,630.000	279,371.000	171,694,056

MO Totals: 6,305,065,000 4,658,665,000 2,311,479.881

2014 Final Initial APQ: 6.200,000,000
2014 Final Revised APQ: 0.000
FDA Est: (2014 Initial APQ 1 + FDA Est): 5.200,000,000
IMS Ests (2014 Initial APQ 1 + IMS Ext): 6.486,440,000

OXYMORPHONE (FOR SALE)

Basic Class: 9144-9

Total PQ Requested:

2016 Initial APQ Worksheets

FDA Est: JNS Est:

1.500

Company OEA Num 2015 Requested MO 2013 Enter 2013 DEA NO. Sales 2013 D

MQ Totals: 2,000 2,000 1,500

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

RACEMETHORPHAN

2,317,176

Batic Ciass: Total PQ Requested: 2016 Initial APQ Worksheets

FDA Est: MAS ELL

035

Company	(JEA Num	2015 Requested MQ	2014 Revised MQ 20	113 Sales	2012 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PC	2013 Greantory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	Adj Avall Calc	WD
(b)(4);(b)(7)(E)		5,000	5.000	B.000	0.683	0.000 0.000	0.000 0.000	0.000 2,723,000	6.500 0.000	1.000 1.820.000	0,500	4,000 2,723 009	3,750 3,407,250	4.000 2,723.000
		1,820,000	1,620,000 1,165,000	0.000 0,000	0.683	0.000	U.000	0.000	0.000	500.000		-	-,	665,000
MG Totals:		2.825.000	2,990.000											3,392.000

2014 Final Inklai APQ: 3,000,000 2914 Final Revised APQ: 0.000 FOA Est: (2014 milial APQ " 1 + FDA Est): 1,000.000 OUS Est: (2014 Inbiat APQ " 1 + OUS Est): 3,105,900

REMIFENTANIL

Basic Class: 8745-4 Total PQ Requested:

714,604,350

4,202.000

)

3,668.000

2015 Initial APQ Worksheets

FDA Ext: INS Eat:

-.244

Company DEA	. Num	2015 Requested MQ 2	2014 Revised MQ	2013 Sales	2013 DEA NO Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 knombry	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected leventory	Adj Avail Cale	MO
(b)(4);(b)(7)(E)	$\neg$	1.000.000	1,000.000	404,700	2,931,700	0.136	106,924.533	837,400	0.000	500,000	. 0,000	200,000	1,378.050	1,000.000
	- 1	2,000	2.000	0.000	2,931,700	0.600	0.000	0.000	0.000	0,500	0.000	1,500	1,500	2.000
	- 1	700,000	650,000	261.000	2,931.700	0.096	74,244.817	127,000	0.000	548 000	000	386,000	582,750	700,000
	- 1	2,500.000	2,215,000	2,248,000	2,931,700	0.766	593,430.900	2,226,000	1,603.000	2,774.000	0.000	1,799,000	3,331,500	2,500.000
MQ Totals:		4,202,000	3,668,000											4,202.000

2014 Finel initial APQ: 5,004,000 2014 Final Revised APQ: 0.000 FDA Est: (3014 bittle) APQ \* 1 + FOA Est): 5,004,000 IMS Est: (2014 Initial APQ \* 1 + MS Est): 3,785.026

SUFENTANIL

Basic Class: \$780-0

Yotal PQ Requested:

2015 Initial APQ Workshoots

14,527,431.000

\_\_\_\_\_\_

- (	0.4	E	61:
	MS	£	E£:

Сопрасу	DEA Num	2016 Requested MQ 2	ota Revised MO	2013 Sales	2013 DEA MQ Sales	% of Zú 13 Sales	Share of 2016 Total PQ	2013 breemary	2014 Projected Exports	2014 Projected Sales	2016 Projected Exports	2014 Projected Inventory	Adj Avall Cat:	
(b)(4);(b)(7)(E)		256,900,000	255,000,000	215.000	10,372,408.760	B.000	301.126	68,485,000	0.000	258,000,000	0.000	0.000	244,864,500	66,787,126
(0)(+),(0)(1)(L)		10,000	10.000	0.000	10,372,408,760	0.000	0.000	3.092	0.000	6,000	0,000	1.992	10.494	7.992
		345,000 000	345,000,000	0.000	19,372,498,760	0.000	0,000	6.000	0,000	345,000,000	0,000	2000,0	258,730.00D	66,250,000
		1,000,000	0.000	10,265,906.560	10,372,408,760	0.990	14,379,666.294	7,015,667,600	0.900	1,000,000	0,000	5.000	1,761,900,700	10,959,715.258
		8,500,000.000	1,702,721,000	840.000	16,372,408,760	0.000	1,175.491	20,267,000	9.000	7,300,000,000	0.000	1,221,000,000	1,292,241.000	6,004,162,683

MG Tetals: 5,104,610,000 2,305,731,000 17,118,923,248

2014 Final Initial APQ: 44,000,000 000
2014 Final Revised APQ: 0,000
PBA Est: (2014 Initial APQ: 1 + FDA Est: 14,000,000 000
PBS Est: (2014 Initial APQ: 1 + PBA Est: 14,000,000 000

2018 Proposed Initial APQ: 10,000,000,000 .000 with 25% buffer: 12,500,000,000

TAPENTADOL

Basic Clera: 91330 ·

Basic Class: \$133-0 Total PC Requested:

5,100,110,000

#### 2015 Initial APQ Workshoots

PDA Est: IM3 Est:

Company	Muli A3G	2016 Requested MG	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2016 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales		2014 Projected Inventory		etq.
(b)(4);(b)(7)(E)		5,000	5.000	0.000	58,114,602,224	0.000	0.000	0 002	0,000	4.000	0.000	1,000	1.752	0.248
(5)(4),(5)(1)(1)		655,000,000	870,000,000	221,845,000	58,114,802,224	0.004	19,466.945	65,416,990	004.0	655,000.000	0.000	0.000	703,612,000	158,420.182
		25,000	25,000	2.604	56,414,802,224	0.000	0.229	56,690	0.000	5,000	0.000	74,590	61.193	76.619
		9,969,000,000	2.171.000.000	44,927,000	56,114,802,224	100,0	3,942,759	48,305,000	0.000	9,968,000,000	0.000	50,000.000	1,584,478 750	6,297,373,448
		23,000,000,000	42,968,039,000	27 999 549 000	56,114,602,224	0.462	2,437,216,719	16,221,412,000	0.000	22,823,004,000	0.000	11,732,425.000	44,360,568.230	36,621,663.719
		1,000,000	2,000,000	34.620		0.000	3.036	45,077,500	0.000	1,000,000	0 000	0.000	35,300.125	46,080,538
		8,900,000,000	10.072.013.000	_		0,160	815.616.150	2,921,970 000	. 0.000	7,500,000.000	0.000	4,393,000,000	9,745,487,250	6,309,599.151
		18.200,000.000	19,068,050,000		,,	0.773	1,035,093,730	10,542,900.000	- 0.000	(6,200,000,000	0.000	7,000,000,000	22,413,962,500	12,747,043.730

MG Totals: 60,529,030,000 75,150,132,000 66,340,259,842

2016 Proposed Initial APQ: 100,000,000,000 with 25% buffer: 125,000,000,000

THEBAINE

# 2015 Proposed Established Annual Assessment of Needs and Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish
  limits on the production of each basic class of schedule I and II controlled substances and for the list
  I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has since
  been delegated to the Administrator of the Drug Enforcement Administration (DEA), who has
  redelegated to the Deputy Administrator.
- The attached Federal Register notice, prepared for your signature, proposes to establish calendar
  year 2015 aggregate production quotas (APQ) for each basic class of schedule I and II controlled
  substances and assessment of annual needs (AAN) for the list I chemicals ephedrine,
  phenylpropanolamine, and pseudoephedrine for which the United States has medical, scientific,
  industrial, export, and reserve stock requirements.
- As stated in the 2013 Federal Register Notices DEA continues to add an additional 25% to the APQ
  for schedule II substances and schedule I substances that are used to produce drugs that have a
  medical need (specifically, GHB and tetrahydrocannabinols) in an effort to prevent potential drug
  shortage issues.
- The Federal Drug Administration (FDA) has not yet responded to DEA's annual letter, sent on February 18, 2014, which requests information on new, continuing, and discontinued drug products containing schedule II substances. Therefore, this information could not be considered in the analysis for the current proposed adjustments
- An expedited review and publication is requested to ensure an uninterrupted supply of schedule I and II controlled substances and the list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for medical, scientific, industrial, and export requirements of the U.S.
- The following points provide brief explanations for some of the proposed AAN & APQ values:

#### Schedule I substances

- The APQ for betamethadol is proposed as an increase from zero for 2014, based on one registrant
  application received as of May 21, 2014. Applications can be received throughout the year and
  those received during the comment period will be considered at that time.
- The APQ for morphine-n-oxide is proposed as an increase from 2014. The change is based on receiving requests from bulk manufacturers for this substance. The manufacturing of this substance will be used for analytical standards, reference, and research material.
- The APQ for marihuana is proposed as a decrease from 2014, but not zero because to accommodate a bulk manufacturer with a new synthesis route for manufacturing API for dronabinol.
- The APQ for tetrahydrocannabinols is proposed as an increase from 2014 to accommodate a new bulk manufacturer that will supply dosage form manufacturers conducting product development efforts to formulate FDA approved generics to dronabinol.

OD/ODO/ODEO

6/4/14

Page - 1 - of 2

### Schedule II substances

- The APQs for amobarbital, dihydrocodeine, diphenoxylate, ecgonine, levorphanol, and opium (tincture) are proposed as increases to accommodate changes in registrant requirements and domestic market demands.
- The APQs for amphetamine (for conversion) and lisdexamfetamine are proposed to accommodate increased registrants' requirements based on brand holder exporting to new markets overseas and changes in domestic market demands.
- The APQs for oripavine and noroxymorphone (for sale) are proposed as increases to accommodate the change in synthesis and growing domestic demand for nal-drugs, and specifically Narcan, by legislators, police, and paramedies in states with rising heroin deaths.
- The APQs for amphetamine (for sale), codeine (for conversion), hydromorphone, methadone intermediate, methamphetamine, methylphenidate, nabilone, oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), phenylacetone, tapentadol, and thebaine were proposed as decreases from 2014 based on registrant applications received as of May 21, 2014. Applications can be received throughout the year and those received during the comment period will be considered at that time.

## List I Chemicals

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

OD/ODQ/ODEQ

#### DEPARTMENT OF JUSTICE

**Drug Enforcement Administration** 

[Docket No. DEA-393]

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

Pseudoephedrine, and Phenylpropanolamine for 2015

AGENCY: Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice with request for comments.

**SUMMARY:** The Drug Enforcement Administration proposes to establish the 2015 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

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

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-393" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web

page or attach a file for lengthier comments. Please go to <a href="http://www.regulations.gov">http://www.regulations.gov</a> and follow the online instructions at that site for submitting comments. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments, in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

#### **SUPPLEMENTARY INFORMATION:**

### **Posting of Public Comments**

Please note that all comments received in response to this docket are considered part of the public record and will be made available for public inspection online at <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

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

### **Legal Authority**

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA pursuant to 28 CFR 0.100(b). The Administrator, in turn, has redelegated that authority to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

Analysis for Proposed 2015 Aggregate Production Quotas and Assessment of

#### **Annual Needs**

The proposed year 2015 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances necessary to provide for the medical, scientific, or other legitimate needs of the United States.

In determining the proposed 2015 aggregate production quotas and assessment of annual needs, the DEA has taken into account the criteria that the DEA is required to consider in accordance with 21 U.S.C. 826(a), 21 CFR 1303.11 (aggregate production quotas for controlled substances), and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The DEA proposes the aggregate production quotas and assessment of annual needs for 2015 by considering: (1) total net disposal of the class or chemical by all manufacturers and chemical importers during the current and two preceding years; (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for such class or chemical as indicated by procurement and chemical import quotas requested in accordance with 21 CFR 1303.12, 1315.32, and 1315.34; and (5) other factors affecting the medical, scientific, research, and

industrial needs in the United States, lawful export requirements, and reserve stocks, as the Deputy Administrator finds relevant. Other factors the DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

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

provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Deputy Administrator, therefore, proposes to establish the 2015 aggregate production quotas for the following schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Proposed Established 2015 Quotas (g)
Schedule I	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45

2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	15
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-N-methylcathinone (3-FMC)	15
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-N-methylcathinone (4-FMC)	15
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-ethylcathinone (4-MEC)	15
4-Methyl-N-methylcathinone (mephedrone)	45

4-Methyl-alpha-pyrrolidinopropiophenone (4-MePPP)	15
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	15
alpha-Pyrrolidinopentiophenone (α-PVP)	15
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-N-oxide	200
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50

Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	21,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	15
N,N-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	15
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	18
Phenomorphan	2
Psilocybin	30
Psilocyn	30

Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)         15           Tetrahydrocannabinols         497,500           Thiofentanyl         2           Tilidine         10           Schedule II           1-Phenylcyclohexylamine         5           1-Piperidinocyclohexanecarbonitrile         5           4-Anilino-N-phenethyl-4-piperidine (ANPP)         2,687,500           Alfentanil         17,625           Alphaprodine         3           Ambotarbital         25,125           Amphetamine (for conversion)         21,875,000           Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for conversion)         137,500           Hydromorphone         6,250,000 <th>Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)</th> <th>15</th>	Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15
Thiofentanyl         2           Tilidine         10           Trimeperidine         2           Schedule II           1-Phenylcyclohexylamine         5           1-Piperidinocyclohexanecarbonitrile         5           4-Anilino-N-phenethyl-4-piperidine (ANPP)         2,687,500           Alfentanil         17,625           Alphaprodine         3           Amobarbital         25,125           Amphetamine (for conversion)         21,875,000           Amphetamine (for sale)         37,500,000           Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Eegonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydrocodone (for sale)         99,625,000           Hydromorphone </td <td>Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)</td> <td>15</td>	Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	15
Tilidine         10           Schedule II           I-Phenylcyclohexylamine         5           1-Piperidinocyclohexanecarbonitrile         5           4-Anilino-N-phenethyl-4-piperidine (ANPP)         2,687,500           Alfentanil         17,625           Alphaprodine         3           Amobarbital         25,125           Amphetamine (for conversion)         21,875,000           Amphetamine (for sale)         37,500,000           Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydrocodone (for sale)         99,625,000           Hydrocodone (for sale)         99,625,000           Hydrocodone (for conversion)         137,500	Tetrahydrocannabinols	497,500
Tilidine         10           Trimeperidine         2           Schedule II           1-Phenylcyclohexylamine         5           1-Piperidinocyclohexanecarbonitrile         5           4-Anilino-N-phenethyl-4-piperidine (ANPP)         2,687,500           Alfentanil         17,625           Alphaprodine         3           Amobarbital         25,125           Amphetamine (for conversion)         21,875,000           Amphetamine (for sale)         37,500,000           Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         33           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5		2
Trimeperidine   2   2   1-Phenylcyclohexylamine   5   1-Piperidinocyclohexanecarbonitrile   5   4-Anilino-N-phenethyl-4-piperidine (ANPP)   2,687,500   Alfentanil   17,625   Alphaprodine   3   3   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,500   37,500,000   37,50		10
Schedule II		
1-Phenylcyclohexylamine         5           1-Piperidinocyclohexanecarbonitrile         5           4-Anilino-N-phenethyl-4-piperidine (ANPP)         2,687,500           Alfentanil         17,625           Alphaprodine         3           Amobarbital         25,125           Amphetamine (for conversion)         21,875,000           Amphetamine (for sale)         37,500,000           Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           Ievo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375	•	
1-Piperidinocyclohexanecarbonitrile         5           4-Anilino-N-phenethyl-4-piperidine (ANPP)         2,687,500           Alfentanil         17,625           Alphaprodine         3           Amobarbital         25,125           Amphetamine (for conversion)         21,875,000           Amphetamine (for sale)         37,500,000           Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine Intermediate-A         6		5
A-nilino-N-phenethyl-4-piperidine (ANPP)		
Alfentanil       17,625         Alphaprodine       3         Amobarbital       25,125         Amphetamine (for conversion)       21,875,000         Amphetamine (for sale)       37,500,000         Carfentanil       19         Cocaine       240,000         Codeine (for conversion)       50,000,000         Codeine (for sale)       46,125,000         Dextropropoxyphene       19         Dihydrocodeine       101,375         Diphenoxylate       1,337,500         Ecgonine       174,375         Ethylmorphine       3         Fentanyl       2,108,750         Glutethimide       3         Hydrocodone (for conversion)       137,500         Hydrocodone (for sale)       99,625,000         Hydromorphone       6,250,000         Isomethadone       5         levo-Alphacetylmethadol (LAAM)       4         Levorphanol       3,375         Lisdexamfetamine       29,750,000         Meperidine Intermediate-A       6         Meperidine Intermediate-B       11         Meperidine Intermediate-C       6		
Alphaprodine         3           Amobarbital         25,125           Amphetamine (for conversion)         21,875,000           Amphetamine (for sale)         37,500,000           Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-B         11           Meperidine I		
Amobarbital         25,125           Amphetamine (for conversion)         21,875,000           Amphetamine (for sale)         37,500,000           Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		
Amphetamine (for conversion)         21,875,000           Amphetamine (for sale)         37,500,000           Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6	· ·	
Amphetamine (for sale)       37,500,000         Carfentanil       19         Cocaine       240,000         Codeine (for conversion)       50,000,000         Codeine (for sale)       46,125,000         Dextropropoxyphene       19         Dihydrocodeine       101,375         Diphenoxylate       1,337,500         Ecgonine       174,375         Ethylmorphine       3         Fentanyl       2,108,750         Glutethimide       3         Hydrocodone (for conversion)       137,500         Hydrocodone (for sale)       99,625,000         Hydromorphone       6,250,000         Isomethadone       5         levo-Alphacetylmethadol (LAAM)       4         Levomethorphan       5         Levorphanol       3,375         Lisdexamfetamine       29,750,000         Meperidine       6,250,000         Meperidine Intermediate-A       6         Meperidine Intermediate-B       11         Meperidine Intermediate-C       6		
Carfentanil         19           Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		
Cocaine         240,000           Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		
Codeine (for conversion)         50,000,000           Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		240,000
Codeine (for sale)         46,125,000           Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		
Dextropropoxyphene         19           Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		
Dihydrocodeine         101,375           Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		
Diphenoxylate         1,337,500           Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6	1 1 11	101,375
Ecgonine         174,375           Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		1,337,500
Ethylmorphine         3           Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		174,375
Fentanyl         2,108,750           Glutethimide         3           Hydrocodone (for conversion)         137,500           Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6		3
Hydrocodone (for conversion)       137,500         Hydrocodone (for sale)       99,625,000         Hydromorphone       6,250,000         Isomethadone       5         levo-Alphacetylmethadol (LAAM)       4         Levomethorphan       5         Levorphanol       3,375         Lisdexamfetamine       29,750,000         Meperidine       6,250,000         Meperidine Intermediate-A       6         Meperidine Intermediate-B       11         Meperidine Intermediate-C       6		2,108,750
Hydrocodone (for sale)         99,625,000           Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6	Glutethimide	3
Hydromorphone         6,250,000           Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6	Hydrocodone (for conversion)	137,500
Isomethadone         5           levo-Alphacetylmethadol (LAAM)         4           Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6	Hydrocodone (for sale)	99,625,000
levo-Alphacetylmethadol (LAAM)  Levomethorphan  5  Levorphanol  Lisdexamfetamine  29,750,000  Meperidine  Meperidine Intermediate-A  Meperidine Intermediate-B  Meperidine Intermediate-C  6	Hydromorphone	6,250,000
Levomethorphan         5           Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6	Isomethadone	5
Levorphanol         3,375           Lisdexamfetamine         29,750,000           Meperidine         6,250,000           Meperidine Intermediate-A         6           Meperidine Intermediate-B         11           Meperidine Intermediate-C         6	levo-Alphacetylmethadol (LAAM)	4
Lisdexamfetamine29,750,000Meperidine6,250,000Meperidine Intermediate-A6Meperidine Intermediate-B11Meperidine Intermediate-C6	Levomethorphan	5
Meperidine6,250,000Meperidine Intermediate-A6Meperidine Intermediate-B11Meperidine Intermediate-C6	Levorphanol	3,375
Meperidine Intermediate-A6Meperidine Intermediate-B11Meperidine Intermediate-C6	·	29,750,000
Meperidine Intermediate-B11Meperidine Intermediate-C6	Meperidine	6,250,000
Meperidine Intermediate-B11Meperidine Intermediate-C6	Meperidine Intermediate-A	6
Meperidine Intermediate-C 6		11
Metazocine 19		6
	Metazocine	19

Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of levo-desoxyephedrine for use in a no product; 750,000 grams for methamphetamine mostly for III product; and 61,375 grams for methamphetamine (for	conversion to a schedule
Methylphenidate	83,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	22,750,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	137,500,000
Oxymorphone (for conversion)	21,875,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000
Thebaine	125,000,000
List I Chemicals	,
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	3,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Deputy Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as necessary.

#### **Comments**

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

Dated:

Thomas M. Harrigan, *Deputy Administrator*.



# INTERNATIONAL TRADE COMMISSION

[USITC SE-14-023]

## **Sunshine Act Meetings**

AGENCY HOLDING THE MEETING: United States International Trade Commission. TIME AND DATE: July 11, 2014 at 11 a.m. PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.
MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.

2. Minutes.

3. Ratification List.

4. Vote in Inv. Nos. 701-TA-515-521 and 731-TA-1251-1257 (Preliminary) (Certain Steel Nails from India, Korea, Malaysia, Oman, Taiwan, Turkey, and Vietnam). The Commission is currently scheduled to complete and file its determinations on July 14, 2014; views of the Commission are currently scheduled to be completed and filed on July 21, 2014.

5. Outstanding action jackets: None. In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

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

William R. Bishop,

Supervisory Hearings and Information Officer.

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

### **DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration** 

[Docket No. DEA-393]

Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

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

SUMMARY: The Drug Enforcement Administration proposes to establish the 2015 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 1, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period. ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-393" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to http: //www.regulations.gov and follow the online instructions at that site for submitting comments. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments, in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia

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

## SUPPLEMENTARY INFORMATION:

# **Posting of Public Comments**

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

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

comment and identify what information you want reducted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

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

## Legal Authority

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA pursuant to 28 CFR 0.100(b). The Administrator, in turn, has redelegated that authority to the Deputy Administrator, pursuant to 28 CFR part 0 subpart R, App.

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

The proposed year 2015 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances, and the list I chemicals ephedrine, pseudosphedrine, and phenylpropanolamine, to be manufactured in the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include

imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances necessary to provide for the medical, scientific, or other legitimate needs of the United States.

In determining the proposed 2015 aggregate production quotas and assessment of annual needs, the DEA has taken into account the criteria that the DEA is required to consider in accordance with 21 U.S.C. 826(a), 21 CFR 1303.11 (aggregate production quotas for controlled substances), and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine. and phenylpropanolamine). The DEA proposes the aggregate production quotas and assessment of annual needs for 2015 by considering: (1) Total net disposal of the class or chemical by all manufacturers and chemical importers during the current and two preceding years: (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for such class or chemical as indicated by procurement and chemical import quotas requested in accordance with 21 CFR 1303.12, 1315.32, and 1315.34; and (5) other factors affecting the medical, scientific, research, and industrial needs in the United States, lawful export requirements, and reserve stocks, as the Deputy Administrator finds relevant. Other factors the DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

The DEA also specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. See 21 CFR 1303,24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA proposes to include in all schedule II aggregate production quotas, and certain schedule

I aggregate production quotas (gammahydroxybutyric acid and tetrahydrocannabinols), an additional 25% of the estimated medical. scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting established aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Deputy Administrator, therefore, proposes to establish the 2015 aggregate production quotas for the following schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Proposed established 2015 Basic class quotas (g) Schedule I (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144) ...... [1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11) ...... 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone) 15 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone) 10 1-(1-Phenylcyclohexyl)pyrrolidine ...... 45 1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201) 45 15 1-(S-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694) .... 1-[1-(2-Thienyl)cyclohexyl]piperidine 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)
1-Bulyl-3-(1-naphthoyl)indole (JWH-073)
1-Cyclohexytethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8) 45 45 45 1-Hexyl-3-(1-naphthcyl)indole (JWH-019) ..... 45 45 45 1-Methyl-4-propionoxypiperidine 1-Methyl-4-phenyl-4-propionoxypiperidine
1-Pentyl-3-(1-naphthoyl)indols (JWH-018 and 'AM678)'
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-203)
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)
1-Pentyl-3-(4-methozyl-1-naphthoyl)indole (JWH-398)
1-Pentyl-3-[(4-methoxy)-banzoyl]indole (JWH-122)
1-Pentyl-3-[(4-methoxy)-banzoyl]indole (SR-19, RCS-4)
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-N) 45 45 45 45 30 30 30 30 30 15 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N) 2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 25C-C-NBOMe; 25C; Cimbi-82)
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 25C-C-NBOMe; 25C; Cimbi-82)
2-(4-lodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 25I; Cimbi-5) 15 2-(Methylamino)-1-phenylpentan-1-one (pentodrone)

Basic class	Proposed e tablished 20 quotas (g
Dimethoxy-4-ethylamphetamine (DOET)	
Dimethoxy 4-n-propylihiophenethylamine	
Dimethoxyamphetamine	
-(Ethylthio)-2.5-dimethoxyphenyllethanamine (2C-T-2)	
-(Isopropylthio)-2 5-dimethoxyphenyllethanamine (2C-T-4)	
5-Trimelhoxyamohelamine	
Methylenedioxyamphetamine (MDA)	
Methylenedioxymethamphetamine (MDMA)	
Methylenedioxy-N-ethylamchetamine (MDEA)	
Mathylenedioxy-N-methylcathinone (methylone)	
Methylenedinyymynyalerong (MDPV)	
ligro-N-methylcathingne (3-FMC)	
ethylfentany	
ethyllhiofeotany!	
romo-2,5-dimethoxyamphetamine (DOB)	I
romo-2.5-dimethoxyohenethylamine (2-CB)	l .
uoro-N-methylcathinone (4-FMC)	
ethoxyamphetamine	I
ethyl-2.5-dimethoxyamphetamine (DOM)	I
ethylaminorex	ı
ethyl-N-ethylcathinone (4-MEC)	ı
ethyl.N.methylcathingge (mephedrone)	ı
ethyl-aloba-ovrrolidinggrooiophengne (4-MePPP)	ı
1-Dimethylhentyll-2-I/1R 3S)-3-hydroxycyclohexyll-phenol	
1-Dimethyloctyli-2-f(1B 3S)-3-hydroxycyclohexyll-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	ı
ethoxy-3,4-methylenedioxyamphetamine	ı
ethoxy-N,N-diisopropyltryptamine	I
ethoxy-N,N-dimethyltryptamine	į
tyl-alpha-mathylientanyl	ĺ
tylcihydrocodeine	ł
tylmethadol	l
proding	i
nacetylmethadol	ĺ
nacetylmernado)na-Ethyltryptamine	ĺ
na-Emylityptamine	ĺ
nameprodine	ĺ
namethadot	ĺ
na-Mernyrientanyi	ĺ
na-Methylthiofentanyl	ĺ
na-Methyltryptamine (AMT)	ĺ
na-Pyrrolidinobutiophenone (α-PBP)	ĺ
na-Pyrrolidinopentiochenone (α-PVP)	ĺ
inorex	1
zylmorphine	ĺ
acetylmethadol	1
-Hydroxy-3-methylfentanyl	Í
a-Hydroxyfentany	
amediadine	
amethadol	ļ
aprodine	
Nenice	ĺ
ninone	ĺ
eine methylbromide	- 1
eine-N-oxide	ĺ
amorphine	ĺ
hyllryotamine	ĺ
nixin	
dromorphine	3,990
athyltryotamine	1
panone	1
elhyline	Ĺ
ma-Hydroxybutyric acid	70,250
oin	ĺ
romorphinol	1
troxypethiding	1
gaine	1
argic acid diethylamide (LSD)	į.
iiiuana	21
scalina	1
	ı
haqualone	1
thaqualonetheathinone	}

cogonine	Basic class	Proposed a tablished 20 quotas (g)
lophine methysus licrate	forchine methylbromide	- <del>-</del>
Inf. Agamanhyl - penhyl - Hrindazole-3-carboxamide (AMB-49)   Inf. America)		
Inf. Agamanhyl - penhyl - Hrindazole-3-carboxamide (AMB-49)   Inf. America)	forphine-N-oxide	3
(:[-Amino-3-dinothyl-1-cobotuan-2-yi)-1-pentyl-1-Hindazole-3-carboxamida (AB-FUBINACA) (:[-Amino-3-metyl-1-cobotuan-2-yi-1-de-(Incobotuan-2-yi-1-ti-indazole-3-carboxamida (AB-FUBINACA) (:[-Amino-3-metyl-1-cobotuan-2-yi-1-de-(Incobotuan-2-yi-1-ti-indazole-3-carboxamida (AB-FUBINACA) (:[-Amino-3-metyl-1-cobotuan-2-yi-1-de-(Incobotuan-2-yi-1-ti-indazole-3-carboxamida (AB-FUBINACA) (:[-Amino-3-metyl-1-cobotuan-2-yi-1-de-Incobotuan-2-yi-1-de-Incobotuan-2-yi-1-de-Incobotuan-2-yi-1-pentyl-1-de-Incobotuan-2-yi-1-pentyl-1-de-Incobotuan-2-yi-1-pentyl-pentyl-1-pentyl-pentyl-1-pentyl-	I-(1-Adamentyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	
Inf. Amino-3-methyl-1-colouran-2-yl-1-(-full-viorbornsyl)-1-findazote-3-carboxamide (AB-FUBINACA)   Inf. Directly improfession (naphyrone)   Inf. Directly imp	I-11-Amino-3.3-dimethyl-1-oxobutan-2-vi)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	
N-Dimethylamphetarrine   Heavy Comment   Hea	-(1-Amino-3-methyl-1-pxobutan-2-vl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	
Schedule   Implement   Imple	N-Dimethylamphetarpine	
Henrylippleataire   Henrylippeataire   Henrylippeat	aphihylovrovalerone (naphyrone)	
Ethyl-I-phenylcysChexystamine   Ethylamphetamine   Ethylamphetamine   Ethylamphetamine   Ethylamphetamine	-Benzylninerazine	
Ethylamphetamine   Hydroxy-34 - Amethylanedioxyamphetamine   Hydroxy-34 - Amethylanedioxyamphetamine   Hydroxy-34 - Amethylanedioxyamphetamine   Hydroxy-34 - H	-Fihyl-1 nhendrychheviamine	
Highdroy/3-4-methylenedoxyamphetamine lorizorgambadido lorizorga	Lethylamohalamina	_
loriseymethadol orientalistone commentation	L-Hydrovy 4. methylenadiovy amphetamine	
orlevophand ormerphine henomorphine henomorp	ryalogy of heartylandowy and production of the company of the comp	
comerphane comorphine	originary	
comorphine henomorphine henomorphine henomorphina silocypin silocy		
henomorphan sistocyhin	Ormeration	
slicoyin slicoyn uninclin-dy-I 1-(5-fluoropentyl)-IH-indole-3-carboxylate (6-fluoro-PB-22; 5F-PB-22) surplin-dy-II-(5-fluoropentyl)-IH-indole-3-carboxylate (FB-22; CUPIC) stratydrocannatinols inclined and surplined surplined and surplined surplin	Omorphine	
slickyn yn tic-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22) utirefolin-8y-11-pentyl-1H-indole-3-carboxylate (FB-22; CUPIC) critishydrocanabicists inidefantary illidina initegrations in the state of the stat		
uurionli-4y-1 (-5-fluoropentyly-1H-indote-3-carboxylate (FB-22: GUPIC)  uurionli-6y-1 (-prohity-1H-indote-3-carboxylate (FB-22		
uirolin 8-yi 1-pentyl-1f-indole-3-carboxylate (PB-22: GUPIC) trahydrocanabinols independine Schedule II  Phenylcydohexylamine Piperidinocyclohexanecarbonitrile 2,587 (Indiana)	SIOCYT	
trahydrocannatricits indicentary indicenta	umonin-a-yr (1-)-igoropentyri-(n-ingone-)-garoxyriau (3-igoro-FD-22; 9F-FD-22)	
inicifentary illicities interpretedite Schedule II  Phenylcyclohexylamine Schedule II  Phenylcyclohexylamine 2,587  Arilino-N-phenethyl-4-piperdine (ANPP) 2,587  Inentani 2,587  Inentani 3,597  Inentani 3,597  Inentani 4,597  Inentani 5,597  Inentani 5,597  Inentani 6,597  Inentani 6,5	unolin-s-yi i-pentyi-iH-indote-3-carooxytate (FB-22; QUPIQ)	407
	erranyorocannatinois	437,
Phenylcyclohexylamine	nicrenianyi	
Phenylcyclohexylamine		
Phenylcyclohexylamine	rimeperidine	
Phenylcyclohexylamine	Schedule II	
Piperdinocycloneancearonimie   2,587	Chandayalahaydamiga	
Anilino-N-phenethyl-4-piperidine (ANPP)	Trenykyyuu lekytattiite	
Identania	Apolica Nahanata Asiparidia (ANDD)	2.687
phaprodine	Animo-repreneutyr-epiperiums (AVEC)	
21.875	(BERGA)	
mphetamine (for conversion) 21,675 mphetamine (for sale) 37,500 arfentanii (or sale) 240 odeine (for conversion) 50,000 odei	ipnaprogine	26
mphetamine (for sale) 37,500 arientenii 240 ocaine (for conversion) 50,000 ocaine (for sate) 50,000 ocaine (for sate) 50,000 ocaine (for sate) 51,000 ocaine (for sate) 51,	mobarbital	
240   doctine		
240   define (for conversion)   50,000   define (for sate)   46,125   extropropoxyphene   101   iphenoxylate   51,337   copinine   61,337   copinine (for sate)   62,500   copinine (for sate)   6	mpnetamine (for sale)	37,500,
Science   Scie	arfentanii	240
101   102   103	ocaine	
extropropoxyphene   101	odeine (for conversion)	
ihydrocodaine   101 iphenoxylate   1,337 cgonine   1,337 cgonine   1,337 cgonine   1,337 cgonine   1,337 chylmorphine   2,108 lutethimide   2,108 lutethimide   39,625 ydromorphone   6,250 ydromorphone   6,250 ydromorphone   6,250 ydromorphone   29,750 ydromorphone   29,750 domethadone   29,750 domethadone   29,750 domethadone   29,750 doperidine intermediate-A   29,750 doperidine intermediate-B   29,750 lethadone intermediate-C   29,750 lethadone intermediate-C   29,750 lethadone intermediate   31,875 lethadone intermediate   34,375 lethylphenidate   20,061 lethylphenidate   23,750 lorphine (for conversion)   23,750 lorphine (for conversion)   23,750 lorphine (for sale)   31,855 lorphi	odeine (for sale)	46,125,
ihydrocodaine   101 iphenoxylate   1,337 cgonine   1,337 cgonine   1,337 cgonine   1,337 cgonine   1,337 chylmorphine   2,108 lutethimide   2,108 lutethimide   39,625 ydromorphone   6,250 ydromorphone   6,250 ydromorphone   6,250 ydromorphone   29,750 ydromorphone   29,750 domethadone   29,750 domethadone   29,750 domethadone   29,750 doperidine intermediate-A   29,750 doperidine intermediate-B   29,750 lethadone intermediate-C   29,750 lethadone intermediate-C   29,750 lethadone intermediate   31,875 lethadone intermediate   34,375 lethylphenidate   20,061 lethylphenidate   23,750 lorphine (for conversion)   23,750 lorphine (for conversion)   23,750 lorphine (for sale)   31,855 lorphi	extropropoxyphene	
cgonine	ihydrocodeine	
cgonine	iphenoxylate	1,337,
thylmorphine contents of the conversion of the c	coonine	174,
entanyl 2,108  ulutethimide ydrocodone (for conversion) 3137 ydrocodone (for sale) 99,625 ydromrphone 6,250 omethadone 90,625 omethadone 9	llyimorphine	
latethimide ydrocodone (for conversion) ydrocodone (for conversion) ydrocodone (for conversion) ydrocodone (for sale) yo-Alphacetylmethadol (LAAM) yeomethorphan yeorphanol yaorphanol yaorphanol yaorphanol yaorphanol yaorphanol yaorphanol yaorphanol ydrocodone (for sale) yaorphanol yaorphanol yaorphanol yaorphanol ydrocodone (for sale) yaorphanol yaorphanol yaorphanol yaorphanol ydrocodone (for sale) yaorphanol yaorphanol ydrocodone (for sale) yaorphanol yaorphanol ydrocodone (for sale) yaorphanol yaor	eniany	2,108
ydrocodone (for conversion) ydrocodone (for sale) ydrocodone (for sale) ydromorphone omethadone yor-Alphacetylmethadol (LAAM) ydromorphone yor-Alphacetylmethadol (LAAM) ydromorphone yor-Alphacetylmethadol (LAAM) ydromorphane ydromorphone y	istathimida	
ydrocodone (for sale) ydrocodone (for sale) ydromorphone omethadone vo-Alphacetylmethadol (LAAM)  evomethorphan avorphanol sdexamfetamine operidine operidine Intermediate-A eperidine Intermediate-B eperidine Intermediate-C ethadone (for sale) ethadone Intermediate	ortropologe (for conversion)	137
ydromorphone omethadone vor-Alphacetylmethadol (LAAM) evomethorphan sevorphanol setexamfetamine speridino speridino speridino intermediate-A speridine Intermediate-B speridine Intermediate-C etazocine ethadone (for sale) sethadone Intermediate sethamphetamine (29,750 6,250 81,875 8		
omethacons vo-Alphacetylmethadol (LAAM) evomethorphan severphanol setexamietamine speridina sper		
vo-Alphacetylmethadol (LAAM)  voorphand  voorphand  seperidino  speridino  speridino  speridine Intermediate-A  speridine Intermediate-B  speridine Intermediate-C  ethadona (for sale)  sthadone Intermediate  speridine Intermediate  conversion to a schedule lil product; and 61,375 grams for methamphetamine (for sale)  sthylphenidate  sthylphenidate  sorphine (for conversion)  sorphine (for sale)  sthylphenidate	yaromarphone	0,200,
evomethorphan  avorphanol  softwamfetamine  speridino  speridino  speridino Intermediate-A  speridine Intermediate-B  speridine Intermediate-C  sethadone Intermediate  sethad	OMERIACONE AND ADMINISTRATION OF THE PROPERTY	
avorphanol sdexamiletamine speridine speridine Intermediate-A speridine Intermediate-B speridine Intermediate-C sethadone (for sale) sethadone Intermediate sethadone Intermediate sethadone (for sale) sethadone Intermediate sethad	vo-Alphacetylmeinadol (LAAM)	
sdexamfetamine 29,750 speridine Intermediate-A 6,250 speridine Intermediate-B 31,875 sethadone (for sale) 31,875 sethadone Intermediate 2,061 sethadone Intermediate 3,375 sethamphotamine 2,061 sethadone of the vo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly conversion to a schedule life product; and 61,375 grams for methamphetamine (for sale)].  sethylphenidate 6,3750 sethylphenidate 6,3750 sorphine (for conversion) 62,5500 sorphine (for sale) 82,550 sorphine (for sale) 18	evometnorphan	•
speridino 6,250 eperidine Intermediate-A eperidine Intermediate-B eperidine Intermediate-C ethadona (for sale) 31,875 ethadona (for sale) 31,875 ethamphotamine 2,061  ,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly conversion to a schedule life product; and 61,375 grams for methamphetamine (for sale)].  ethylphenidate 63,750 orphine (for conversion) 62,500 orphine (for sale) 83,750 ethylphenidate 62,500 ethylphenidate 750,000 grams for methamphetamine (for sale)].	evorphanol	
eperidine Intermediate-A eperidine Intermediate-B eperidine Intermediate-C etazocine ethadona (for sale) 31,875 ethadona (for sale) 34,375 ethamphotamine 2,061 ethylphenidate econversion to a schedule lif product; and 61,375 grams for methamphotamine (for sale)].  ethylphenidate 6 e3,750 orphine (for conversion) 62,500 ethylphenidate 6 e3,750 ethylphenidate 6 e3,7	sdexamfetamine	
eperidine Intermediate-A eperidine Intermediate-B eperidine Intermediate-B eperidine Intermediate-C ethadona (for sale) ethadona Intermediate ethadona Int	eperiding ,	6,250
eperidine Intermediate-B aperidine Intermediate-C etazocine etazocine etazocine ethadona (for sale) 31,875 ethadona (for sale) 2,061 ethadona Intermediate 2,061 ethadona Intermediate 2,061 ethadona eth	eperidine Intermediate-A	
eperidine Intermediate-C etazocine ethadons (for sale) ethadons Intermediate ethadons In	eperidine Intermediate-B	
ethadone (for sale)  stradone Intermediate  ethamphotamine  ,250,000 grams of tevo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly  conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)].  ethylphenidate  orphine (for conversion)  orphine (for sale)  62,500  62,500  61,000	eperidine Intermediate-C	
ethadone (for sale)  sthadone Intermediate  ethadone Intermediate  2,061  250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)].  ethylphenidate  orphine (for conversion)  orphine (for sale)  62,500  62,500  61,000	etazocine	
ethadone Intermediate	ethadone (for sale)	31,875,
1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly conversion to a schedule lif product; and 61,375 grams for methamphetamine (for sale)].    Each phine (for conversion)	ethadone Intermediate	34,375, 2,061,
ethylphenidate	250 000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methampheta	
lorphine (for conversion)		83 750
torphine (for sale)	etryphenidate	
lahilona 18	lorphine (for conversion)	
lahilona 18	torphine (for sale)	
	labilone	18, 17,500,

	Basic class	Proposed es- tablished 2015 quotas (g)
Noroxymorphone (for sale)		1,475,000
Dolum (powder)		112,500
		687,500
		22,750,000
		8,350,000
		137,500,000
Dyymorphone (for conversion)		21,875,000
	DATE OF THE PROPERTY OF THE PR	7,750,000
		35,000,000
		6
		19
		. 3
		9,375,000
Racemethorphan		. 3
Remitentanii		3,750
		215,003
		6,259
Tapantadol		12,500,000
Thebaine		125,000,000
	List I Chemicals	
Ephedrine (for conversion)		1,000,000
Ephedrino (for sale)		3,000,000
	islon)	44,800,000
		8,500,000
		7,00

The Deputy Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as necessary.

#### Comments

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

pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.11(c) and 1315.11(f).

Dated: June 26, 2014.
Thomas M. Harrigan,
Deputy Administrator.
[FR Doc. 2014–15549 Filed 7–1–14; 8:45 am]
BILLING CODE 4410–09-P

# OFFICE OF MANAGEMENT AND BUDGET

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

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

ACTION: Notice of availability and request for comments.

summary: The Office of Management and Budget (OMB) requests comments on its Draft 2014 Report to Congress on the Benefits and Costs of Federal Regulations, available at: http://www.whitehouse.gov/omb/inforeg\_regpol\_reports\_congress/. The Draft Report is divided into two parts. Part I contains two chapters. Chapter I examines the benefits and costs of major Federal regulations issued in fiscal year 2013 and summarizes the benefits and costs of major regulations issued

between October 2003 and September 2013. It also discusses regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. Chapter II offers recommendations for regulatory reform. Part II summarizes agency compliance with the Unfunded Mandates Reform Act.

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

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

ADDRESSES: Submit comments by one of the following methods:

... www.regulations.gov; Direct comments to Docket ID OMB-2014-

Fax: (202) 395–7285

 Mail: Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: Mabel Echols, NEOB, Room 10202, 725 17th Street NW., Washington, DC 20503. To ensure that your comments are received, we recommend that comments on this draft report be electronically submitted.

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

Drup	- Company	Comment	Amount	Response	Primosed APO	Extablished APO	_ Change
25B-NBOMe		increase APO	5	APO sufficient	15	15	
25C-NBOMe	(b)(4)	increase APO	- 3 _	APQ sufficient	[ 15]	15	
2SI-NBOMc		increase APO		APO sufficient	15	15 [.	
3-FMC		increase APO	5	APO sufficient	15	_15	
4-FMC		increase APO	51	APO sufficient		. 15	
4-MEC		increase APO	5	APQ sufficient	15	.15	
4-McPPP		increase APO	- 5	APO sufficient	15	15	
5-Fluoro-PB-22		increase APO	<u></u>	APO sufficient	15]	15	
AB-FUBINACA		increase APO	5	APO sufficient		15[	•
ADB-PINACA	<del></del>	increase APO	5	APO sufficient		, , 12	
elcha-PBP	-	increase APO	<del></del>	APO sufficient	15	15	
alpha-PVP	<del></del> -	increase APO		APO sufficient	13	15	_:
amphetamine (for sale)		increase APO	1.807.600	APO sufficient	30,000,000	39,000,000	
ANFP	· -	increase APO	1.320.000	APO sufficient	[2,150,000]	2,150,000	
burylane		increase APO	5	APO sufficient	15	15	
codeine (for sale)	<del></del>	increase APO	25,501,000	justified, increase APO	136,900,000	39,600,000	2,700
dihydrocodeine		increase APO	180,000	justified, increase APQ	81,100	181,100	- 100
diphenoxylate		increase APO	740,000	APO sufficient	1,070,000	1,070,000	<u> </u>
fentanyl		increase APO	940,000	justified, increase APO	1,687,000	1,720,000	33
hydrocodone (for sale)		increase APO	32 302 0001	APO sufficient	79,700,000	79,700,000	
hydromorphoes		increase APO	2.585,000	justified, increase APO	5,000,000	5,600,000	690
levomhanol		increase APO	5.600	justified, increase APO	2,700	5,700	
marihuana		increase APO	100,000	justified, increase APO	21,000	125,000	<u> </u>
morphine (for conversion)	<del></del>	increase APO .	26.251.000	APO sufficient	73,000,000	73,000,000	
гарутопс		increase APO	5	APO sufficient	15	15	
Oripaying		increase APO	6 231,000	justified_increase APO	18,200,000	28,000,000	9,800
exycodone (for conversion)		increase APO	3 000,000	_APO sufficient	6,680,000	6,680,000	
oxymorphone (for conversion)		increase APO	6 151 000	justified, increase APQ	7,500,000	23,200,000	5,700
oxymorphone (for sale)		increase APO	1,609,000	APO sufficient	6,200,000	6,200,000	
PB-22		increase APO	5	_APO sufficient	15	15	
nentedrone	<del></del> 1	increase APO	_ 5	APO sufficient		15	
pentylone	·	increase APO	5	APQ sufficient	[		

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

5 32

		_					_
. 1	CMEA Chemical	Company	Comment_	Amount	Response	Pennosed AAN   Fatablish AAN   Change	
	NIES CHARGE	- S.OHIDAHY	+	Amberia			
							_

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

Additional Drug Considerations:				
Drue	Response	Pennased APO	Established APO	Change
alfentanil	increase histified based on registrant applications	14,1001	14.200	100/
cocaine	increase justified based on increased demand	192,000	220,000	28 <u>,000</u> \
eodeine-n-oxide	increase justified based on registrant applications	· 200	305	105)
		[ ·]	[	

Additional Chemical Considerations:				
Drug	Response		Established AAN	
ephedrine (for sale)	reviewed final AAN for 2011-2014, ave of AAN	3,000,000	4,000,000	(,000,600) V
		٠.,	1	

(b)(4)
July 31, 2014
Acting Deputy Administrator Drug Enforcement Administration Washington, D.C. 20537
Attn: DEA Federal Register Representative [Docket No. DEA-393]
This letter constitutes (b)(4) comments on the Proposed Initial Aggregate Production Quotas for 2015, as published in Federal Register on July 2, FR Vol. 79, No. 127, pages 37772-37776. In light of the fact that (b)(4) has no knowledge of either the amounts of any available aggregate quotas or the planned allocation of any aggregate,
requests that DEA make any adjustments to the aggregate quotas sufficient to satisfy its requests for increased manufacturing quotas, which are outlined below. Because this comment contains confidential business information on its manufacturing quota needs, we also request that DEA treat this entire document as confidential.
satisfy its requests for increased manufacturing quotas, which are outlined below. Because this comment contains confidential business information on its manufacturing quota needs,
satisfy its requests for increased manufacturing quotas, which are outlined below. Because this comment contains confidential business information on its manufacturing quota needs, we also request that DEA treat this entire document as confidential.
satisfy its requests for increased manufacturing quotas, which are outlined below. Because this comment contains confidential business information on its manufacturing quota needs, we also request that DEA treat this entire document as confidential.  All requests below are stated in grams anhydrous base ("AA").  8333 4-Anilino-N-phenethyl-4-peperidine (ANPP)  [b)(4)
satisfy its requests for increased manufacturing quotas, which are outlined below. Because this comment contains confidential business information on its manufacturing quota needs, we also request that DEA treat this entire document as confidential.  All requests below are stated in grams anhydrous base ("AA").  8333 4-Anilino-N-phenethyl-4-peperidine (ANPP)  [b)(4)
satisfy its requests for increased manufacturing quotas, which are outlined below. Because this comment contains confidential business information on its manufacturing quota needs, we also request that DEA treat this entire document as confidential.  All requests below are stated in grams anhydrous base ("AA").  8333 4-Anilino-N-phenethyl-4-peperidine (ANPP)  [b)(4)

Contains Confidential and Proprietary Information

<u> </u>
(b)(4)
RE: 2015 Revised Initial Aggregate Quota Requests for (b)(4),(b)(7)(E)
9801 Fentanyl
(b)(4) requests that the initial aggregate be sufficient to include its request for 940,000 grams AA of Fentanyl manufacturing quota for 2015.
9220 Levorphanol
requests that the initial aggregate be sufficient to include its request for 5,60 grams AA of Levorphanol manufacturing quota for 2015.
9143 Oxycodone (for conversion)
requests that the initial aggregate be sufficient to include its request for 3,000,000 grams AA of Oxycodone (for conversion) manufacturing quota for 2015.
9652 Oxymorphone (for sale)
requests that the initial aggregate be sufficient to include its request for 1,600,000 grams AA of Oxymorphone (for sale) manufacturing quota for 2015.
All other quota requests remain unchanged from (b)(4) original request.
Sincerely, (b)(6)
Supervisor, Controlled Substance Compliance
(b)(6) (b)(4);(b)(6)

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

July 30, 2014

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

RE: Docket No. DEA-393

Comment to Federal Register Volume 79, Number 127 (Wednesday, July 2, 2014)
Notices Pages 37772-37776 FR Doc No: 2014-15549

# Dear DEA Federal Register Representative:

herewith comment to a portion of the above referenced Federal Register proposal. Specifically, (b)(4) believes that Proposed 2015 Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for the listed drug codes below may not be adequate for the medical, scientific, research and industrial needs of the United States.

Drug	Drug Code
Codeine (45)	9050
Morphine for Conversion	9300
Oxymorphone for Conversion	9652
Hydrocodone (f5)	9193
Oripavine	9330
Hydromorphone	9150

	Regards	٠,	
(b)(6)			
			'
	Director, Controlled	Substance Co	moliance

IMS Data 202014 (est)

Substance	2011	2012	% Change	2013	% Change	2014*	% Change
Amphetamine (D,L)	9,703.48	10,938.98	12.73%		-0.10%	11,781.22	
Amphetamine (D)	10,594.66	11,725.36		_	-1.09%	12,428.08	
Cocaine	48.53	44.03	-9.28%	39.63	-9.99%	37.76	-4.73%
Codeine	26,170.71	22,758.42	-13.04%	21,717.57	-4.57%	20,712.17	-4.63%
Dihydrocodeine	107.21	75.02	-30.03%	36.22	-51.72%	4.33	-88.04%
Diphenoxylate	462.60	413.01	-10.72%	406.21	-1.65%	387.76	-4.54%
Dronabinol	110.82	106.13	-4.24%	110.93	4.52%	115.72	4.32%
Ephedrine	1,535.52	1,973.12	28.50%	2,083.35	5.59%	2,175.64	4.43%
Fentanyl	539.85	575.08	6.53%	548.24	-4.67%	536.96	-2.06%
Hydrocodone	64,934.12	63,178.66	-2.70%	61,628.67	-2.45%	59,076.69	-4.14%
Hydromorphone	1,675.27	1,912.79	14.18%	1,926.37	0.71%	1,828.21	-5.10%
Levorphanol	0.32	1.54	378.02%	2.33	51.13%	2.61	11.65%
Lisdexamfetamine	12,336.18	14,001.30	13.50%	13,653.66	-2,48%	14,195.78	3.97%
Meperidine	2,303.07	1,885.75	-18.12%	1,537.43	-18.47%	1,296.65	
Methadone	7,639.42	6,776.37	-11.30%	5,804.95		5,358.57	-7.69%
Methamphetamine	13.86	14.40	3.87%	13.09	-9.11%	12.33	
Methylphenidate	19,212.63	19,534.89	1.68%	17,949.19	-8.12%	17,989.12	
Morphine	30,435.83	28,705.57	-5.68%	26,267.70		25,007.07	-4.80%
Nalbuphine	61.42	63.63	3.60%	1		39.10	
Naloxone	391.27	430.32	9.98%	478.98	11.31%	502.16	
Naltrexone	4.56	0.00	-99.98%			0.00	
Opium	84.96	81.02	-4.63%	77.44	-4.43%	76.79	
Oxycodone	70,885.82	66,703.74	-5.90%	60,313.66	-9.58%	58,971.27	-2.23%
Oxymorphone	2,655.74	1,958.25	-26.26%	1,865.59	-4.73%	1,936.85	
Pentazocine	839.71	698.43	-16.82%			412.71	
Pentobarbital	79.12	46.62	-41.07%	<b>24.25</b>	-47.99%	22.90	
Pseudoephedrine	104,476.73	93,933.95		93,208.94		92,381.64	
Remifentanil	1.05	1.11	5.83%	1.16		1.21	<u> </u>
Secobarbital	20.78	15.67					<del></del>
Sufentanil	0.05	0.05	-2.53%	0.05	-7.93%	0.04	-11.50%

<sup>\*</sup>Estimates based on Jan-Jun 2014 Data

Basic Class; Total PG Reg,

326,100,000

2015 Initial APQ

FDA Est: IMS Est: .015 -.021

(used fentanyl %)

DEA Num 2015 Requested MQ 2014 Projected Exports 2014 Projected Expo Company 0.000 1,205,129.000 520,039,000 938,123.250 938,123.250 1,040,000,000 777,862,000 777,876.940 1.000 326,093 737 210,631,000 1.320,000.000 (b)(4);(b)(7)(E) 0.000 9,000.000 4,105.200 4,920.000 4,920.000 0.000 13,500,000 6,560,000 0,000 777,876,940 0.000 0.000

MQ Totals: 1,333,500,000 1,046,560,000 943,043,250

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

APQ sufficient, no adjustment required

Basic Class; Total PQ Requ.

104,000

2015 Initial APQ Ws

FDA Est: IMS Est: , n/a

Company	DEA Num	2015 Requested MQ	2014 Rovised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Ad] Avall Calc	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	5,838.000	0,000	0.000			0.500	1.500	1,500	1.500
		14,100.000	14,680,000	5,836,000	5,838,000	1.000	104.000	6.937,000	0.000	13,760,000	6,936.000	17,262.750	9,361,000

MQ Totals: 14,102,000 14,082,000 9,362,500

 2014 Final Initial APQ:
 14,100,000

 2014 Final Revised APQ:
 0,000

 FDA Est: (2014 Initial APQ\*1+FDA Est):
 14,100,000

 IMS Est: (2014 Initial APQ\*1+IMS Est):
 14,100,000

2015 Extablish APQ: 14,200.000 2016 Extablish APQ with 25% buffer: 17,750.000

ALFENTANIL

Sesic Cires: Total PO Requess.

2015 Initial APQ Workshoots 28,734,232,940

FDA Est: -.04

Cate Using CFR 60% DEA Num 2015 Requested MG 2014 Revised MG 2013 Sales 2013 DEA MO Salos % of 2013 Sales Share of 2015 Total PG 2013 Inventory 2018 Projected Exports 2014 Projected Sales 2014 Projected furnment Adj Avail Cate 0,000 5.000 1.000 5.100 26.011,176,528 0.000 0,000 1.800 5 000 5.000 5 000 0.000 (b)(4);(b)(7)(E) 104,093 107,020 -91,456 100.000 100 000 1.039 26,011,178,528 0.000 1,146 43.893 0.000 26.000 100,000 0.000 558,670,000 0.000 0,000 556,670,000 0.000 0.000 \$58,670,000 628,000 000 0.000 0.000 26,011,176.528 0.000 234,397,000 453,297,750 -124,104.641 106,687,000 26.011,176.526 0.004 117,633,727 458,397,000 0.000 296,000,000 296 000,000 296,000,000 146,000,000 150 220 000 10,903,400,000 5,692,152,000 13,737,672,000 12,624,442.221 11.600,000.000 13,281,051,977 5,171,263,000 26,011,178,526 0.462 11,600,000,000 13,145,613,000 12,022,449,000 8,923,000,000 16,769,523,750 19,303,026,598 19,303,026,698 0.000 19,168,000.000 17,231,565.000 13,170,419.000 26,011,178,526 0.506 14,549,200.358 5,127,800,000 25,501,000.000 0.000 1.000,000 0,000 750,000 251.637 1,000,000 0 000 1,330 26,011,178,528 1 469 0.000 1,000,000 1.000,000 147,330 000 1,816,185,500 3,478,000,000 7.544,490.657 2.544,490.857 26,011,178 526 0,027 786,141.086 0,000 0.000 4,935,000,000 2,554,914,000 711,641.000

MQ Totals: 43,161,165,009 33,061,197,000 34,503,292,555

2016 Final Initial APQ: 36,900,000,000
2014 Final Revised APQ: 0.000
FDA Est: (2014 Initial APQ 1 + MS Ect): 35,424,000,000
IMS Est: (2014 Initial APQ 1 + MS Ect): 35,202,000 000

2016 Proposed Initial APQ: 36,900,000,000
2015 Established APQ: 39,600,000,000
2016 Established APQ w/ 25% buffer: 49,500,000,000

APQ adjustment based on Noramco's increased export regularments

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA							
Request ID. 120268	ALFRICAL LON I	Att THE TABLE IN		Date Submitted	31-JUL-14		
Name of Basic Class or List 1 C	hemical (only	1 per DEA-189)		le/List Number	0		
ODEINE (FOR SALE)							
tame and Address of Registrant b)(4)			Drug C Quota		9050-B 2015		
~				gistration Number			
ontact Person(b)(6)			Fax. N	o	(b)(6)		
Address (h)(4)(h)(6)  NOTE: All Quantities are to be Expressed in Grams of Anhydrous Acid, Base, or Alkaloid(not as Salts).							
NOTE: All Quantities	are to se express		Quotas Previo	ially leared by DEY			
lota History	<u> </u>	2013	2014	2015	Quota Requested 25,501,000.0		
roduction Data		15,730,716.0 2nd Preceding Year	17,231,565.0	Escimate for	Retinate for Year		
				Current Year	Requested		
nventory as of Dec 11	Ch == 1 == 3	4,400,200.0	0.0	8,923,000.0			
a.Bulk Controlled Substance/List 1 b.In-Process Material		727,600.0	0.0				
c. Contained in FINISHED Dosage Fo		0.0 5,127,800.0	0.0	<del></del>			
Laposition(Sale)/Utilization		10,848,619.0	0.0	19,168,000.0	19,168,000		
a.Domestic		2,330,220.0			15,100,000		
b Exports		13,178,839.0	0.0	19,168,000.0	19.168,000		
quisition/Production		0.0	0.1	25,501,000.0	25,501,000		
a.Domestic Sources		0.0	0.				
the Purpose is to Manufacture Anothe	r Substance(s), F	Turnish the Following	Information:	<del>.</del>			
Name of New Substance	Drug	2012	Amount Used for t	his Purpose 2015	Yield		
			2013				
	<del>  </del>	/Satch   0 of Batc	hes Batch Purpo	e Est. Quantity	Est. Completion Ti		
Freduct Development Dosago Form St	rength Units	/Satch # of Batc	Bacch Porgo	Bor, Quantity			
Date of Destruction		Bx	planation	·	·		
		•					
ackaging Product Name	Strength	Units/Pkg f of	PRGG	Purpose	Total Quantity		
_							
enarks							
roduction loss estimated at 2,291.0 eference# 119691	00 grams 1,000	grams to support :	elerence standard	business Replaces A	pplication		
TETERGER YTAGY			~^	م ۸ مید این	= 117d		
•			20	14 expors 14 est ex	- 1114		
Current Vini	tin ac		10	14 pst ex	= 6000		
Willer III	(4 A)		20	A	_ 7002		
2015 est ex = 7992							
· · · · · · · · · · · · · · · · · · ·							
2,781	ı						
1, 193	;				•		
		ote + ot	hece				
11,141	+ 044	United & Ot	1100				
	•				٠,		



2014 Quote	Crent	Comment
CPS-ACA	6,290	
		Initial grant 17,231,565
Codeine For Sale (from (b)(4) CPS)	4,971	kgB

2014 (b)(4) Codeine Phosphate Inventory	With Correct
Calculations	Quela
2013 Ending Inventory	2,522
Non saleable material	12
2013 Available End. Inv.	2,510
2014 API Quota	4,971
2014 Dispositions	
Sales	4,755
Processing Losses	(591)
2014 Ending Inventory	2,135
Converted to % Yearend	59,9%

	kgs, base
2013 Dispositions	2,320
2014 Est. Dispositions	4,755
Average	3,567
50% Inventory Allawance	1,784

	ACTUAL YEAR TO DATE (JUNE 30, 2014)				ESTIMATE ON		
			Net output	Loss by	Input to	Output	Loss by
Description	Emport to Step	Process Yield	of step_	step	Step	of Step	step
CPS-ACA to Codeine for Sale	1,825	84,1%	1,535		4,085	3,436	
Codeine for Sale							
Codeine(fr CPS) to Codeine Phosphate	1,218	88.5%	1,079	(344)	3,683	3,432	(44.5)
Codeine Phosphate Finished	•	99,5%		0	4,517	4.510	(7)
Total				(140)	<u> </u>		(452)

2014 CPS-Codeine Inventory Calculations	With Current Queta
2013 Ending Javenton	1,867
Non salcable material	
2013 Available End. Inv.	I 567
2014 API Quota	6,290
2014 Dispositions:	
Converted to ACA for Sale	5,910
2014 Ending Inventory	2,247
Converted to % Yearend	37.9%

	kgs, base
2013 Dispositions	5,941
1014 Est. Dispositions	5,910
Average	5,925
30% Inventory Allowance	1,778

2015 Quota	Apr-15	Aug-15	Delta	Comment
CPS-ACA	7,500	15,000	7.500	
Codeins For Salc	5,700	11,000	5,300	Tutal Codeme for Sale: 25,500 kgB

2015 (b)(4) Codeint Phasphate Inventory			
2014 Ending Inventory	2,135_		
Non saleable material	ō		
2014 Aveilable End. Inv.	2,135		
2015 API Quota	11,000		
2015 Dispositions;			
Sales	7,992		
Processing Losses	(1,276)		
1015 Ending Inventory	3,867		
Converted to % Yearend	60.7%		

-	kgs, bear
2014 Est. Dispositions	4,753
2015 Est. Dispositions	7,992
Average	6,373
50% Inventory Allowance	3,117

3015 Queta Calc					
	Import to	Process	Net suppol		
Description	Step .	Yidd	of step	Loss by step	
CP5-ACA to Codeine for Sale	13,076	\$4.1%	11,000		
Codeine for Sale .			(		
Codeine(fr CPS) to Codeine Phosphate	11.000	88,5%	9,740	(4.260)	
Codeme Phosphate Finished	9,740	99.8%	9.724	116)	
Total				(1.276)	

2015 CPS-Codrine Inventory Calculations			
2014 Ending Inventory	2,247		
Non saleable material	0		
2014 Aveilable End. lav.	2,247		
2015 API Quota	15,000		
2015 Dispositions:	_		
Converted to ACA for Sale	13,076		
2015 Ending Investory	4,171		
Converted to 1/4 Yearend	43.9%		

	kgs, base
3014 Est. Dispositions	5,910
2015 Est. Dispositions	13,076
Average	9 193
30% Inventory Aflewance	2,848

2015 Forecast				
Customer	DEA #	1015 Total, kg Salt	2015 Total, kgB	
(b)(4)	EXPORT	8,900	5,920	
	EXPORT	2,000	1,460	
	EXPORT	600	414	
	EXPORT	700	148	
		10.800	7 497	

39ab(Inv) = 11,972 necd (205)

1276

7/30/2014



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

2014 Morphine for Conversion Inventory	Initial 2014	Additional
Calculations	Grant	2014 Grant
2013 Ending Inventory	2.454	2.454
Non saleable material	3	3
2013 Ayaifable End. Inv.	2,451	2,451
2014 API Quota	10,431	14,501
2014 Dispositions:	<u> </u>	
Converted to Codeine	13,120	13,120
Converted to 14-HM	0	999
Processing Losses		-
2014 Ending Inventory	-238	2,833
Converted to % Yearend	-2.2 %	25.8%

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

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

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

Codeine From N Requirements

2015 Quota	April Submission	August revision	Delta	Comment
Morphine for Conversion	22,000	19,395	(2.605)	
Morphine for Conversion for 14-HM	0	6,855	6,855	_
Total Marphine for Conversion	22,000	26,250	4,250	
Codeine For Sale	090,01	14,500	(4,500)	Total Codeine for Sale: 25,500 kgB

2015 Morphise for Conversion Inventory Calculations		
2014 Ending Inventory	2.833	
Non salcable material	. 0	
2014 Available End. Inv.	2,833	
2015 API Quota	26,250	
2015 Dispositions;		
Converted to Codema	15.516	
Converted to 14-HM	6,855	
Processing Losses	-	
2015 Ending Inventory	6,712	
Converted to % Yearend	30.0%	

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

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

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

(b)(4) confidential

7/30/2014

Page 1



				ESTIMATE ON REMAINING					
	ACTU	AL YEAR TO I	QUOYA						
-	Input to	T		Net output	Loss by	Input to	Output of	Loss by	
Description	Step	Process Yield	MWC	of step	Hep	Step	Step	step	
CPS-AMA to Morphine for Conv	7,657	85.60%		6,554		4,529	3,876		
Codeine for Sale							1		
Morphine for Conv to Codeine for Sale	7,478	89,0%	1.05	6,986		5,642	5,272		
Codeine(fr Morph) to Codeine Phosphate	5,220	93,60%		4,886	(334)	5,775	5,406	(379)	
Codeine Phosphate Finished	5,114	99,16%		5,081	(33)	5,490	5,455	(35)	
Total					(367)			1495)	

	2015 Quota Calc										
Description	Input to Step	Process Yield	MWC	Net output of	Loss by						
CPS-AMA to Morphine for Conv	30,666	85.60%		26,250							
Codeine for Sale											
Morphine for Conv to Codeine for Sale	15,516	89.00%	1.05	14,500							
Codeine(& Morph) to Codeine Phosphate	14,500	93.60%		13,572	(928)						
Codeine Phosphate Finished	13,572	99.36%		13,485	(87)						
Total					(1.015						

	2015 Forecast				
Customer	DEA#	2015 Total, kg Salt	1015 Total, kgB	Comment	, 
b)(4);(b)(7)(E)		1,900	1,406	7 . <del>-</del>	1
N N N N N		300	222	THY _	1
		158	117	V	1
		300	222		1
		300	222		. ــ ــ ا
				Includes Generic Bidco	583 25 26
		12,100	8,954	RG0360115	15.0
		45	33	'2	] (0,
Total		15,103	11,176		
ND MORPHINE CODEINE)	_	√ 5,58		>	
2015 Total Codeine Inventory Ca	lculations	]	16,7	164 KE	લ્લે

# COMBINED CODEINE INVENTORY (TASMAN AND MORPHINE CODEINE)

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

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

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

	kgs, base
2014 Est. Dispositions	16,114
2015 Est. Dispositions	19,168
Average	17,641
50% Inventory Allowance	8.821

(b)(4) Confidential

7/30/2014

Page 2



MQ Totals:

9,113.000

161,010.000

80,260,000

## 2015 Initial APQ Worksheets



Carres DEA Num 2	2015 Requested MCL 2014	Beidsed MO	2013 Safes (	2013 DE A MO Sales	% of 2013 Sales	Stare of 2015 Total PQ	2013 Inventory	014 Projected Exports	2014 Projected Sales	015 Projected Exports	2014 Projected Inventory	Adj Aveil Calc	Colc Using CFR 50% Invest	MQ
(b)(4);(b)(7)(E)	5,000 5,000 180,000,000 1,000,000	5 000 5 000 80,000,000 250,600	0.000 0.764	7,988,764 7,988,764 7,988,764 7,988,764	0,000 0,000 1,000	0.000 8 &72 9,110.980 0.228	0,000 14 945	0 000 0 000 0 000 0 000	5,000 3,000 184,250,000 1,000,000	0.000 0.000 0.000 0.000	1,000 15,946 122,387,000 0,000	3 750 14 959	1,250 -14 606	5,600 5,000 107,283 968 675,625

107,969 813

2014 Final Initial APQ:	80,600,000
2014 Final Revised APQ:	0.000
FOA EAU (2014 Initial APO * 1 + FOA EAU):	80,600 000
THE EST (2014 HIBLI APO 1 1 + MS EST):	80,800 000
2015 Proposed Extablish APQ:	81,100.000
2015 Established APQ:	181,100.000
with 25% buffer:	226,375 000

DIHYDROCOCEINE

Basic Class: Total PO Request.

1 000

2012 Initial APQ Workshoots

							Share at 2015							Cate Using CFR 50%		
Company D	DEA Num	2015 Requested MO 2	014 Revised MG	2013 Sales	2013 DEA MO SAINA	% of 2013 Salds	TOLLIFO	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2015 Projected Exports	2014 Projected Inventory	PQÎ AANI CEJC	invant	KI	
(b)(4);(b)(7)(E)		2 000	2,000	0.000	707,727 000	000,0	0.000	0.000	0.000	0,500	0.000	1.500	1.500	-1,000	\$ 000	
(0)(+),(0)(1)(L)		31,650,000	19,000,000	465 000	702,222,000	0.001	0,001	13,489,000	0.000	31,620,000	0.000	13,488 000	24,366.750	1,881.001	24,386,750	
		740,000 000	•	703 577,000		1.002	1.002	265,969,000	16,400.000	712,056 000	0.000	347,825.000	881,975,750	-227,011 748	740.000.000	
HO Tobile		771652.000	909.002.000									•			764,368,750	

771,652,000 909,002 000 MO Totals:

2014 Finel Initial APO: 600,000.000 2014 Final Revised APQ: 1,931,000,000 FDA Est (2014 Initial APO \* 1 + FDA Est): 500,000 000 IMS Eat (2014 Initial APQ \* 1 . INS Ear): 572,760 000

2015 Proposed Establish APO: 1,031,000.600

APQ sufficient, no adjustment required

DIPHENOXYLATE (FOR SALE)

Vol. I Page 805

Basic Clave: Total PQ Reque

1,007,216,255

1,799,637.000 1.459,029.000

2015 Intital APQ Works

FDA Est: IMS Est: .015 -.021

Company	DEA Num	2015 Requested MG	2014 Roylsed MQ	2013 Sales	2013 DEA MQ Salos	% of 2013 Sales	Share of 2015 Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory		Cate Using CFR 60% Invent	MQ
(b)(4);(b)(7)(E)		5,000	5.000	0.000	998,926.931	0,000	0.600	0,101	0.000	4,000	1.900	3.826	0.149	5.000
(5)(1),(5)(1)(2)		200,000,000	1\$1,000,000	36,960,000	998,926.931	0.037	37,266.703	\$3,892.000	0.000	200,000,000	50,000,000	153,669.000	79,441.378	153,669,000
		2,000	2,000	0.538	998,926,931	0.000	0.542	1,010	0.000	0.500	1.711	2.258	+1.332	2,000
		13,330,000	14,151,000	9,082,000	998,926.931	0.009	9,157,365	103.000	0.000	13,330,000	1,000,000	10,690,500	14,060,456	13,330.000
		600,000.000	461.271.000	245,042.000	998,926.931	0.245	247,075.415	230,548.000	0,000	600,000.000	236,303,000	518,865.000	,	518,885,000
		940,000,000	810,000,000	645,039,000	998,926,931	0.646	650,391,681	298,686,000	189,170,000	900,111,000	379,269,000			940,000,000
		32,000,000	16,000,000	4,460,000	998,928.931	0.004	4,497.010	17,597,000	0.000	33,000.000	13,000.000	25,197.750	9,024,263	25,197,750
		13,500,000	6,600.000	0.000	998,926,931	0.000	a 900	0,000	0 000	8,500,000	7.214,900	4,950,000	3,550,000	4,950,000

1,658,018,750

2014 Final Inhiai APQ: 1,687,000,000
2014 Final Revised APQ: 0,000
FDA Est: (2014 Initial APQ\*1+FDA Est): 1,712,305,000
IMS Est: (2014 Initial APQ\*1+6MS Est): 1,652,247,800

APQ adjustment made based on convention from ANPP and FDA estimate

2015 Establish APQ:

MQ Temis:

1,720,000.000

2015 Establish APQ with 25% buffer:

2,150,000,000

Besic Class: Total PO Request.

05,133,438,749

2015 Initial APQ Worksheets

FDA Eet; -.022 IMS Cet; -.046

68,915,498,204

Company	DEA Num	2015 Requested MO 20	016 Revised MQ	2013 Sales				2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Aveli Cale 3.788	Calc traing OFR 50% Invent 0.199	MQ \$.000
(b)(4);(b)(7)(E)		3 5000	5.000	0.000	45,088,169,355	5,000	0,000	0.051	0.000					
(U)(4),(U)(1)(L)		200,000 000	99,400,000	0.000	45,068,169,355	000.0	0.000	0.000	5.000	200,000 000	40,000,000		125,450.000	125,450,000
		20,000	20 000	3,575			7.546	74.093	0.000	5.000		70.570	-74,660	20,000
		365,000,000	175,079,000	39,742,000	45,068,169,355	0 001	63,890,541	12,258,000	0.000	195,000.000	5,000.000	140,502,750	347,295,927	347,295.927
		5,500,000	7.320.000				23,207.064		0.000	5,500.000			29,018,830	5,500,000
		610,000,000	3,200,000,000			0.072	6,819,318,143	5,043,303,000	0.000	610,000.000		6,162,477,250		-
			19,274,159,000	22,652,826 000	45,068,169,355	0.507	48,239,543,643	7,741,178 000	12,200,000		, ,	20,261,502.750		20,261,502,750
		3,602,000,000	1,865,910,000	148 721 000	45,068,169.35\$	0.003	313,931,891	2,031,970,000	0,000	3,100,000.000	1,983,000,000	2,938,410.000	46,012,489	2,838,410,000
		32,302,000,000	22,958,387,000		• •		38,155,037.262	3,655,635,900	0.000	29,000,000.000		19,960 502.)75		32,302,000,000
		10,000,000,000	2,184,719,000			0.013	1.276,014.622	2,209,940,000	0,000		-, ,	3,295,994,250		4,205,039,028
1		11,600,000,000	6,981,532,000	103,852,000	45,066,169.355	0 002	219,248,975	3,845,502,000	0.000	9,150,000,000	1,203,600,000	8,120,275,500	342,372,718	0,120,275.500

MQ Totals: 84,705,825,000 56,766,511,000

20 14 Final Initial APQ: 75,700,000.000
2014 Final Revised APQ: 0,000
FOA Est: (2014 Initial APQ 1 1 + FOA Est): 77,945,500,000
HS Est: (2014 Initial APQ 1 1 + INS Est): 75,400,420,000

APQ sufficient, no adjustment required

HYDROCODONE (FOR SALE)

Basic Class: Total PQ Requ

5,507,526,429

5,569,993,000 4,337,436,000

2015 Initial APQ Work

FOA Est: .067 (MS Est: - 051

						Share of 2015			****	2014 Projected	4-0-4	Cate Using CFR	
	2015 Requested MO	2014 Revised MQ	2013 Sales	2013 DEA MQ Sales	% of 2013 Sales	Total PQ	2013 inventory	2014 Projected Exports	2014 Projected Sales	(Aventory	Adj Avall Calc	50% invent	MQ
(b)(4);(b)(7)(E)	5.000	5.000	0.000	3,574,775.079	0.000	C.000	0.000	0.000	4.000	1.000	3,750	0.250	5.000
	64,089,000	76,700,000	0.000	3,574,775,079	0.000	0.000	0.000	0.000	60,000,000	28,000,000	\$7,\$25,000	-7,525,000	57,525.000
	30.000	30,000	2.921	3,574,775.079	0.000	4,500	49,447	0.000	14.000	63.848	59,585	-52.322	30,000
	116,000.000	78,000,000	0.000	3,574,775.079	0.000	0,000	0.000	0.000	112,470.000	9.000	58,500.000	\$3,970.000	78,000.000
	165,700,000	229,064,000	128,462,930	3,574,775.079	0.036	197,918,181	35,920,696	0.000	165,700.000	0.000	198,739.522	205,379,031	165,700,000
	625,178,000	558,298,000	679,938.334	3,574,775.079	C.190	1,047,556,353	209,218.035	5,900.000	568,344.000	130,000.000	574,137,026	1,257,247,906	574,137,026
	534,000.000	445,000.000	334,715.000	3,574,775.079	0.094	515,683,272	251,602.000	9.000	534,000.000	251,602.000	522,451,500	593,252,090	522,451,500
	1,180,000.000	1.179.810.000	997.252.000	3,574,775.079	0.279	1,536.430.020	392,859.000	1,780.000	937,820.000	535,539,000	1,179,501.750	1,582,421,025	1,179,601.750
	2,585,000.000	1,674,818,000	1,389,805,400	3,574,775 079	0,269	2,141,222,819	855,997,\$50	0,000	2,425,000.000	677,000.000	1,898,111,663	2,889,417.474	1,698,111.663
	300,000,000	97,711 000	44,542.000	3,574,775.079	0.012	68,624,245	31,189.000	0.000	133,500,000	84,000.000	96,875,000	114,608.057	114,808,057

4,590,259,995

2014 Final Initial APQ:

MQ Tetals:

5,400,000,000

1014 Final Revised APQ:

0.000

FDA Eat: (2014 Initial APQ \* 1 + FDA Est): 5,761,800,000 IMS Est: [2014 Initial APQ \* 1 + IMS Est]: 5,124,600,000

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

5,600,000,000

2015 Establish APQ: 2016 Establish APQ with 25% buffer

7,000,000.000

**HYDROMORPHON€** 

Request ID. 120281	WALTGWITON	FOR INDIVIDUAL M	anufacturing Quo	ra		
Reducise IDI FEORDI				Date Submitted	31-JUL-14	
Name of Basic Class or List 1	Chemical (onl	v 1 per DEA-189)	data da	e/List Number	2	
HYDROMORPHONE	<u> </u>		Drug Co		9150-0	
Name and Address of Registrant (b)(4)			Duota 1	esr	2015	
-7.7			DEA Reg	istration Number	(b)(4);(b)(7)(E)	
Contact Person (b)(6)	1		Pax. No		(b)(6)	
Email Address (b)(4)(b)(6)			Phone_1	io		
NOTE: All Quantitie	on are to be Expre	seed in Grame of Anby	droug Acid, Base, or	Alkaloid(not as Salts		
Quota History		2013	2034	2015	Quota Requested	
		1,940,000.0	1,674,818.0	0.0	2,585,000.0	
Production Data		2nd Preceding Year	lat Preceding Year	Estivate for Current Year	Satimate for Year Requested	
Inventory as of Dec 31				677,000.0	677,000.	
a. Bulk Controlled Substance/List	1 Chemical	855,997.55	0.0		877,000.	
b.In-Process Macerial		0.0	0.0	0,0	_ 0.	
c. Contained in FINISHED Desage	Forms	855,997.55	0.0	677,000.0	677,000.	
Disposition (Sale) /Utilization		926,092.72	0.0			
a.Domesticb Exports		462,731.07	0.0	2.425.000.0	2,425,000.	
		1,390,823.79	0,0	2,425,000.0	4,925,000.	
Acquisition/Froduction a.Comestic Sources		69,642.5				
		69,642.5	••	2,585,000.0	2,585,000	
If the Purpose is to Manufacture Anot.	her Subotance(s).	Furnish the Following				
Name of New Substance	Dry		Amount Used for t	als Purpose 2015	¥ Yield	
		. 2013	.			
1						
	Strength Uni	te/Batch # of Bat	hes Batch Purpor	n Bat. Quantity	Est. Completion Tim	
Product Davelopment Dosage Form	Strength Uni	Ca/Batch + Of SEC.	Hes Dates Forpal			
			· · · · · · · · · · · · · · · · · · ·			
Transfer Regiserant		Explanst	ion of Transfer			
			•			
Date of Destruction		R.	plenstion			
Date of Destruction		P.	plenstion		·····	
Date of Destruction		P	plenstion			
Date of Destruction		<u> </u>	plenation	·		
Date of Destruction		<u> </u>	planstica			
·	G			Purpose	Total Quantity	
Date of Destruction	Strangth	Units/Pkg     of		Purpose	Total Quantity	
·	Strangth			Purpose	Total Quantity	
·	Strangth			Purpose	Total Quantity	
·	Strangth			Purpose	Total Quantity	
·	Strangth			Purpose	Total Quantity	
Packaging Product Name	Strangth			Purpose	Total Quantity	
Packaging Product Name		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks  Production loss estimated at 3,900		Units/Fkg # of	ÿkga			
Packaging Product Name  Remarks Production loss estimated at 3,900		Units/Fkg # of	ý kga			

	1	Additional 2014
CPS AOA	Grant 5,139	Grant 5.850
Origavine (TOR)	3,284	5,250
Hydromorphone (HMH)	1,675	2,110

<del></del> ,	Initial 2014	Additional 2014
2014 Inventory Calculations HMH	Grant	Grant
2013 Ending Inventory	R74	874
Non salcable material	18	1,8
2013 Avadable End. Inv.	456	856
2014 API Quota	1,675	2,110
2014 Dispositions:	I	
Sales	2,258	2,257.9
Processing Losses	(187)	(187.2)
2014 Ending Inventory	86	520.9
Converted to % Yearend	4.7%	23.6%

	kgs, base
2013 Dispositions	1,391
2014 Estimated Dispositions	2,158
Average	1,824
50% Inventory Allowance	912

<del></del>	ACTI	JAL YEAR TO D	ATE (\$/31/14	1	REMA	AINING (	LOCA	ADDI	TIONALO	ATOU
Description	Luput to Step	Process Yield	Net output of step	Loss by step	Input to Step	Output of Step	Loss by	Input to	Output of Step	Loss by
CPS-AOA Requirements							_			
CPS-AOA to Technical Oripavine (TOR)	1,977	90.12%	1,782	<u> </u>	1,666	1,502		2,182	L,966	
Oripavine							ļ	<u> </u>		
CPS-AOA to Technical Oripavine (TOR)	1,782	90.12%	1,606	İ	1,502	1,353	<u> </u>	2,182	1,966	
TOR to Dihydrooripavine (DHO)	1,606	87,30%	1,402	(204)	1,353	1,181	(172)	1,966	1,717	(250)
DHO to Purified Dihydrooripavine (pDHO)	1,412	82,50%	1,165	(217)	1,181	975	(207)	1,717	1,416	(360)
DHO to Punited Dihydrooripavine (pDHO) for Aesica		82.50%	٥		0	a	a		0 .	٥
Total			<u> </u>	(451)	i —		(\$79)			(550)
Hydromorphone For Sale						1				
pDHO to Hydramorphone (HMH)	1,030	78 00%	203	Ī	1,117	871		558	435	
HMH Sized & Packaged	1,294	99.87%	1,292	(2)	871	870	(1)	435	435	(0)
Reprocessing OOS HMH	B77	79,04%	693	(184)						
Total				(185)			(4)			1740

2014 Inventory Calculations TOR	Initial 2014 Grant	Additional 2014   Grant
2013 Ending Inventory	161	16!
Non saleable material	10	10
2013 Available End. Inv.	151	151
2014 API Quota	3,284	5,250
2014 Dispositions:		
Conversion to Hydromorphone	2,147	2,705
Exported to (b)(4	0	ő
Processing Losses	(830)	(1,380)
2014 Ending Inventory	458	1,316
Converted to % Yearend	17.4%	59,0%

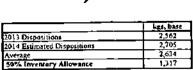
2015 Quota	Apr+15_	Aug-15	Delta
CPS AOA	5,139	7,000	1,861
Oripavine (TOR)	5,150	6,230	1,080
Hydromorphone (HMH)	2,059	2,584	525

2015 Inventory Calcula	tíons
2014 Ending Inventory	521
Non saleable material	0
2014 Available End. Inv.	521
2015 API Quota	2,584
20t5 Dispositions:	
Sales	2,425
Processing Losses	(3)
2015 Ending Inventory	677
Converted to % Yearend	28,9%

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

	Ī	2015 Queta	Calc	
Description	Input to Step	Process Yield	Net autput of step	Loss by step
CPS-AOA Requirements	<u> </u>			
CPS-AOA to Technical Oripavine			1 - 1	
(TOR)	6,182	90.12%	5,571	
Oripavine				
CPS-AOA to Technical Oripavine				
(TOR)	5.571	90,12%	5,020	
TOR to DHO	5,020	87,30%	4,3B3	(638)
DHO to pDHO	4,363	62,50%	3,616	(767)
DHO to Purified Dihydroon pavine	1			
(pDHO) for (b)(4)	303	82.50%	250	
Tota	:L		ļ <u></u> .	11,495)
Hydromorphone For Sale	I		1 3	
pDHO to HMH	3,313	78.00%	2,584	
HMH Sized & Packaged	2,584	99,87%	2,581	(3)
Reprocessing OOS HMH	0	79.04%	0	
Tota	4			(3)

<del></del>	
2015 Inventory Calculation	TOR
2014 Ending Inventory	1,316
Non saleable material	0
2014 Available End. Lov.	1,316
2015 API Quota	6,230
2015 Dispositions:	
Conversion to Hydromorphone	3,616
Exported to (b)(4)	350
Processing Losses	(1,405)
2015 Ending Inventory	2,176
Converted to % Yearend	65.2%



2014 CPS-Oripavine Inventory Calculations	Creet	Additional 2014 Grant
2013 Ending Inventory	786	786
Non saleable material	2	2
2013 Available End. Inv.	784	784
2014 API Quota	5,139	5,850
2014 Dispositions:		
Converted to Oripavine	5,466	5,466
2014 Ending Inventory	457	1,168
Converted to 1/4 Yearend	12.2%	31.3%

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

2014 Hydromorphone for Sale Forecast								
Custonner	DEA#	1015 Total, kg Sale	2015 Total, kgB					
(b)(4);(b)(7)(E)		50	45					
		31	28					
		130	116					
		11	. 10					
		542	482					
		16	_ 14					
		t <u>o</u>	9					
		g	. 8					
		184	(64					
		378	116					
		411	366					
		138	(23					
		200	178					
		42	37					
		2	2					
		35	31					
		150	134					
		28	25					
		47	42					
		. 6	5					
		26	23					

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

2015 CPS-Oripavise Inventory	Celculations
2014 Ending Inventory	1,168
Non saleable material	Ö
2014 Available End. Inv.	1,162
2015 API Quota	7,000
2015 Dispositions:	
Converted to Oripavine	6,182
2015 Ending Inventory	1,987
Converted to % Yearend	34.1%

	kgs, base
2014 Estimated Dispositions	5,465
2015 Estimated Dispositions	6,182
Average	5,824
30% Inventory Allowance	1,747

2015 Hydromorphone for Sale Forecast									
Customer	DEA#	2015 Total, kg Salt	2015 Total, kgH						
(b)(4);(b)(7)(E)		50	45						
(-N-N-N-N-)		100 350 355 540 667 104 15 2 50 8 10	89 312 316 481 594 93 13 2 45 7						
		200	178 121						
		17	15						
	Yat	1, 2,724	2,425						

2015 Oripavine for Sale Porecast											
	2015 Total, kg										
Customer	DEA#	Salt	Total, kgB								
(b)(4)	EXPORT	<u> </u>	350								
(-/(-/											

Basic Class; Total PQ Requ.

4,347,000

5,602,000

3,602,000

2015 Initial APQ Worksh

FDA Est: IMS Est:

.117

5,602,000

							Share of 2015						Calc Using CFR	
Company	DEA Num	2015 Requested MQ	2014 Revised MQ	2013 Sales	2013 DEA NO Sales	% of 2013 Sales	Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	2014 Projected Inventory	Adj Avail Calc	50% invent	MQ
(b)(4);(b)(7)(E)		2,000	2.000	0.000	1,907.000	0.000	0,000	0.000	0.000	0.500	1,500	1,500	-1.000	2,000
(=)(-),(=)(-)(=)		5,600.000	3,600.000	1,907.000	1,907,000	1.000	4,347,000	42,000	6.000	4,994.000	1,838.000	2,731,500	7,691,750 5	5,600.000

2014 Final Initial APQ:

MQ Totals:

1,600.000 2014 Final Revised APQ: 0.000 FDA Est: (2014 Initial APQ \*1 + FDA Est): 1,600.000 IMS Est: (2014 Initial APQ = 1 + IMS Est): 1,786,400

2015 Proposed Initial APQ:

2,700,000

2015 Established APQ: 5,700,000 2015 Exablished APQ with 25% buffer: 7,125 000

LEVORPHANOL



1,382,775,000

73,302,005,000 68,812,875.000



FOA Est:

65,438,207.625

								Share of 2015				2014 Projected		Calc Using CFR 30%	
	Company	DEA Num	2015 Requested MQ 2	014 Revised MO	2013 Sales	2013 DEA MQ Sales	% of 2013 Safes	Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	Inventory	Adj Avall Calc	lowerst	MQ.
	/b\/4\·/b\/7\/E\		1 5,000	0.000	0.000	47,603,753,601	0.000	0.000	0.000	9.000	5.000	0.000	000	5.000	5.000
	(b)(4);(b)(7)(E)		749,000,000	0.000	0.000	47,603,753,801	0.000	0.000	0.000	0.000	749,000,000	0.000	0.000	749,000,000	749,000,000
			4,600,000,000	5,350,000,600	3,335,263,000	47,803,753,801	0.070	95,476.070	24,303,000	3,648,000.000	3,640,000,000	1,944,381,000	4,030,727,250	3,763,792.087	4,800,000.000
٠			37,000,000,000	44,000,000,000	36,564,554,000	47,603,753,801	0.765	1,057,669 114	12,904,910 000	0,000	37,123,902.000	9,983,206,600	42,678,682,500	-7,458,921,808	37,000,000 000
			2,000,000	2,875.000	160.000	47,803,753.801	0.000	4.626	69.210	0.000	2,900,000	8.000	2,208.158	-219,675	2,000,000
			26,251,000,000	15.500,000,000	7 877 794 000	47,603,753,801	0,165	227,873.665	2,451,207.000	0.000	22,371,000,000	6,712,000.000	13,483,405.250	6,579,635,052	19,857,202,825
			4,500,000,000	1,960,000.000	0.000		0,000	0.000	0.000	0.000	4.590,000,000	0.000	1,470,000.000	3,030,000.000	3,030,000.000

MQ Totals;

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

APO sufficient, no adjustment required

MORPHINE (FOR CONVERSION)

APPLICAT	TION FOR IN	DIVIDUAL KA	NUPACTURING QUO	TA Date Submitted	31-JUL-14
ame of Basic Class or List 1 Chemical	(orly 1 pe	r DEA-189)			
ORPHINE (FOR CONVERSION)				e/List Number	0 0 0
ame and Addross of Registrant			Drug Co		9300-A 2015
b)(4)				istration Number	
ontact Person(b)(6)			Fax. No		(b)(6)
mail Address (b)(4):(b)(6)  NOTE: All Quantities are to be	Expressed in	Grame of Anbyd	Phone 1 rous Acid, Base, or	Alkaloid(not as Salt	a)
		2013	Quotas Previou 2014	ply Issued by DEA 2015	Quota Requesta
uota History	12	796,000.0	15,500,000.0	0.0	26,251,000.0
roduction Data		receding Year	lee Preceding Year	Estimate for	Escimate for Year
nventory as of Dec 31				Current Year	Requested
a.Bulk Controlled Substance/List 1 Chemical		2,451,207.0	0.0		
b.In-Process Material		0.0	0.0	0,0	
c. Contained in FINISHED Dosage Forms	•••	2,451,207.0	0.0	6.712,000.0	6,712,000
isposition(Sale)/Utilization		5,787.0	0.0		
a.Domasticb Exports	<u> </u>	5.787.0	0.0	22,371,000.0	<del></del>
equisition/Production					
a.Domestic Sources		0.0	0.0	26,251,000.0 26,251,000.0	
the Purpose is to Manufacture Another Substance	e(s). Furnish		Information:		
Name of New Substance	Drug		Amount Used for t	bio Purpose	Yield
	9050-B	2012	2013	2015	
DEINE (FOR SALE)	3020-B	10,276,811	7,400.7		
Product Development Dossge Form Strength	Unite/Betch	of Batch	98 Patch Purpos	e Est. Quantity	Est. Completion I
· ·	<u> </u>				
Date of Feetruction		<u>Ex</u>	lamation .		<u> </u>
				•	
schaging Product Name Strengt	b Unite	/Pkg of 1	kgs	Purposs	Total Quanti
•					
ema f ka		<del> </del>			
2,371,000 grams for conversion to codeine for	r sale, of	hich 6,855,00	0 grams for conve	sion to 14-HM 1,000	grams to suppor
eference standard business Replaces Applicat	ion Referen	se# 119688			
				•	
			•		
				1	
			•		



2014 Quota	Initial 2014 Grant	Additional 2014 Grant	Comment
Morphine for Conversion for Cod for Sale	10,431	14;501	
Morphine for Conversion for 14-HM	0	999	
Total Morphine for Conversion	10,431	15,500	
Codeine For Sale (from Morphine)	12,260		Total Codeine for Sale Initial grant 17,231,365 kgB

2014 Marphine for Conversion Inventory	Initial 2014	Additional	
Calculations	Grant	2014 Grant	
2013 Ending Inventory	2,454	2,454	
Non saleable material	_3 _		
2013 Available End, Inv.	2,451	2,451	
2014 API Quota	10,431	14,501	
2014 Dispositions:	1		
Converted to Codeine	13,120	13,120	
Converted to 14-HM	0	999	
Processing Losses	-	-	
2014 Ending Inventory	-238	2,833	
Converted to % Yearend	-2,1%	25.8%	

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

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

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

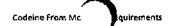
2015 Quota	April Submission	August revision	Delta	Comment
Morphine for Conversion	22,000	19,395	(2.605)	
Morphine for Conversion for 14-HM	0	6,855	6,855	
Total Morphine for Conversion	22,000	26,250	4,250	
Codeine For Sale	(9,000	14,500	(4,500)	Total Codeine for Sale: 25,500 kgB

2015 Morphine for Conversion Inventory Calculations					
2014 Ending Inventory	2,833				
Non saleable material	0				
2014 Available End. Inv.	2,833				
·					
2015 API Quota	26,250				
2015 Dispositions:					
Converted to Codeins	15,516				
Converted to 14-HM	6,855				
Processing Losses	-				
2015 Ending Inventory	6,7[2				
Converted to % Yearend	30.0%				

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

2015 Codeine Phosphate from Morph Calculations	ince mirentory
2014 Ending Inventory	2.747
Non saleable material	0
2014 Available End. Inv.	2,747
2015 API Quota	14,500
2015 Dispositions:	
Sales	11,176
Processing Losses	(1,01:
2015 Ending Inventory	5,056
Converted to % Yearend	44.9%

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



	ACTUAL YEAR TO DATE (JUNE 30, 2014)			ESTIMATE ON REMAINING QUOTA				
Description	Input to Step	Process Yield		Net autput of step	Loss by step	laput to Step	Output of Step	Loss by
CPS-AMA to Morphine for Conv	7,657	85.60%		6,554		4,529	3,876	
Codeine for Sale						i	<u> </u>	
Morphine for Conv to Codeine for Sale	<u>7,47</u> 8	89,0%	1.05	6,988		5,642	5,272	
Codeine(ft Morph) to Codeine Phosphate	5,220	93.60%	_	4,886	(334)	\$,775	5,406	(370)
Codeine Phosphate Finished	5,114	99.36%		5,081	(53)	5,490	5,455	(35)
Total					(367)			(4(15)

	1015 Quota Calc								
Description	Input to Step	Process Yield		Net output of step	Loss by				
CPS-AMA to Morphine for Conv	30,666	85.60%		26,250					
Codeine for Sale				1					
Morphine for Conv to Codeine for Sale	15,516	89.00%	1.05	14,500					
Codeine (fr Morph) to Codeine Phosphate	14,500	93.60%		13,572	(928)				
Codeine Phosphate Finished .	13,572	99.36%		13,485	4871				
Tota	1				(1.015)				

	2015 Forecast			•
Customer	DEA#	2015 Total, kg Salt	2015 Total, lgB	Comment
(b)(4);(b)(7)(E)	•	1,900	1,406	
(=/(-//(-/(-/		300	222	
		158	117	
		300	222	
		300	222	
				Includes
				Generic
		ŀ		(b)(4)
		12,190	8,954	1
		45	33	
Tatal		15,103	11,176	

# COMBINED CODEINE INVENTORY (TASMAN AND MORPHINE CODEINE)

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

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

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

	kgs, base
2014 Est. Dispositions	16,114
2015 Est. Dispositions	19,168
Average	17,641
50% Inventory Allowance	8.821

b)(4)

Confidential

7/30/2014

Page 2

2614 Quate	2014 CmM	Additional 2814 Grant	Delta
PSC-AOA	5,232	6,900	1,668
Morphise for Conversion	(0,41)	14,501	4,070
Окуппериясы Сончтиков Сонинства)	2,608	2,080	-528
Oxymorphane Conversion Development	0	671	671

	المالسل	YOUR PLANE
	2814	2014
2014 COM6 Inventory Calculations	Crust	Grant
2013 Eading Inventory	272	272
Non sales ble meternal	1	,
2013 Available End. lav.	269	249
2014 API Quata	2//08	7,000
2017 Development Quarte (not		i
included in inventory)		671
2014 Dispositions:		
Soler	1,584	1,588
Processing Coases	(13)	(la)
Non-entrable (Sent out to	(77)	(17)
2014 Enting Investory	1,199	67.8
Converted to % Yearend	79.0%	44.3%

(b)(4)

	legs, bare
2013 Dispersions	1,416
2016 F.d. Dispositions	1,552
Avenuet	8,502
50% Interesty Allement	731

			ARTODA			QUOTA		wŗ	TH INCREAS	
Description	CPS-AOA Imput	Present Vield	MWC	Fiel exityed of step	(PS-ADA)	MWC	Net susperi	Laped to Step	MWC	Net setpos of the
CPS-AUA to Crude University for										
Consectations	0	69.4%	10133	0	3,708	1013	2,608	(642)	1.0133	(526)

	AUT	UAL YEAR	TO DATE	JUNE 14,	20(4)	1	QUQT	A	WITH	4 DYCREAS	
	Inper la	Present		Net output	Loca by	Judget to	Output of		Japen to	Output of	الأوا هما
Description	Step	Yield	MWC	of perp	rtep	Sterp	Step	Late by step	Step	Біар	rtep
Osymorphene For Conventors										I	<u></u>
COM to COMP	0	99.5%	1.0000	0	0	3,609	7.594	(1)	± 5241	(125)	3
Teral	1				0			(13)			3
	1									1	$\Box$

2014 CTS-Origanise Unrentary Calculations	16/bill 1914 Grani	Additions) 3914 Creat
2013 Ending Investors	751	752
Non micebic material	_ o	. D
2013 Available End bre.	7,58	758
		Щ.
2014 API Queta	5,232	6,900
2014 Dispositions.	Ι	
Morphine for Conversion		1,190
Osymorphone for Conversion	3.021	1,021
Cromorphone for Sale	1,477	1,473
2014 Ending Inventory	1,494	1,975
Corrected in 'A Yearend	13%	10%

	Aga, here
2013 Despositions	3,464
2014 Est. Dispositions	5,683
Averspe	4,574
30% Inventory Allemanor	1,372

ZC 15 Quart	Apr-15	Aug-15	Delta
PSC-AGA	5,139	12,900	7,761
Morphaic for Convention	22,000	26,250	4,250
Occupantant Convention	450	6.150	\$,700
Chrystophone Copyrigation Development	0	0	0.

	INIS COME Inventory Colculations			
2014 Endury Inventory	674			
Non extensio meterus	0			
2014 Available End. Inv.	674			
2015 API Queta	6,150			
2015 Dysperitions.	1			
Sales	5,130			
Processing Losses	(31)			
Validation Inventory	0			
2015 Ending Inventory	1,443			
Converted in W. Yearand	49,5%			

	kp, have
2014 Fin Dispositions	3,588
2015 Est (Aspositions	\$,130
Average	3,359
50% Inventory Allowance	1,679

	2015 Quota Calc					
Description	CPS-AOA Process Net autput laput Vield MWC af step					
LPS-ADA to Crude Deymorphene for Conversion		404%	1.0133	6,150		

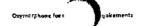
	1	2015 Quela Calc							
Description	Unput to Step	Yield	MWC	Net suspect of stage	Lem by				
Osverorphene her Conversion	1 –								
COM to COM	6,150	99.5%	1,0000	6,119	(ñ)				
Tend	1	Π		I	OT:				
	]	[	$L^-$						

2015 CPS-Oripevine Inventory Co	akculatjons	
2014 Ending Inventory	1,975	1
Non sales ble majeria	- 4	1
2014 Available End. ber.	1,975	1
2015 API Questa 2015 Dispositions	12,900	(asya)
Morphine for Convention		Customer has not told (D)(4 which grade will be ordered for 2015.
Oxymorphone for Conservice	8,745	Since more CPS is required for old process, using that as basis for 2015.
Chymerphone for 54 le	1,196	- ·
28 IS Ending Inventory	3,013	•
Converted to % Vencered	14%	

	kgs, base
2004 Est Dispositions	5,683
2015 Est. Disposaciona	11,851
Average	1,757
30% Inventory Allewater	2,630

b)(4) Consident

7/30/2014



	Tarial .	U.T. DIE
2014 Marphine for Currentha Lawylary Calculation	- 2014 Grant	2014 Great
2013 Eading Investory	2,454	2,454
	46,54	2,034
Non uscable material		, ,
2013 Aveilable End. Jav.	2,451	2,451
2014 APS Quasta	10,431	14,501
2014 Dupostions.		
Converted to Codeine	13,120	19,120
Converted to 14-104	999	999
Processing Lottes	$\equiv$	
2014 Ensing Investory	4,237	7,633
Converted to % Ventored	-11.27-	25.8%

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

Description	Number of Bestver	Brich Ispet, KgB	Petern Yali	Berth cartput, KAB	Lau by Nep, Kg9	Tetal Input, KgB	Total Charpert, KgB	Total Late KgS	Total output, kgB on AMA for Conversion
			idala R	remark the	1				•
Marphine For Conversion	-				1			i	I
CPS AOA to 14HM	1	197		150		1,179	999		341
Oxymerphone For Conservion					i			1	1
(Commercial)					L			l .	
14394 to CCM24	, , ,	263	95%	224		789	671	,	
COM to COM Dry	3 -	224	999	221	(2)	671	663	<u> </u>	
		v	elidar — P.	aquirement					
Oftener been Fat Sale (Validation - filing Impact)									
14 <b>10</b> 4 to COM	0	132	i Ey.	116		•			1
COM to OMFI Dry	0	·  14	74%	15	(21)	ľ	•		
OMH Dry to OMULFinished API	0	85	5497	83	(2)	•	•		
	Overpall ?	Totala						•	1 7

2014 Opperargitume for Contraction Foretass						
Continuer DZAN happan bags						
(b)(4);(b)(7)(E)		1,857	1,584			

013 Morphise for Conversion Calculations	Distriction.	
2014 Ending Investory	2,833	
Non pakable material	0	) .
2014 Available End. Inc.	2,833	
2015 APJ Quela	36,150	·
2015 Durpositions:		(b)(4)
Consumer to Code inc	15,516	Customer has not sold (10)(17) tuck grade will be ordered for 2015.
Converted to 14 - M	6,855	Requesting marphine or conversion whitein the new prode be requested
Processing Losses	<del>-</del> -	
2015 Ending leventury	6,712	
Converted to % Yearstad	34.8%	,
<del></del>	ka ben	1
Est. Dispositions	34,319	1
Est. Dispositions	22,372	

Description	Number of Batches	Baich Inper, KgB	Process Vicid	Baich sulpus, KgB	Lou by step, KgB		Total Output, KgB	Total Lara KgB	egrae, kgg an AMA ter Conscrine
Morphine For Cunversion	<del> </del>	├─				<del>  -</del>		<del></del>	_
CPS AOA to 14HM	27.57	297	18%	261		8,200	7,216		4,855
Osymorphone For Convention		ļ	]	,	ļ		J		
TANM to COM	26 57	263	R847	231		6,989	6,150		
COM to COM Pry	26.57	231	99%	729	(2)	6,150	6.089	(61)	
Validation Requirements									
Ovymerphone For Sale	1	L	_	L		Į		L	l
14)-fiv( to COM	1	132	68%	116		526	463		·
COM to OMH Day	1	116	74%	\$5	(31)	463	341	(122)	
OMH Dry to OMH Familied APL	4	8.5	98%	83	(1)	341	334	0	
Overall Totals							$\overline{}$	(129)	_

2015 Oxymerpher	ne for Conversion Forecast
Customer	DEAD RepublikgB
(b)(4);(b)(7)(E)	6,000 ( 5,170

b)(4)

2/30/2014

Basic Class: Total PO Regu

1,130,005,000

543,450 000

465,000.000



FDA Est: IMS Est:

								Share of 2015				2014 Projected		Cels Using CFR 50%	
	Соправу	DEA Num	2015 Requested MQ 20	014 Revised MQ 20	13 Sales	2013 DEA MQ Sales	% of 2013 Sales	Total PQ	2013 Inventory	2014 Projected Exports	2014 Projected Sales	inventory	Ad) Avail Calc	lavegi	MO
(b)(4);(b)(			53,450,000	35,000.003 21	1,0\$4,000	386,654,000	0.054	61,530,788	14,352,000	2.000	38,000,000	19,000.000	37,014,000	74,311.485	37,014.000
(0)(4),(0)(	(1)(L)		450,000,000	430,000,000 565	5,600.D30	386,654,000	0.946	1,068,474.212	173,187,000	0.000	440,000.000	203,914.000	452,390.250	1.279,905.765	450,000,000
			40,000.000	0.000	8.000	386,654,000	0 000	0.000	0,000	0.000	40,000 000	9.000	. 0,000	40,000.000	40,000.000

527,014.000

2034 Final Initial APQ: 500,000,000
2014 Final Revised APQ: 0,000
FDA Eat; (2014 Initial APQ \* 1 + FDA Eat): 500,000,000
IMS Est; (2014 Initial APQ \* 1 + IMS Est): 500,000,000

2015 Proposed Initial APQ: 550,000.000

APQ sufficient, no adjustment required

MO Totals:

Basic Class: 9330-0 Total PQ Requested: 2015 Initial APQ Worksheets

FDA Est: IMS Fat: .07 (avg naloxone + natirexone data)

.048 (nalexene dala)

							Stare of 2015				2014 Projected		Calc Using CFR 50%	•
	ompany DEA Num	2015 Requested MO	2014 Revised MQ	2013 Sales	2013 DEA NO Sales	% of 2013 Sales		2013 Inventory	2014 Projected Exports	2014 Projected Salos	Investory	Adj Avail Calc	fovent	MQ
(b)(4);(b)(7)(	=)	5.000	5.900	0.000	13,621,761.460	0.000	2.000	0,000	0.000	5.000	0 000	3.750	1.250	5.000
. (2)(.),(2)(.)(.	-,	1,200,000,000	1,100,000,000	639,490.000	13.621,761.460	0.047	152,622,346	3,167,000	0.000	1,200,000.000	0.000	627,375,250	562,610.932	1,200,000,000
		1,131,000,000	1,674,318,000	178,502,000	13,621,761,460	0.013	42.601.751	253,484,000	0.000	1,131,000.000	0.000	1,445,851,500		1,131,000.000
		19,000,000,000	10,732,298,000	10,146,533,000	13,621,781,480	0,745	2,421,597.036	69,242.000	0,000	18,777,778,000	316,179.000	8,101,185,000		13,688,289,923
		6.231.000.000	3,283,650,000	2,585,244,480	13,521,761,480	0,168	612,227,915	151,100,000	350,000.000	3,966,000,000	2,176,000 000	2,578,062.500	2,457,447.394	3,283,650,000
		1,000,000,000		0.000		9,000	0.000	324,264,000	0.000	1,000,000.000	1,400,000,000	702,573.000	215,351.000	702,573,000
		1,000,000.000	430,000.000	0.000	13,621,761,460	0.000	0.000	0 000	0,000	1,403,000.000	21,000,000	322,500,000	1,080,500.000	1,000,000,000

21,003,497,923

2014 Final Initial APQ: 18,200,000,000
2014 Final Revised APQ: 0,000
FDA Est: (2014 Initial APQ \* 1 + FDA Est): 19,464,900,000
WMS Est: (2014 Initial APQ \* 1 + IMS Est): 19,080,880,000

2015 Establish APQ:

MQ Totals:

28,000,000.000

3,251,005.000

29,562,005,000 17,832,771,000

2016 Establish APG with 25% buffer: 35,000,000,000

APQ adjustment made based on increased dispersion of natidruga to fad, state, local law enforcement (same rationals for oxymorphone - for conversion)

ORIPAVINE

0.0 0.0 0.0 1,131,000.0 1,1  90.0 0.0 1,131,000.0 1,1  90.0 0.0 1,131,000.0 1,1  owing Information:    Xmount Goad for this Purpose	-0 5 (E)
Puota Year   201	5 (E)  Queste: 000.0  or Year ced  0 0 31,000 31,000 31,000
Fax. No (b)(6)  Phone No.  Anhydrous Acid, Bass, or Alkshold(not as Balts).  Quotas Previously Issued by DES.  2014 2015 Quota Re  1,674,318.0 0.0 1,131,  BY lat Preceding Year Satimate for Current Year Pequest  84.0 0.0 0.0 0.0  0.0 0.0 0.0  84.0 0.0 0.0 0.0  84.0 0.0 1,131,000.0 1,1  0.0 0.0 0.0 0.0  43.0 0.0 1,131,000.0 1,1  90.0 0.0 1,131,000.0 1,1  90.0 0.0 1,131,000.0 1,1  90.0 0.0 1,131,000.0 1,1  90.0 1,131,000.0 1,1  Powing Information:  Amount Wand for this Purpose 2015 0 116,000	Questec 000.0 or Year 0 0 0 31,000 0 31,000
### Phone No.    Anhydrous Acid, Bass, or Alkaloid(not as Salts).   Quotas Previously Issued by DEA     2014   2015   Quota Re     1,674,318.0   0.0   1,131,     1st Preceding Year   Setimate for Current Year   Request     64.0   0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   0.0     0.0   0.0   1,131,000.0   1,1     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   1,131,000.0   1,2     0.0   0.0   0.0   1,131,000.0   1,2     0.0   0.0   0.0   1,131,000.0   1,2     0.0   0.0   0.0   1,131,000.0   1,2     0.0   0.0   0.0   1,131,000.0   1,2     0.0   0.0   0.0   1,131,000.0   1,2     0.0   0.0   0.0   1,131,000.0   1,2     0.0   0.0   0.0   1,131,000.0   1,2     0.0   0.0   0.0   1,131,000.0   1,2     0.0   0.0   0.0   0.0   1,2     0.0   0.0   0.0   0.0   0.0     0.0   0.0   0.0   0.0   0.0     0.0   0.0   0.0   0.0     0.0   0.0   0.0   0.0     0.0   0.0   0.0   0.0     0.0   0.0   0.0   0.0     0.0   0.0   0.0   0.0     0.0   0.0   0.0   0.0     0.0   0.0   0.0   0.0     0.	000.0 or Year red 0 0 0 0 31,000 31,000 31,000
Anhydrous Acid, Bass, or Alkaloid(not as Balts).  Quotas Previously Issued by DEA  2014  1,674,318.0  0.0  1st Preceding Year  Satisate for Current Year  Fequesi  84.0  0.0  0.0  0.0  0.0  0.0  0.0  0.	000.0 or Year red 0 0 0 0 31,000 31,000 31,000
2014   2015   Quota Re   1,674,318.0   0.0   1,131,	000.0 or Year red 0 0 0 0 31,000 31,000 31,000
Second   S	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0
84.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0	0 0 0 31,000 31,000
0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.0	31,000 31,000 31,000 31,000
84.0 0.0 0.0 0.0 1.131,000.0 1.1 0.0 0.0 0.0 0.0 0.0 0.0 0.0 0.	31,000 31,000 31,000
0.0 0.0 0.0 1,131,000.0 1,1  90.0 0.0 1,131,000.0 1,1  90.0 0.0 1,131,000.0 1,1  owing Information:    Xmount Used for this Purpose 2013 2015 0 116,000	31,000 31,000 31,000
43.0 0.0 1,131.000.0 1,1 90.0 0.0 1,131.000.0 1,1 90.0 0.0 1,131.000.0 1,2  Desired Information:    Amount Used for this Purpose 2013 2015 116,000   1	31,000
90.0 0.0 1,131,000.0 1.1  Dwing Information:  Amount Used for this Purpose  2013 2015  0 116,000	31,000
Neount Used for this Purpose   2015   0   116,000	
Amount Used for this Purpose 2015 0 116,000	Tield
0 116,000	
17,237 166,000	45.00
	45.00
Batches Hatch Purpose Est. Quantity Est. Comple	tion T
anation of Transfer	
Explanation	
of Pkgs Purpose Total	Quanti
	•

Request ID, 119726		OK INDITIONE W	ANUPACTURING QUO	TA .	
				Date Submitted	01-MAY-14
Name of Basic Class or List 1 Chemic ORIPAVINE	al (only	1 per DEA-169)	Schedu	le/List Number	2
Name and Address of Registrant			Drug C		9330-0
(b)(4)			guota		2015
			PEA RO	gistration Number	D)(4);(b)(7)(E)
Contact Person(b)(6)			Fax. N		(b)(6)
Email Address (h)(4)(h)(6)			Phone :	No	. , ,
NOTE: All Quentities are to	be Express	ed in Grans of Anhy	drous Arid, Base, or	Alkeloid (not as Salts	1
wota History		2013	2014	Bly Issued by DEA	Quota Requeste
- -		1,000,000.0	1,100,000.0	0.0	1,200,000.0
roduction Data		2nd Preceding Year	lat Preceding Year	Estimate for	Estimate for Year
Inventory as of Dec 31				Current Year	Requested
a, Bulk Controlled Substance/List 1 Chemic	<u> </u>	3,167.0	0.0	0.0	. 0
b.In-Process Material		0.0	0.0		
c. Contained in PINISHED Dosage Forms		3,167.0	0.0		<u>-</u>
Disposition(Sale)/Utilization					
a,Domestic,	-	648,094.0	0.0	1,200,000.0	1,200,000
b Exports	⊢	640,094.0		1,200,000.0	1,200,000
equisition/Production					
a.Domestic Sources		731,568.0 731,568.0	0.0		1,200,000
				1,200,000.0	1,200,000
f the Purpose is to Manufacture Another Subst		Irmish the Pollowing			
Name of New Substance	Drug	2012	Amount Used for t	2015	• Y101d
	<del></del>	.,			
Product Development Dosage Form Strength	Unit#/	Batch # of Batc	hen Batch Purpos	e Est. Quantity 6	st. Completion Ti
			<u> </u>		
ranefer Registrant			on of Transfer	<u>-</u>	
Tandial Magastrant			OH OT TIERWEEK		
,					
Dato of Destruction	_	Per	lanation		
Date of Destruction		£γ	lanation	·	
Date of Destruction		Exp	planation	·	
Date of Destruction		Exp	planation	<u> </u>	
Dato of Destruction		Exp	planation	·	
Date of Destauction		Esq.	Planation		
	ngth   U			Puxpone	Total Ounnete
	ngth V			Puxpone	Total Quantic
	ngth V			Эихропе	Total Quantic
	ngth V			Purpone	Total Quantit
	ngth V			Эихроле	Total Quantit
	ngth V			Fuxpose	Total Quantic
	ngth V			Puxpone	Total Quantity
ackaging Product Nama Stra		nits/Pkg # of I	Pkgs		Totel Quantit
scheging Product Name Strains	oripavine	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
scheging Product Name Stree smarks ripavine mfg quota is requested to convert rug code the the Intermediate quota is bei	oripavine	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
marks  Tipsvine mfg quota is requested to convert  Tug code the the Intermediate quota is bei	oripavine	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
scheging Product Name Stree smarks ripavine mfg quota is requested to convert rug code the the Intermediate quota is bei	oripavine	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
marks ripavine mfg quata is requested to convert ripa code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
marks ripavine mfg quota is requested to convert rug code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
marks ripavine mfg quata is requested to convert ripa code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
scheging Product Name Stra	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
marks ripavine mfg quata is requested to convert ripa code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
scheging Product Name Stra	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
emarks ripavine mfg quota is requested to convert rug code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
emarks ripavine mfg quota is requested to convert rug code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
emarks ripavine mfg quota is requested to convert rug code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
emarks ripavine mfg quota is requested to convert rug code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
scheging Product Name Stra	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
emarks ripavine mfg quota is requested to convert rug code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific
emarks ripavine mfg quota is requested to convert rug code the the Intermediate quota is bei	oripavine ing request 2014.	mitw/Pkg W of I	rkgs	r (b)(4) As there is	is no specific

APPLICA Request ID. 119506	TION P	OK INDI	VIDUAL MA	NOF ACTUR	LAG QUOT.		bmitted	29	-APR-14
Name of Basic Class or List 1 Chemical	(only	1 per	DEA-189)		Schedule	/7 ( a.b. M	imbe#	1	2
ORIPAVINE Name and Address of Registrant					Drug Coc	le		-	330-0
b)(4)					PRA Regi		n Number	(b)(4);(b	2015 ))(7)(E)
ontact Person(b)(6)					Fax. No			(b)(6)	
mail Address (b)(4);(b)(6)  NOTE: All Quantities are to be	Pyryse	ed to Gr	ame of Bobut	cove Acid.	Phone No	lkalöid(n	ot as Salt	a)	
			13	Quota 201	EB LEBATORE	ly Issued 20	NA KEY		a Requested
ucts History	-		0,000.0		,298.0		, 0	19,	0.000,000
roduction Data		2nd Prec	ding Year	lat Preced	ling Year	Corren			Ace for Year quested
nventory as of Dec 31	,		69,282.0		0.0		316,179.0		316,179
a.Bulk Controlled Substance/List 1 Chemical b.In-Process Material	· · · ·		0.0		0.0		0.0		0
c. Contained in FINISHED Dosage Forms			69.282.0		0.0		316,179.0		316,179
isposition(Sale)/Utilization			0.0		0.0	18	777,778.0	·	18,777,778
a.Domestic	-		0.0		0.0	18	0.0 777,778.0		0
equisition/Production			0.d		0.0	19	000,000.0	o <b>T</b>	19,000,000
a.Domeatic Sources			9.0		0.0		000,000.0		19,000,000
I the Purpose is to Manufacture Another Substant		urnish Cl	e Following						A 192.5.
Name of New Substance	Drug		2012	Amount U	ged for the		2015		* Yield
NYMORPHONE (FOR CONVERSION)	9652-7	A	3,530,345		7,854,778	16,9	, ۱۹,777 ص ۱٫۱۶۲	778	77.00
Hyd no nearphone							Lince	٠,	
Product Development Dasage Form Strength	Units	/Batch	# of Batel	zon Bo	tch Purpose	Est.	Quantity	Est. Co	apletien Ti
				•					
Date of Destruction	_		Exp	lanation		<u> </u>	<del>-</del>		
·									
ackaging Product Name Streng	th	Unica/Pk	# # af 1	kga		Purpose		To	stal Quantit
							٠.	-	
							•		
	-								
Remarks						· · · · · · · · · · · · · · · · · · ·			
						•			

	APPLICA	TION	FOR IN	M LAUGIVIC	ANUFACTUR	ING QUO	ra		
Request ID. 120282							Date Submitted	31-JUL-14	1
Name of Basic Class or List : ORIPAVINE	Chemical	_(on)	y 1 per	DEA-1891		Schedul	e/List Number	2	
Name and Address of Registrar	1t			_		Drug Co		9330-0	_
(b)(4)						Duota Y	ear	2015	٠
						DEA Reg	istration Number	(b)(4);(b)(7)(E)	
Contact Person (b)(6)	-					Zax. No		(b)(6)	
Email Address (h)(4)(h)(6)						Phone N		(3)(3)	
HOTE: All Quantiti	es are to be	Expre	psed in G	rame of Anhy			Alkaloid(not as Salt	, (q.	_
Quota History				2013	201		sly Issued by DEA	Quota Request	ted
			3,12	6,000.0	3,293,	650.0	0.0	6,231,000.0	o
Production Data			and Pre	ceding Year	int Preced	ing Year	Estimate for Current Year	Betimate for Ye Requested	**1
Inventory as of Dec 31									
a.Bulk Controlled Substance/List	t 1 Chemical	١		151,100.0		0.0	2,176,000.		0.000
b.In-Process Material				0.0		0.0	0.		0.0
c. Contained in FINISHED Dosage	Forms			151,100.0		0.0	2,176,000.	2,176,0	00.0
Disposition(Sale)/Otilization				4,676.705		0.0	3,616,000.	3,616,0	00.0
a.Domesticb Exporta				0.075		0.0	350,000.	350,0	
			<u> </u>	4,676,78		0.0	3,966,000.	3,966.0	00.0
Acquisition/Production				2,003,516.0		0.0	5,151,000.	5,151.0	00.0
a.Domestic Sources				2,003,510.0		0.0	5,151,000.		
If the Purpose is to Manufacture And:	her Substanc	e (s) ,	Furnish C	he Following	Informatio	n:			
Name of New Substance		Dru	9		Amount Us		is Purpose	N Yiel	14
HYDROMORPHONE		9150		1,140,220		.2013	2015		
BX() MO( St. Ore		3730	1-0	1,140,220	•	1, 703, 100.	2,00		•
010111011							2,00		
							<i>-</i>		
Product Development Desage Form	Strength	Uni	Le/Batch	# of Bato	hea Bat	ch Pu <del>r</del> pake	Est. Quantity	Est, Completion	Time
-									
Transfer Registrent				Explanati	on of Trens				
Date of Destruction				Rx	planation		·		
								-	
•									
Packaging Product Name	Strengt	<u>ь</u> Г	Unite/Pk	g bot	Pkan		Purpose	Total Quant:	ilv
	1					<u> </u>		Total Games	,
Recarks									
3,616,000 grams for conversion to	hydromorpho	ne.	Loes on n	roduction e	stimated a	£ 1,405.0	00 grams 1,000 or	ams for orinavin	ne -
reference standards/conversion to									
							:		
									-
,						•	•		]
•									Ì
•									
									ļ

	BDDT.TCAT	TON FO	IR TATE	VIDUAL MA	MISYCALIA	ING OUOT	'A		· <del>-</del>
Request ID. 119606	AFFIILAT	-UR FU	'- TADI			5001	Date Submitted	30-	APR-14
Name of Basic Class or List 1	Chemical	(only	1 per	DEA-189)		<del></del>			
ORIPAVINE							e/List Number		2
Namo and Address of Registran	<u> </u>			<del></del>		Drug Co. Quota Y			330-0 2015
(b)(4)						DEA Reg	istration Number		
(h)(e)	1					Fax. No	<u></u>	(b)(6)	
Contact Person (b)(6)  Rmail Address (h)(4):(b)(6)						Phone N	Q	,,,,	
NOTE: All Quantities	s are to be	Expresse	ed in Gr	of Anhyd	irous Acid,	Base, gr	Alkaloid(noc as Salt	•)	
Quota Mistory		-+		13	Quota 201	8 Previous	ly Insued by DEA 2015		Requested
dace proces				0.000	612,5	00.0	0.0	•	0.000,000
Production Data			Ind Prece	ding Year	lor Preced	ling Year	Estimate for Current Year		ate for Year quested
Inventory as of Dec 31						0.0	1,400,000.0		1,400,000.0
a.Bulk Controlled Substance/List	1 Chemical.	├-	·	324,264.0 0.0	_	- <del>0.0</del>	0.0		G. 0
b.In-Process Material				0.0		0.0	0.0		0.0
c. Contained in FINISHED Dosage	FORMS,	···_[_		324,264.0	<del> </del>	0.0	1,400,000.0	<u>'</u>	1,400,000.0
Disposition (Sale) /Utilization				67.0		0.0	1,000,000.0		1,000,000.0
a.Comestic,				0.0		0.0	1,000,000.0		1,000,000.0
		<b></b> -├-		67.0		0.9	1,000,000.0	·	2,000,000,0
Acquisition/Production a.Domestic Sources				327,581.0		0.0	1,000,000.0		1,000,000.0
				327, <u>58</u> 1.0		0.0	1,000,000.0	¥	1,000,000.0
If the Purpose is to Manufacture Anoc	her Substance	els), Fu	rnish th	e Following					
Name of New Substance		Orug				ead for th	1c Purpose 2015		\$ Yiold
Suprenorphine base		0000-0	1	2012	L	2013	500,00		50.00
Buprenorphine HCl		0-000		ė.		ō	500.0		50.00
. •									
Product Development Dosage Form	Strength	Unite/	/Batch	# of Bato	hes Dat	tch Purpose	Kst. Quantity	Est. Co	apletion Time
								<u></u>	<del>.</del>
Trensfer Registrent				Explanat	on of Tran	-for	<del>-</del> •		
Date of Destruction				Ex	planation				
·									
<u> </u>		<del></del>		<del></del>		_		1 =-	es) Constalant
Packaging Product Fame	Strangt	<b>t</b>	Unita/Pka	1 1 01	Fèga		Purposo	10	tal Quantity
,									
}									
							•		
			_						
Remarks Hultistep conversion of intermedia		4 /	- 000	animat ava	wasse -	uara ro B	unrenorphine base a	nd Aunz	enorphine
Multistep conversion of intermedia MC1 against manufacturing quota.	te purchase	a from	a CMO a	gainse prod	drement q	udca co B	obteworbuing page p	ma bopt	
Met against mandracturing quote.									
<b>{</b>									
1									

		FOR INDIVIDUAL M	ANOPACIO		Date Submitted	27-MAR-14
lame of Basic Class or List 1 Cher	mical (only	/ 1 per DEA-189)		Sahadul a	/List Number	2
RIPAVINE Ame and Address of Registrant				Drug Cod		9330-0
o)(4)				luota Ye	ar	2015
				BA Regi	stration Number	(b)(4);(b)(7)(E)
ontact Person(b)(6)				Fax. No		(b)(6)
mail Address (h)(4) (h)(6)  NOTE: All Quantities are	to he Trous	und in Grams of Anh	MINUS ACID	<u> Phone No</u> . Boss. Or A	lkoloidinot as Sulte	),
			Quat	as Previous	ly Issued by DEA 2015	Quota Requeste
uota History		0.0	<u> </u>	000.0	0.0	1,000,000.0
reduction Data	-	2nd Proceding Year		ding Year	Estimata for	Entimate for Year
					Curtent Year	Requested
nventory as of Dec 31	}	0.1	<del>a</del>	0.0	23,000.0	23,000
a.Bulk Controlled Substance/List 1 Ch b.In-Frocess Material		0.		0.0	0.0	·
c. Contained in FINISHED Dosage Forms		0.0	<del>•</del>	0.0	0.0 23,000.0	23,000
Isposition(Sale)/Utilization						1,403,000
a.Domestic		0.	· · · · · · · · · · · · · · · · · · ·	0.0	1,403.000.0	1,403,000
b Exports	·····	0.		0.0	1,403,000.0	1,403,000
equisition/Production			a	0.0	1,000,000.0	1,000,000
a.Domestic Sources	, <u>}</u>			0.0	1,000,000.0	1,000,000
the Purpose is to Manufacture Another S	what appeaded		<u> </u>			
the Purpose is to Manufacture Another St	Drug			Oned for thi		\ Yield
NAME OF NAME STREET		2012		2013	2015	
Product Development Dosage Form Stren	gth Vait	Batch W of Bat	chee 3:	tch Purpose	Est. Cuantity	Bet. Completion T
· · · · · · · · · · · · · · · · · · ·		•	ρ			
			,20			
ransfer Registrant		Explana	ion of Tra	nefor		
				2	•	
·						
Date of Destruction		<u></u>	planation		<del>-</del> -	
					•	
ackacing Product Name	Strength	Units/Pkg   W of	Pkga	<del></del> -	Purpose	Total Quanti
ackaging Product Name	Strength	Unite/Pkg # of	Pkga		Purpose	Total Quanti(
ackaging Product Name	Strength	Unite/Pkg # of	Pkga	<del></del>	Purpose	Total Quanti
ackaging Product Name	Strength	Unita/Pkg # of	Pkga	<del></del>	Purpose	Total Quanti
ackaging Product Name	Strength	Unita/Pkg # of	Pkgs	<del></del>	Purpose	Total Quanti
ackaging Product Name	Strength	Unite/Pkg # of	Pkgs	<del></del>	Purpose	Total Quanti
ackaging Product Name	Strength	Unita/Pkg # of	Pkgs		Purpose	Total Quanti
smarku	-			in Oxymorp		Total Quanti
smarku	-			in Oxymorp		Total Quanti
emarks  O).000g is planned for use in Hydromor	-			in Oxymorp		Total Quanti
emarks  O).000g is planned for use in Hydromor	-			in Cxymorp		Total Quanti
smarks	-			in Oxymorp		Total Quanti
nmarks  O).000g is planned for use in Hydromor	-			in Oxymorp		Total Quanti
nmarks 0).000g is planned for use in Hydromor	-			in Cxymorp		Total Quanti
nmarks 0).000g is planned for use in Hydromor	-			in Cxymorp		Total Quanti
nmarks  O).000g is planned for use in Hydromor	-			in Oxymorp		Total Quanti
nmarks  O).000g is planned for use in Hydromor	-			in Oxymorp		Total Quanti
emarks 0).000g is planned for use in Hydromor	-			in Cxymorp		Total Quanti
emarks 0).000g is planned for use in Hydromor	-			in Cxymorp		Total Quanti
emarku  O).000g is planned for use in Hydromor	-			in Cxymorp		Total Quanti
emarks  O).000g is planned for use in Hydromor	-			in Cxymorp		Total Quanti
nmarks  O).000g is planned for use in Hydromor	-			in Cxymorp		Total Quanti

Basic Class: Total PQ Requ

5.000

2015 Initial APQ We

FDA Est:

3,900,005.000

DEA Num 2015 Requested MQ 2014 Revised MQ 2013 Sales 2013 DEA MQ Sales % of 2011 Sales Share of 2015 Total PQ 2013 Inventory 2014 Projected Exports 2014 Projected Sales Acj Avail Calc Calc Using CFR 50% Invent (b)(4);(b)(7)(E) 5.000 0.000 0.000 5,624,322,000 0.000 0.000 0.000 0.000 4 000 0.000 4.000 5 000 3,000,000,000 6,157,639.000 5,624,322.000 5,624,322.000 1.000 5.000 972,879,000 0.000 2,807,018.000 5,347,888.500 -2,784,084.000 3,000,000.000

MQ Totals: 3,000,005.000 6,157,639.000

2014 Final Initial APQ: 7,400,000,000 2014 Final Rayland APQ: 0,000

FDA Ext: (2014 Initial APQ \* 1 + FDA Ext): 7,400,000.000 IMS Cat: (2014 Initial APQ \* 1 + (MS Ext): 7,400,000.000

APQ sufficient, no adjustment required

OXYCODONE (FOR CONVERSION)

2015 Initial APQ Worksheets

Basic Class: 9662-7
Total PO Requested:

6,226,005.000

FDA Est: 1M9 Est: .07 (avg caloxone + narrexone data) .048 (natoxone data)

								Share of 2015				2014 Projected		Cale Using CFR	
. C	ompany DEA	Num ZD	15 Requested MQ 2	014 Revised NO	2013 Sales	2013 DEA MQ Sale4	% of 2013 Sales	Total PQ	2013 inventory	2014 Projected Exports	2014 Projected Sales	Inventory	Adj Avali Cate	50% invent	MQ
(b)(4);(b)(7)(E	:)		5.000	0.000	0.000	7,793,788,000	0.000	0,000	0.000	0.000	4,000	1,000	0.000	4 000	5.000
(5)(1),(5)(1)(2	-/		16,900,000,000	11,300,000,000	6,300,568,000	7,793,766,000	0,608	5,033,159,477	1,579,762,000	0.000	15,632,103,000	1,737,633.000	9,659,821.500	15,038,790,347	13,068,790,347
			1,000,000	0.000	0.000	7,793,766,000	0,000	0.000	0.000	0.000	1,000.000	0.000	0 000	1,000,000	1,000,000
			6,151,000.000	2,751,000.000	1,493,218,000	7,793,766,000	0.192	1,192,845,523	269,660,000	0,000	5,130,000.000	1,663,000.000	2,265,610,000	4,288,126.903	4,288,126,903

MQ Totals: 23.052,005,000 14.051,000,000 17.357,922,250

2014 Final Initial APQ: 20,000,000 000 2014 Final Revised APQ: 0,000 FDA Est; (2014 Brittal APQ \* 1 • M45 Est): 20,390,000,000 IMS Est; (2014 Initial APQ \* 1 • M45 Est): 20,968,000 000

2015 Establish APQ:

23,200,000.000

w/ 25% buffer; 29,000,000.000

APQ adjustment made based on increased disposition of natidrugs to fed, state, local law enforcement (same rationals for origavine)

APPLIC	CATION	POR INDIVIDUA	J, MA	NUFACTU	TRING QUOT	ľA .	
Request ID. 119507	,					Date Submitted	29-APR-14
Name of Basic Class or List 1 Chemics	l (only	v 1 per DEA-1	89)				
OXYMORPHONE (FOR CONVERSION)						e/List Number	9652-A
Name and Address of Registrant (b)(4)					Drug Co Quota Y		2015
(~,·,·					PEA Reg	istration Number	
(1)(4)(1)(0)							(h)(6)
Contact Ferson(b)(4):(b)(6) Email Address (b)(4):(b)(6)					Phone N		(b)(6)
MOTE: All Quantities are to	ba Expres	sed in Grame of	Anhyd	rove Act	d, Bass, or	Alkaloid(not se Salta	e)
		2013		000	tas Previcus 014	aly Isauad by DEA 2015	Quota Requested
Quota Ristory	ŀ	9,400,000.0	,		0.000.0	0.0	16,900,000.0
Production Data		2nd Preceding Ye		lat Prec	eding Year	Estimate for	Retimate for Year
						Current Year	Requested
Inventory as of Dec 31	· · · · · · · · · · · · · · · · · · ·	1.579,7	62.0		0.0	737,633.0	737,633.0
a.Bulk Controlled Substance/List 1 Chemic b.In-Process Material			0.0		0.0	1,000,000.0	
c. Contained in FINISHED Dosage Forms		1,579,7	0.0	_	0.0	1,737,633.0	
Disposition(Sale)/Utilization			92.4		0.9		
a.Domestic	[		0.0		<u></u>	16,832,103.0	
b Exports			0.0		0.0	16,832,103.0	
Acquisition/Production	——∤	·· <del>·····</del>	<u> </u>		, v, v	10/832/103.0	
a,Domestic Sources	[		0.0		0,0	16,900,000.0	
	-		0.4		0.0	16,900,000.0	16,900,000,0
If the Purpose is to Manufacture Another Subet	ance (e)	Furnish the Foll	cwing				
Name of New Substance	Drug	2012		Amount	Used for th	ie Purposa 2015	* ¥ield
NOROXYMORPHONE (FOR SALE)	9668-		<u> </u>	!	2913	6,707	
NOROXYMORPHONE (FOR CONVERSION)	9668		952		4,333,93		
Product Development Dosage Form Strength	Frate	a/Batch   # of	Batci	hed B	atch Furpose	e Pat Ouantity	Est. Completion Time
1100hCf hangrahmenr namada 101m annaman		*					•
				on of Tra	200		<del></del>
Transfer Registrant				07 05 125			<del></del>
•							
	•						
			T	lamation		···	<del>_</del>
Date of Destruction			LES	IBMAC100	<del>_</del>		
-							
•							
Deskrains Burdhat Mana		Units/Pkg	V of i	ekan		Purpose	Total Quantity
Packaging Product Name Stre	ngen	CHILDIPAG		Aga			
•		•					
<u> </u>							
Remarks							-
•							
1							

3007741	TYCH	FOR INDIV	TOTAL P	NITE & CTTT	ימוות מווים	ra	
	F.TON	EON INUIA	TOWN WA	MOFRCIUN	200		20.200.14
Request ID. 119508						Date Submitted	29-APR-14
Name of Basic Class or List 1 Chemical	(onl	v 1 mer D	KA-189]		0-2-3-3	-/r/a+ V	0
NOROXYMORPHONE (FOR CONVERSION)						e/List_Number	9668-A
Name and Address of Registrant		_			Drug Co		2015
(b)(4)					Quota Y	istration Number	
					Pan Reg	TOTTECTOR WORDER	(D)(+),(D)(1)(L)
Contact Person(b)(4)					Fax. No		(b)(6)
<b>Exall Address</b> (b)(4):(b)(6)					Phone N	·	. , ,
NOTE: All Quencities are to be	Pryre	seed in Gran	e of Ambre	rous Acid,	BAUG, OF	Alkaloid(not as Salte	J
				Quoc	a <u>e Previou</u>	aly Issued by DEA	Quota Requested
Quota History	ļ	201		20:		2015	
		5,371,			,557.0	0.0	10,600,000.0
Production Date	- 1	2nd Preced	ted Asar	lat Prece	ding Year	Estimate for Current Year	Equipate for Year Requested
						Current tear	Reducated
Inventory as of Dec 31			745.529.0		0.0	1,230,032.0	1,230,032.0
a.Bulk Controlled Substance/List 1 Chemical			310,505.0		0.0	1,314,035.0	1,314,035.0
b.In-Process Material			0.0		0.0	0,0	
c. Contained in FINISHED Dosage Forms	···· [	1,0	064,034.0		0.0	2,544,067.0	2.544.067.0
Disposition (Sale) /Utilization			0.d		0.d	8,170,000.0	B,170,000.0
a.Domestic.,	-		0.0		0.0	0.0	
b Exports,	-		0.0		0.0	8,170,000.0	
<u> </u>		-	0. <b>q</b>			0,210,000,0	5/2/0/004/0
Acquisition/Production	1		0.0		0.0	10,600,000.0	10,600,000.0
a.Domestic Sources	1		0.0		0.0		
If the Purpose is to Manufacture Another Substanc			Fallawing				
Name of New Substance	Drug	J	2017	Amount C	ned for the	ii Purpose 2015	\$ Yield
AND MADE AND ADDRESS AND ADDRE		<u> </u>	2012		. 2013	575,90	<del></del>
MALBUPHINE (EXCEPTED) NALTREXONE (EXCEPTED)	0000		0		0	575.30 6,887.3	
NALOXONE (EXCEPTED)	0000		Ö		٥	706,73	
PALOACAE (BACEPIED)	0000		•		-		<b>-</b>
<u> </u>						_8, \_	70 kg
Product Development Dosage Form Strength	Unit	te/Batch	9 of Bate	haa Ba	tch Purpos	e Est. Quantity	Est. Completion Time
							<u> </u>
Transfor Registrant			Explanati	on of Tran	gler		
Date of Descriction			Pr.	lenstion	-		
Date of peneroccion ;				20405104	<del>-</del> :		
Packaging Product Name Strang	¢b Ţ	Units/Pkg	f of	Pkgs		Putposo	Total Quantity
<del></del>			<del>'</del>		_		
, ·							
•							
					2		
Remarks					<del></del>		<del></del>
Aemor Ku						<del></del>	
		٠					

	APPLICATION	YOR INDIVIDUAL !	ANUFACTURING QU	OTA .	
Request ID. 119509	_	•		Date Submitted	29-APR-14
Name of Basic Class or List 1	Chemical (on)	v 1 per DRA-189)			
NOROXYMORPHONE (FOR SALE)			Schody Drug (	le/List Number	9668-B
Name and Address of Registrant (b)(4)			Quota		2015
(0)(4)			DEA Re	gistration Number	
				'-	(b)(6)
Contact Person (h)(6) Email Address (h)(4):(h)(6)			Fax. 1		(b)(6)
NOTE: All Quentities	are to be Expre	seed in Grams of Anh	ydrous Acid, Basn, o	z Alkaloid(not as Salt	a)
Quota History		2013	Ouotas Previo	usly Issued by DEA	Quota Requested
Grora gracos		2,618.0	2,364.0	0.0	3.000.0
Production Data		2nd Preceding Year	1st Preceding Year	Estimate for	Estimate for Year
			<u> </u>	Current Year	Requested
Inventory as of Dec 31		403.	0 0.	d 378.0	378.0
a.Bulk Controlled Substance/List b.In-Process Material		<u>0.</u>	<del></del>	0.0	d.
c. Contained in FINISHED Dosage F		0.			
		403_	<u>al</u> 0.	0 _ 37.6.0	1
Disposition(Sale)/Utilization a.Domestic		3.			
b Exports		1.	- <del> </del>		
<u> </u>		4.	αο.	oj 3,620.0	3,020.
Acquisition/Production a.Domestic Sources		10.			
G.Domesele Doutees,,		10.	o <u>o</u> .	3,000.0	3.000.
If the Purpose is to Manufacture Anothe	er Substance(s),	Furnish the Followin	g Information;		-
Name of New Substance	Dru	g	Amount Used for	this Pursose	# Yield
		2012	2013	2015	
Product Development Dosage Form S	trength Uni	ts/Betch   4 of Bet	chee Batch Purpo	see Est. Quantity	Set. Completion Time
Transfor Registrent		2007-1-1-1	tion of Transfer		
Date of Destruction		я	wplanation .		
		#24 2 2 5 b = 1	Pkgs	Purpose	Total Questity
Fackaging Product Name	Strongth	Units/Pkg # of		terkan	Total Authorey
Kemarks	<del> </del>				
					,
	•				•

Request ID. 119780		FOR INDIVIDUAL M				
					Date Submitted	02-MAY-14
Name of Basic Class or List 1 Cb	emical (onl	v 1 per DRA-1891	_			
XYMORPHONE (FOR CONVERSION)		3_*. =V=,=====		chedul	e/List Number	0
lame and Address of Registrant				rug Co		9652-A
b)(4)	•	<del></del>		Quota Y	ear	2015
-N-7			Ī	EA Reg	istration Number	(b)(4);(b)(7)(E)
			L		<u> </u>	
ontact Ferson (b)(6)				ax. No		(b)(6)
mail Address (b)(A):(b)(6)				hone N		
NOTE: All Quantities a	re to be Expre	seed in Grams of Anhy	<u>droue Aoid, E</u>	ANG, OF	Alkaloid(not as Salt	<u> </u>
		2013	Quocas 2014	Previau	aly Insued by CEA 2015	Quota Requests
woth Mistory			0.0		0.0	1,000,0
		0.0			Estimate for	Estimate for Year
roduction Data	1	2nd Preceding Year	lst Precedis	ig rear	Current Year	Requested
			L			
nventory as of Dec 31	en 1	0.0		0.0	0.0	
a.Bulk Controlled Substance/List 1		0.0		0.0	0.0	
b.In-Process Material		0.0		0.0		
c. Contained in FINISHED Dosage For	ths	0.0		0.0	0.0	1
isposition(Sale)/Utilization			<u> </u>	0.0	1,600,0	1,000
a.Domestic	, . ,	0.0	<del></del>	0.0	1,000,0	1,000
b Exports		0.0		0.0	1,000.0	
				<b>0. q</b>	1,000.0	1,000
equisition/Production		0.0	_	0. d	1,000.0	1,000
a,Domestic Sources		0.0		0.0	1,000.0	
the Purpose is to Manufacture Amother	Substance(s).	Furnish the Pollowing				
Name of New Substance	Drug		Amount Coo		is Furpose	* Yield
		2012		2013	2015	
	ength Cai	ts/Batch   f of Batc	Nan I Bata	h Purpos	Bet. Quantity	Est. Completion Ti
Product Development Dosage Form Str	ength Val	CB/Baten T Or Bate		u 101pcu	2501 (24411)	
ransfer Regiotrant		Explanat	ion of Transf	or		
Date of Destruction		EJ EJ	planation		·	
Date of Destruction		E)	planation		·	
Date of Destruction		23	pianation		·	
Date of Destruction		E3	planation			
Date of Destruction		<u> </u>	planation			
Date of Destruction		Ε.	pianation			
Date of Destruction		E	planation			
	Strength	Units/Fkg # of			Purpose	Total Quant2
	Strength				Purpose	Total Quanti
	Strength				Purpose	Total Quanti
	Strength				Purpose	Total Quanti
	Strength				Purpose	Total Quanti:
	Strength				Purpose	Total Quanti
	Strength				Purpose	Total Quanti
ackaging Product Name	Streagth				Purpose	Total Quanti
ickaging Product Name					Purpose	Total Quanti
ackaging Product Name					Purpose	Total Quantit
ackaging Product Name					Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name					Purpose	Total Quanti
ickaging Product Name			Pkgs		2urpose	Total Quantit
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quantit
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quanti:
ackaging Product Name			Pkgs		Purpose	Total Quantit
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quanti
ackaging Product Name			Pkgs		Purpose	Total Quanti:
ackaging Product Name			Pkgs		Purpose	Total Quanti
Packaging Product Name  Remarks  O support reference standards busine			Pkgs		Purpose	Total Quanti

APPLICATION	N FOR INDIVIDUAL	ANUPACTURING QUO	<del></del>	
Request ID. 120272	7 100		Date Submitted	31-JUL-14
Name of Basic Class or List 1 Chemical (or OXYMORPHONE (FOR CONVERSION)	ITA T DOL DRY-1831	Schedu	le/List Number	0
Name and Address of Registrant		Drug C	ode	9652-A
(b)(4)		luota	Year	2015
		DEA Re	gistration Number	(D)(4);(D)(7)(E)
Contact Person (b)(6)	1	Fex. N		(b)(6)
Mms(1 Address (b)(4):/b)(6)		Phone	No	
NOTE; All Quentities are to be Exp	resent in Grame of Anh	Ougtag Braylo	Alkeloid(not as Salt	<u></u>
Quota History	2013	2014	2015	Quote Requested
•	3,030,649.0	2,751,000,0	0.0	5,151,000.0
Production Data	2nd Preceding Year	lot Preceding Year	Estimate for Current Year	Earimate for Year Requested
		<u> </u>	Current sear	кефиясно
<pre>inventory as of Dec 31     a.Bulk Controlled Substance/List 1 Chemical</pre>	269, <u>68</u> 0.		<del></del>	
b.In-Process Material,	0.			
c. Contained in FINISHED Dosage Forms			+- <del></del>	
Disposition(Sale)/Utilization		0.0	5,130,000.	5,130,000.0
a.Domestic.,	1,416,201.			· · · · · · · · · · · · · · · · · · ·
b Exports	1,493,218.	<del> </del>		5,130,000.0
Acquisition/Production			E 151 ACC	6,151,000.
a.Domestic Sources	1,317,098. 1,317,098.			
If the Purpose is to Manufacture Another Substance(s)		g Information: Amount Used for t	his Durage	Yteld
Name of New Substance D:	2012	Amount Used for t	2015	
				_
				•
Froduct Development Desage Form Strongth Us	mits/Estch   # of Bat	ches   Batch Purpo	ed . Ret . Quantity	Bet. Completion Tim
Storides Pareidbings possible total perovides or				
		, -		
Transfer Registrant	Explana	ion of Transfer		
				-
-				
Date of Destruction		xplemetion		
	•			
•				
Packaging Product Name Strangth	Units/Pkg # of	Pkga	Purpose	Total Quantity
	<del></del>			
•				
				•
			•	
Remarks	<del></del> -			
Production loss estimated at 31,000 grams 1,000	grams to support re.	ference standard bu	siness Replaces app	ication reference
119708				
•				
			-	
,				
1				



2014 Quata	1014 Grant	Additional 2014 Great	Delta
PSC-AGA	3.732	6,900	1,668
Morphine for Conversion	T0,431	[4,50]	4,070
Osymorphone Conversion Commercial	2,60\$	2,980	-52R
Окупратурняе Сопустия: Development		671	671

	Tollial.	Additional
	1914	TO CL
2014 COMM Issuring Calculations	Grapi	Genat
2013 Ending Investory	272	172
Non releable material		,
2013 Available End. Inv.	169	269
20) ( AP) Quata	2,608	2,(30)
2014 Development Quara (nor		
included in investory)		671
Z014 Daspositsona:		
54,49	1,588	1,588
Processing Losses	(11)	(10)
Non-saleable (Sent rad to Rev Dist)	(77)	מיז
2014 Ending basening	1,175	674
Converted to % Venrend	79.5%	44.9%

· <del>-</del>	kgs, bant
2013 Dispositiona	1,496
2014 Eat. Dispositions	1,588
Average	(,50)
10 % herce ory Allemanus	751

	ACTUAL YEAR TO DATE				QUOTA		WI	TH INCREA	SE_	
	CPS-AOA	Proces		Net output	CPS-AUA		Per support	Date of the		Pet surper
Description	ingree _	YEM	MWC	of step	Lagrad	MWC	of step	Step	MWC	of play
CO'S AUX to Chule Oxymorphone for										1 :
Convestion	D	67.4%	1.0133	0	3,708	10133	2,601	11-47	_1.0133	_05265

	ACT	ACTUAL YEAR TO DATE (JUNE 14, 2014)			QUOTA			WITH INCREASE			
<del></del>	Input to	Protein		N-1	LOII by	In pad to				Overput of	Loss by
_ Cescs ipcom	Step	Yield	MWC	of skep	#tp	Sterp	Step	Lost by step	Step	_50-7	Her
Oyegaephase For Carrensies											
COM to COMM	n	97.5%	1.0000	0	_ n	2 (43)	2,594	(I)te	5351	19751	_,_
Tetal						$\perp$		(kJ)			1
	1								_		

	اعتالها	Addition
2014 CPS-Origonian Investory	3014	2014
Calculations	Crew	Crent
2013 Ending Institutes	758	738
Non micable material	] e	0
1013 Available End. lor.	758	758
2010 AFT Quels	5,232	6,900_
2014 Despositions:		1
Morphine for Conversion	<u> </u>	1,190
Onymorphone for Convertion	1,021	7031
Ocumorphone for Sale	. 1,473	1,473
2014 Ending Inventory	1,4%_	1,273
Converted to 24 Yearend	33%	U%

	kgs, base
2013 Dispenitions	3,464
2014 Est. Dispositions	5,683
Америре	4,574
10% Leventery Allemance	1,372

hall G. a.		Áug-15	Deite
2015 Quide	Apr-15		
PSC-AOA	5,139	12,900	7,761
Morphine for Conversion	22,000	26,350	4750
Окуппограцияе Совьетніков	450	6,150	3,700
Organorstone Conversion	Г -		
Development		9_	٥

2015 COMd [Amplery Calculations				
2014 Easing Inventory	674			
New salestile reprepat	٥			
20) a Annilably End. inv.	674			
2015 APL Quota	6,130			
2015 Dispensions				
Selics	3,010			
Processing Larses	(9)			
Validation Inventory	0			
2015 Ending Learning	1,663			
Conversed to % Yearship	19.5%			

i i	Lign, Name
2014 Est. Dispositions	1,388
2015 East Dispositions	5,130
Average	3,359
10% Inventory Allawares	9,629

	2015 Queta Cuic					
	CAS-YOY	Pressure		Net mapped		
Description	Input	YEM	MWC	and sheep		
CPS-AUA to Crude Oxymorphose for						
Conversion	8,745	69 4%	1.0133	6,150		

	1	20  5 Queta Calc					
Description	Input to Sup	Year	MWC	Nel malpad afatep	Low by Hep		
Daymorphore For Consenses							
COM to COM6	6,130	99.5%	Lucas	6,819	(34)		
Total	<b>↓</b>	<u> </u>	<u> </u>	<b>└</b>	(JI)		
<b>1</b>				1			

		1
2015 CFS-Oripavine Inventory C	a ke lether	] .
2014 Ending Inventory	1,975	<b>1</b> '
Non salcable material	1_0	1
1914 AvaBable Fad. Inv.	1,973	1
2015 APT Quesa 2015 Origoniosas	12,960	
Morphise for Conversion		Customer has not told $(D)(4)$ which goeds will be ordered for 2015.
Oxymorphose (at Conversion	1,715	Street more CPS is required for old process, using their or bear for 2015.
Osymorphone for Sale	3,106	
2015 Ending Investory	1,013	1

	ligs, base
2014 En. Dimonitions	3,687
2015 Eat. Depositions	11,851
Average	8,767
14 % Investory Allemance	064,5

b)(4) Confidentia



2014 Marphios for Conversion Investory Calculations	2:14 Gran	1014 Crain
2013 Finding Inventory	2,454	2,454
Non autouble mutaria)	,	1
2013 Assitable End. Inc.	1,451	2,451
2014 API Queta	10,431	14,501
2014 Dispositions		
Converted to Coderge	_13,120	13,120
Conversed to 1440M	+99	999
Preorestra Lement		
2014 Ending Investory	+1,237	t'irr)
Conterted to % Ventered	411.1%	25.8%

	Light Enter
2013 Dispetitions	7,872
2014 Est. Dirpos tions	14,339
Average	10,795
34% Immiery Allometer	5,494

	Namber of		Разми	Batch seaped,	Lone by	Total Imped,	Tarist Output,	Total Lass	erget, kgB erght, kgB
Dest High less	Batcher	KgB	Yarid		step Kell	Keb	KeB	_K <sub>Z</sub> B	Centrales
		<u>_</u>	Maritim R	a gaire ment	• •				
Morphine For Compension									
CPS AOA to 14HM	1 4	197	24%	150		1,190	299		349
Ocymorphone For Conversion (Commercial)			[ i	$\Gamma_{-}$				J	
IAHM to COMA	1	263	15%	134		789	671	_	
ODM to COM Dry	3	224	999	. 121	. (2)	671	8	(2)	
			<u> مياسكالد</u>	agui remani	,				
Osymurphum For Sele (Validation - filing impact)						Γ			
MHM to COM	٥	131	88%	116		*			
COM to CMH Div		116	74%	83	700	-		·	
ONCI DIT TO ONCI F Incident API	0	1,5	75%	6)	(2)			-	l .
	Overall	Totalo							

2014 Oxymorphope for Conversion Forcesal						
Cinteret	DEAd	kerubi	NgB_			
(b)(4);(b)(7)(E)		1.657	1,548			

Colesiations		(b)(4)
2014 Ending Insentag	1,811	(5)(4)
Mon sales He resterned	- 0	]
2014 Available Fad, Inv.	1,533	]
2015 API Quas	25,250	<u> </u>
2015 Dispositums,		·
Conversed to Codeine	11,316	Christment has not told which great will be ordered for 2015.
Converted to 14-10M	6,835	Requesting morphine for conversion should the new grade by requested
Propertional Locales	<del></del>	
2015 Eading Inventory	6,712	]
Competited to % Vennetch	10.5%	]
		_ <b>_</b>
	Hagen, better	<u>-                                    </u>
014 Est. Digrositions	_[4,]19	J
005 Est. Dispositions	22,172	]
Lyenze	18,241	٦
30% Inventory Allewance	9,121	

Description	Namber of Balcher	Boich lagut, KgB	Pracess Yield	Batch surput, KgB	Lats by they, KgB		Total Outgot KgB	Total Las KgB	FeFat entput, kgB as AMA Ser Conversion
Marphine For Conversion	<del>  -</del>	_	<del>                                     </del>				_	-	
CTS ADA to 14104	27.51	197	86%	262		2	7,216		6,655
Ozvymeplana Far Canversion	l .		,			ļ	1 .	<u> </u>	l
MHM to COM	26 51	263	88%	211		6,949	6,150		
COM IF COM DIV	26 57	231	99%	219	(2)	6,150	6,089	(62)	1
Validation Regulerzon to			=				$\vdash$		
Occumentance For Sale				l .		l			
14I DA I o COM	1 4	172	88%	ìlió		526	463	1	
COM to DMH Dry	1	116	74%	13	[PD	463	<u>н</u> Т	(122)	
DMAIDay to QMII Finished API	4	14.5	98%	E3	(1)	341	] 314		
Dykrall Totals	1	${}^{-}$	1		1		1 -	(129)	

2015 Onymosphene for Conversion Forestant						
DEAD	[دموسا	NugB				
	6,000	3,130				
	DEA#	DEAD LEADS	BEAR Kerepi NASO			

(b)(4) Confidentia

7/30/2014



3,614,401,070

7,105,065,000

4,982,035,000

2015 Initial APO Workshi

FDA Est: IMS Est;

. rva .018

2014 Projected Calc Using CFR DEA Num 2016 Requested MQ 2014 Revised MQ 2013 Sales 2013 CEA MQ Sales % of 2013 Sales Share of 2015 Total PQ 2013 Inventory 2014 Projected Exports 2014 Projected Sales Adj Avail Calc 3 50% Invent Company 3.755 5,000 1.000 0.243 5.000 0.900 3 504 592,071 0.000 0.000 0.007 0.000 4.000 5.000 (b)(4);(b)(7)(E) 258.258 206.901 -245.590 60,000 10.000 60,000 4.211 3,604,592.071 0.000 4.222 215.668 0.000 60,000 0.000 166,000,000 25,000,000 125,011.500 46,123,002 166,000.000 143,000,000 6,820,000 3,604,592.071 0.002 6,844,001 23,682,000 186,000.000 471,501,749 617,142,000 623,000,000 295,541,000 817,142,000 611,638 000 413,633,000 3,604,592.071 0.115 414,758,599 211,216,000 0.000 715,000.000 581,319.000 2,857,391,750 1,714,360,691 1,600,000,000 1,442,681.000 1,600,000,000 2,610,558,000 2,602,150,000 3,604,592,071 0.777 2,809,775.353 1,132,591,000 0.000 3.000,000 3,000,000 0.000 25,492,718 16,315.915 0.912 42,044.964 34,990,290 0.000 3,000,000 3,000,000 41,930,860 3,604,592.071 492,703.450 1,163,734.000 387,000.000 1,120,854.750 1,183,734,000 330,495,000 3,684,592,071 0.092 331,394,380 210,739.900 0,000 1,277,000,000 3,501,000.000 275,630,000 379,371,000 172,396,452 379,371,000 816,250,000 1,120,000,000 210,000,000 7,659,000 3,604,592,071 0,002 7,579,570 295,828.000 0.009

3,949,312,000

2014 Final Initial APQ: 6,200,000,000
2014 Final Revised APQ: 0,000
FDA Est; (2014 Initial APQ \* 1 + FDA Est): 6,200,000,000

FDA Est; (2014 Initial APQ \* 1 + IDA Est): 5,200,000.000 IMS Est: (2014 Initial APQ \* 1 + IMS Ext): 5,436,840.000

2015 pd efforts 561,297,000
2014 noviced MQ 4,962,035,000
IM3 est change 183,549,737

est need for APQ 5,712,881.737

APG sufficient, no adjustment required

MQ Totals:

# 2015 Establish Adjusted Aggregate Production Quotas and Annual Assessment of Needs

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to
  establish the production amount of each basic class of Schedule I and II controlled substances
  and for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This
  responsibility has been delegated to the Administrator of the Drug Enforcement
  Administration (DEA), and redelegated to the Deputy Administrator.
- DEA regulations allow the Deputy Administrator to revise the established annual aggregate
  production quota (APQ) and assessment of annual needs (AAN) after review of pertinent
  information provided from various sources including DEA-registered manufacturers and the
  Food and Drug Administration (FDA).
- The attached Federal Register notice, prepared for your signature, reflects the calendar year 2015 established aggregate production quotas (APQ) for schedules I and II controlled substances and assessment of annual needs (AAN) for the list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for which the United States has medical, scientific, industrial, export and reserve stock requirements.
- As stated in the 2013 Federal Register Notices, DEA continues to add an additional 25% to
  the APQ for schedule II substances and those schedule I substances that are used to produce
  drugs that have a medical need (specifically, GHB and tetrahydrocannabinols) to prevent
  potential drug shortage issues.
- Expeditious review and publication of this notice is necessary to ensure an uninterruptable supply of schedule I and II controlled substances as well as list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for the legitimate medical, scientific, industrial, and export requirements of the U.S.
- The following points provide brief explanations of the changes from the proposed revised AAN & APQ values:

# List 1 Chemicals:

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

### Controlled Substances:

- OD is recommending an increase in the APQ for alfentanil. The increase is based on the increased domestic sales and exports.
- OD is recommending an increase in the APQ for cocaine. The increase is based on the increased domestic product which leads to the production of cocaine as a by-product.
- OD is recommending an increase in the APQ for codeine (for sale). The increase is based on the increased domestic sales and exports.

DEA/OD/ODQ 8/12/2014 - Page 1 of 2

- OD is recommending an increase in the APQ for codeine-n-oxide. The increase is based on the increased domestic sales and the need for increased reference standards.
- OD is recommending an increase in the APQ for dihydrocodeine. The increase is based on the increased domestic sales.
- OD is recommending an increase in the APQ for fentanyl. The increase is based on the increased domestic sales and product development efforts.
- OD is recommending an increase in the APQ for hydromorphone. The increase is based on the increased domestic sales and exports.
- OD is recommending an increase in the APQ for levorphanol. The increase is based on the increased domestic sales.
- OD is recommending an increase in the APQ for marihuana. The increase is based on the
  requirements from bulk manufacturers to supply cannabidiol or other marihuana extracts to
  dosage-form manufacturers conducting product development activities with the objective of
  receiving FDA approval of their products.
- OD is recommending an increase in the APQ for oripavine. The increase is based on the
  increased domestic sales and exports of hydromorphone and the non-controlled substances
  naltrexone, naloxone, and nalbuphine which utilize oripavine as the starting material.
- OD is recommending an increase in the APQ for oxymorphone (for conversion). The
  increase is based on the increased domestic sales and exports the non-controlled substances
  naitrexone, naloxone, and nalbuphine which utilize oxymorphone (for conversion) in the
  route of synthesis.

DEA/OD/ODQ

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

Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

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

ACTION: Notice.

SUMMARY: This notice establishes the 2015 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

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

# SUPPLEMENTARY INFORMATION:

# Legal Authority

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA) through 28 CFR 0.100(b). The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

# Background

The 2015 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine,

pseudoephedrine, and phenylpropanolamine to be manufactured in the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes.

On July 2, 2014, a notice titled, "Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Proposed Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015," was published in the Federal Register (79 FR 37772). That notice proposed the 2015 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before August 1, 2014.

# Comments Received

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

Anilino-N-phenethyl-4-piperidine (ANPP), 4-Methyl-N-ethylcathinone (4-MEC), 4-Methyl-α-pyrrolidinopropiophenone (4-MePPP), alpha-Pyrrolidinobutiophenone (α-PBP), alpha-Pyrrolidinopentiophenone (α-PVP), amphetamine (for sale), codeine (for sale), dihydrocodeine, diphenoxylate, fentanyl, hydrocodone (for sale), hydromorphone, levorphanol, marihuana, morphine (for conversion), N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA), N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA), naphthylpyrovalerone (naphyrone), oripavine, oxycodone (for conversion), oxymorphone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-Flouro-PB-22), and Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

# Determination of 2015 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2015 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the consideration of 2014 manufacturing quotas, current 2014 sales and inventories, 2015 export requirements, industrial use, additional applications for quotas, as well as information on research and product development requirements. Based on this information, the DEA has determined that adjustments to the proposed aggregate production quotas and assessment of annual needs for alfentanil, cocaine, codeine-N-oxide, codeine (for sale), dihydrocodeine, fentanyl, hydromorphone, levorphanol, marihuana, oripavine, oxymorphone (for conversion), and ephedrine (for sale) are warranted. This notice reflects those adjustments.

Regarding 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone), 2-(4-Bromo-2,5dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe), 2-(4-Chloro-2,5dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe), 2-(4-Iodo-2,5dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe), 2-(Methylamino)-1phenylpentan-1-one (pentedrone), 3-Fluoro-N-methylcathinone (3-FMC), 4-Fluoro-Nmethylcathinone (4-FMC), 4-Anilino-N-phenethyl-4-piperidine (ANPP), 4-Methyl-Nethylcathinone (4-MEC), 4-Methyl-α-pyrrolidinopropiophenone (4-MePPP), alpha-Pyrrolidinobutiophenone (α-PBP), alpha-Pyrrolidinopentiophenone (α-PVP), amphetamine (for sale), dihydrocodeine, fentanyl, hydromorphone, levorphanol, marihuana, N-(1-Amino-3,3dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA), N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA), naphthylpyrovalerone (naphyrone), oxycodone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-Flouro-PB-22), and Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22), the DEA has determined that the proposed aggregate production quotas are sufficient to provide for the 2015 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This notice finalizes these aggregate production quotas at the same amounts as proposed.

As described in the previously published notice proposing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. See 21 CFR 1303.24. This would be concerning if a natural disaster or other

unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all proposed revised schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting revised established aggregate production quota will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

In accordance with 21 USC 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Deputy Administrator hereby establishes the 2015 aggregate production quotas for the following schedule I and II controlled substances and the 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Established 2015 Quotas (g)
Schedule I	
(1-Pentyl-1 <i>H</i> -indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	. 15
[1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45

1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	15
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (251-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	-30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35

3-Fluoro-N-methylcathinone (3-FMC)	15
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetaminc (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-N-methylcathinone (4-FMC)	15
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-ethylcathinone (4-MEC)	15
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	15
alpha-Pyrrolidinopentiophenone (α-PVP)	15
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betamethadol	4
Betaprodine	2

Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-N-oxide	305
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	125,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	15
N,N-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	15
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52

Normethadone	2
Normorphine	18
Phenomorphan	2
Psilocybin	30
Psilocyn	30
Quinolin-8-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate (5-fluoro-	
PB-22; 5F-PB-22)	15
Quinolin-8-yl 1-pentyl-1 <i>H</i> -indole-3-carboxylate (PB-22; QUPIC)	15
Tetrahydrocannabinols	497,500
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	21,875,000
Amphetamine (for sale)	37,500,000
Carfentanil	19
Cocaine	275,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	49,500,000
Dextropropoxyphene	19
Dihydrocodeine	226,375
Diphenoxylate	1,337,500
Ecgonine	174,375
Ethylmorphine	3
Fentanyl	2,150,000
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	5
Levomethorphan	7,125
Levorphanol Lisdexamfetamine	29,750,000
	6,250,000
Meperidine Meperidine Intermediate-A	6
Meperidine Intermediate-B	11

Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of <i>levo</i> -desoxyephedrine for use in a neprescription product; 750,000 grams for methamphetam a schedule III product; and 61,375 grams for methamphetam	ine mostly for conversion to etamine (for sale)]
Methylphenidate	83,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	35,000,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	137,500,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

The Deputy Administrator also establishes aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy

Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as needed.				
		,		
		,		
Dated:		Thomas M. Deputy Adi	Harrigan, ninistrator	

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



equipment manufacturers, separation system designers, and end users,

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2014-21286 Filed 9-5-14; 8:45 am]

### DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. DEA-393]

Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

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

SUMMARY: This notice establishes the initial 2015 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Effective date: Effective September 8, 2014.

FOR FURTHER INFORMATION CONTACT: Imelda Paredes, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 598–6812. SUPPLEMENTARY INFORMATION:

### Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the 'Controlled Substances Act' or the "CSA" for the purpose of this action. 21 U.S.C. 801-971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA through 28 CFR 0.100(b). The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

### Background

The 2015 aggregate production quotas and assessment of annual needs represent those quantities of schedule I and II controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes.

On July 2, 2014, a notice titled, "Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Proposed Assessment of Annual Needs for the List I Chemicals Ephodrine, Pseudoephedrine, and Phenylpropanolamine for 2015" was published in the Federal Register, 79 FR 37772. This notice proposed the 2015 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before August 1, 2014.

### Comments Received

Five comments were received from DEA-registered manufacturers within the published comment period, offering comments on a total of 32 schedule I and II controlled substances. None of the respondents commented on the list I chemicals ephedrine,

pseudosphedrine, and phenylpropanolamine. Commenters stated that the proposed aggregate production quotas for 1-(1,3-Benzodioxol-5-yl)-2-(methylamino) butan-1-one (butylone), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino) pentan-1-one (pentylone), 2-(4-Bromo-2,5-dimethoxyphenyl)-*N-*(2methoxyhenzyl)ethanamine (25B-NBOMe), 2-(4-Chloro-2,5dimethoxyphenyl]-N-(2methoxybenzyl)ethanamine (25C-NBOMe], 2-(4-lodo-2,5dimethoxyphenyl)-N-(2methoxybenzyl)ethanamine (25I-NBOMe), 2-(Methylamino)-1phenylpentan-1-one (pentadrone), 3-Fluoro-N-methylcathinone (3-FMC), 4-Fluoro-N-methylcathinone (4-FMC), 4-Anilino-N-phenethyl-4-piperidine (ANPP), 4-Methyl-N-ethylcathinone (4-MEC), 4-Methyl-αpyrrolidinopropiophenone (4-MePPP), alpha-Pyrrolidinobutiophenone (α-PBP), alpha-Pyrrolidinopentiophenone (α-PVP), amphetamine (for sale), codeine (for sale), dihydrocodeine, diphenoxylate, fentanyl, hydrocodone (for sale), hydromorphone, levorphanol, marihuana, morphine (for conversion), N-(1-Amino-3,3-dimethyl-1-oxobutan-2yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA), N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1Hindazole-3-carboxamide (AB-FUBINACA), naphthylpyrovalerone (naphyrone), oripavine, oxycodone (for conversion), oxymorphone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1H indole-3-carboxylate (5-Flouro-PB-22), and Quinolin-8-yl 1-pentyl-1H-indole-3carboxylate (PB-22) were insufficient to provide for the estimated medical. scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

### Determination of 2015 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2015 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826 (a), and other relevant factors, including the consideration of 2014 manufacturing quotas, current 2014 sales and inventories, 2015 export requirements, industrial use, additional applications for quotas, as well as information on research and product development requirements. Based on this information, the DEA has determined

that adjustments to the proposed aggregate production quotas and assessment of annual needs for alfentanti, cocaine, codeine-N-oxide, codeine (for sale), dihydrocodeine, fentanyl, hydromorphone, levorphanol, marihuana, oripavine, oxymorphone (for conversion), and ephedrine (for sale) are warranted. This notice reflects those adjustments.

Regarding 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone), 2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2methoxybenzyl)ethanamine (25B-NBOMe), 2-(4-Chloro-2,5dimethoxyphonyl)-N-(2methoxybenzyl]ethanamine (25C-NBOMe), 2-(4-Ioda-2,5dimethoxyphenyl)-N-(2methoxybenzyl)ethanamine (25I-NBOMe), 2-(Methylamino)-1phenylpentan-1-one (pentedrone), 3-Fluoro-N-methylcathinone (3-FMC), 4-Fluoro-N-methylcathinone (4-FMC), 4-Anilino-N-phenethyl-4-piperidine (ANPP), 4-Methyl-N-ethylcathinone (4-MEC), 4-Methyl- $\alpha$ pyrrolidinopropiophenone (4-MePPP), alpha-Pyrrolidinobutiophenone (a-PBP), alpha-Pyrrolidinopentiophenone (α-PVP), amphetamine (for sale), dihydrocodeine, fentanyl, hydromorphone, levorphanol, marihuana, N-(1-Amino-3,3-dimethyl-1oxobutan-2-yl)-1-pentyl-1H-indazole-3carboxamide (ADB-PINACA), N-(1-Amino-3-methyl-1-axobutan-2-yl)-1-(4fluorobenzyl]-1H-indazole-3carboxamide (AB-FUBINACA), naphthylpyrovalerone (naphyrone). oxycodone (for conversion), oxymorphone (for sale), Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3 carboxylate (5-Flouro-PB-22), and Quinolin-8-yl 1-pentyl-1H-indole-3carboxylate (PB-22), the DEA has determined that the proposed aggregate production quotes are sufficient to provide for the 2015 estimated medical. scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This notice finalizes these aggregate production quotas at the same amounts as proposed,

As described in the proviously published notice proposing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. See 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate

public need. As such, the DEA has included in all established schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting established aggregate production quota will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Deputy Administrator hereby establishes the 2015 aggregate production quotas for the following schedule I and II controlled substances and the 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Éstablished 2015 quotas (g)
. Schedule I	
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1H-indol-3-vI](2,2,3,3-tetramethyloyolopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yi)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	· 45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexylipiperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indote (JWH-200)	45
1-Butvl-3-(1-naphthovi)indole (JWH-073)	45
1-Cyclchexylethyl-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-chlorophenylacelyt)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-naphthoyi)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	] 30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbl-36)	15
2-(4-Chloro-2,5-d[methoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyi)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15
2-(4-lodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	. 30

·	2015 quotas (g)
2-(4-todo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (251-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpenian-1-one (pentedrone)	18 25
2,5-Dimethoxy-4-ethylamphotamine (DOET)	25
2,5-Dimethoxyamphetamine	29
2-14-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylithio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3.4.5-Trimethoxyamphetamine	25
3.4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	5: 4:
3.4-Methylenedioxy-Methylamphetamine (MDÉA) 3.4-Methylenedioxy-M-methylcathinone (methylone)	5(
3,4-Methylenedioxypyrovalerone (MDPV)	3:
3-Fluoro-Almelhyloathingne (3-FMC)	1
3-Methylfentacyl	
3-Methylthinfentanyl	
4.Bromo-2 5-dimethoxyamohetamine (DOB)	2: 2:
4-Bromo-2,5-dimethoxyphenethylamine (2-OB)	1:
4-Fluoro-M-methylcathinone (4-FMC)	10
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2
4-Methylaminorex	2
4.Methyl.N-ethylcathinone (4-MEC)	1
4-Methyl-N-methylcathingne (mechedrone)	4
4.Methyl-g-pyrmlidinonropiophenone (4-MePPP)	1 6
5-(1,1-Dimethylheptyl)-2-((1R,35)-3-hydroxycyclohexyl]-phenol	
5-(1,1-Dimethyloctyl)-2-[(1,3,5)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C6-homolog)	ž
5-Methoxy-N,N-disopropyitryplamine	2
6. Methovy-N Midmethyllryntamine	2
Acetyl-alaba-methylientanyi	
Acatyldihydrocodeine	
Acetylmethadol	
Allylproding	
Alphacetylmethadol aipha-Ethyltryptamine	2
Alphamoprodine	
Alchamethadol	
a/nha-Methylientary	
a/pha-Mothylthinfentanyl	
aloba-Methyltryotamine (AMT)	2
alpha-Pyrrolidinobutiophenone (α-PBP)	1
a/pha-Pyrrolidinopentiophenone (α-PVP)	ż
Benzylmorphine	_
Betacely/methadol	
hota-Hydroxy-3-methyllenlanyl	
beta-Hydroxyfenlanyl	
Retamenrodina	
Retame(hado)	
Betaprodine	
Bufotenine	7
Codeine methylbromide	
Codeine-N-oxide	30
Desprior phine	
Diethyltryplamine	2
Difenoxin	3 000 00
Dihydromorphine	3,990,00
Dimethyltryptamina Dipipanone	•
Dipipanone	
namma-Hydroxybutyric acid	70,250,00
Heroin	2
Hydromorphical	
Hydroxynethidine	
loogaine	1 3
Lysergic acid diethylamide (LSD)	125.00
Marihuana	• 25,55
Mossaine	
Mescaline	1 2

Basic class	Established 2015 quotas (g)
lethyldlhydromorphine	
Orphine methylbromide	
lorphine methylsulfonate	
torphine-M-oxide	35
-(1-Adamanlyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	
/(1-Adamanly)-1-penty-17-410220e-3-carboxamide (ANS-9) /(1-Amino-3,3-dimethyl-1-exobutan-2-yl)-1-pentyl-11-indazole-3-carboxamide (ADB-PINACA)	
P(1-Amino-3,3-dimetriy)-1-oxobitan-2-yi-1-penty-17-muzzie-3-danbuzinte (ADD-11-14-0-3)	
-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	:
A-Dimethylamphetamine	
aphthylpyrovalerone (naphyrone)	
PBenzylpiperazine	;
/Ethyl-1-phenylcyclohexylamine	
/Ethylamphetamine	
Hydroxy-3.4-methylenedioxyamphetamine	
ioracymethadol	
lorlevorphanel	,
ormethadone	
lormorphine	
henomorphan	
silocybln	
Silocyn	
luinolin-8-yl 1-(5-fluoropentyl)-1/H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	
luinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	
etrahydrocannabinols	497,5
hiofentanyl	
ilidine	
rimeperidine	
_ <del>`</del>	<del></del>
Schedule II	
-Phenylcyclohexylamine	
-Piperidinocyclohexanecarbonitrile	
-Anilino-A-phenethyl-4-piperidine (ANPP)	2,687,5
Atentanii	17,7
ILECTION III	
Iphaprodine	25,1
mobarbital	
unphetamine (for conversion)	21,875,0
umphetamine (for sale)	37,500,0
Cartentani	
Cocaine	275,0
Adeina (for conversion)	50,000,0
Adeine (for sale)	49,500,0
Octropropoxyphene	
exircpropoxypitene ,	226,3
Dinydrocodeine	1,337,5
Diphenoxylate	
cgonine	174,3
thylmorphine	
entanyi	2,150,0
Alutethimide	
lydrocodone (for conversion) ,,,,,,	137,5
lydrocodone (for sale)	99,625,0
ydromorphone	7,000,0
	1,550,0
somethadone	İ
evo-alphacetylmethadol (LAAM)	l
evomethorphan	
eyorphanol	7.1
isdexamfetamine	29,750,0
Reperidine	6,250,0
leperidine Intermediate-A	
Appariding Intermediate-B	İ
Reperiding Intermediate-C	i
leiazocine	į
	31,875,0
lethadone (for sale)	34,375,0
Methadone Intermediate	2,061,3
dethamphetamine	<u> </u>
1,250,000 grams of lavo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for method for conversion to a schedule-III product; and 61,375 grams for methomphetamine (for sale)]	imphetamine most
	00.370.1
Methylphenidate	83,750,0
Morphine (for conversion)	91,250,0
Morphine (for sale)	62,500,0
Nabilone	18,7
(CUIVITO ELIPPOPER PROPERTIES IN CONTRACTOR	l 17,500,0

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

The Deputy Administrator also establishes aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as needed.

Dated: September 2, 2014.
Thomas M. Harrigan,
Deputy Administrator.
[FR Doc. 2014-21280 Filed 9-5-14; 8:45 am]
BILLING CODE 4410-09-P

# OFFICE OF SCIENCE AND TECHNOLOGY POLICY

National Nanotechnology Coordination
Office

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

ACTION: Notice of public meeting.

SUMMARY: The National Nanotechnology Coordination Office (NNCO), on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC), will hold a technical

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

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

ADDRESSES: The technical interchange meeting will be held at the National Aeronautics and Space Administration (NASA) Headquarters, 300 E Street Southwest, Washington, DC 20548.

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

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

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

### Ted Wackler,

Deputy Chief of Staff and Assistant Director. [FR Doc. 2014-21201 Filed 9-5-14; 8:45 am] BILLING CODE P

						/	
Substance	2012	2043	- Lange	2018	e Chance		
AMPHETAMINE *	22,664.555	22,574.791	-0.40%	24,622.361	9,07%	26,533.368	7.76%
COCAINE	43.833	38.680	-11.30%	35,481	-8:74%	35.828	0.98%
CODEINE	22,756.728	21,747.588	-4.43%	21,716.915	-0.14%	27,997.461	28.92%
DIHYDROCODEINE	75.021	35.987	-52.03%	3,314	-90.79%	18.836	468.38%
DIPHENOXYLATE	413.016	411.425	-0.39%	385.932	-6.20%	389.646	0.96%
DRONABINOL	106,128	111177	4.76%	117.394	5.59%	116,165	-1.05%
EPHEDRINE	1,972.090	2,079.301	5.44%	2,234.629	7.47%	2,133.284	-4.54%
FENTANYL	515.025	471.712	-8.41%	472.441	0.15%	467,650	-1.01%
HYDROCODONE	63,179.515	61,710.790	-2,32%	56,372.635	-8.65%	50,046.773	-11.22%
HYDROMORPHONE	1,913.040	1,927.636	0.76%	1,834.406	4.84%	1,752,294	4.48%
LEVORPHANOL	1.544	2.314	49,87%	2.691	16.29%	2.882	7.11%
LISDEXAMPETAMINE	14,001.470	13,652.692	-2.49%	14,245.693	4.34%	15,111,185	6.08%
MEPERIDINE	1,880,965	1,522.736	-19.04%	1,243,493	-18.34%	1.147.088	-7.75%
METHADONE	6,777,086	5,805,070	-14.34%	5,251,161	9.54%	4,957.310	-5.60%
METHAMPHETAMINE	14.399	13.192	-8.38%	11.910	-9.72%	11.278	-5.30%
METHYLPHENIDATE **	21,759.744	20,137.904	-7.45%	20,175.671	0.19%	18,893.332	-6.36%
MORPHINE	28,705,443	26,272.879	-8.48%	24,603.452	-6.35%	24,084.883	-2.11%
NALBUPHINE	63.599	41.766	-34.33%	40,868	-2.15%	36.675	-10.26%
NALOXONE	433.684	481.367	10.99%	522.199	8.48%	550.850	5.49%
NALTREXONE	646.518	743,593	15.02%	927.244	24.70%	1,388.838	49.78%
Noroxymorphone products (su		1,266.726	10.75%	1,490.310	17.65%	1,976.362	32.61%
OPIUM	80.986	77,417	4,41%	76.702	-0.92%	74,977	-2,25%
OXYCODONE	66,704.849	60,357.506	-9.52%	58,911.473	-2.40%	59,620.924	1,20%
ОХУМОКРНОМЕ	1,958.281	1,863,432	4.84%	1,930.455	3.60%	1,946.653	0.84%
PENTAZOCINE	698.430	565.292	-19.06%	422.871	-25.19%	428.603	1.36%
PENTOBARBITAL	46.612	24.226	-48.03%	16.541	31.72%	15.872	-4.04%
PHENYLPROPANOLAMINE	many management of the second	2.966	#DIV/0!	1.058	-64.34%	0.792	-25.11%
PSEUDOEPHEDRINE***	187,867,353	186,436.285	-0.76%	181,452.065	-2.67%	103,271.206	-43.09%
REMIFENTANIL	1.105	1.158	4.75%	1.225	5.83%	1.270	3.71%
SECOBARBITAL	15,670	12.040	-23.17%	11.470	4.73%	12.480	8.B1%
SUFENTANIL	0,051	0.047	-8.62%	0.041	-11.40%	0.042	1.94%
TAPENTADOL	6,388.449	5,989,766	-6.24%	5,645,768	5.74%	5,642.812	-0.05%
<ul> <li>executive content at the same of the second o</li></ul>	er i dan i dan i Sang Amerikan dan b	off of any of the state of the State of the	or other a coll. A.E.4.16 to	والنار وتهفأه فأطعاه والماران	Albert State Att and Late Apr. Page	3'045'9TS	

2015 Data based on Jan - Mar 2015 data

IMS DATA 2012 - 2015 (est)

<sup>\*</sup> corrected based on historical IMS data for d,I and d

<sup>\*\*</sup> added dexmethylphenidate to mehtylphenidate

<sup>\*\*\*</sup> corrected based on IMS capture of OTC market



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

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

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

Dated: June 1, 2015.

Michael A. Caldwell,

Regional Director, Northeast Region, National Park Service.

[FR Doc. 2015-14927 Filed 6-16-15; 8:45 am] BILLING CODE 4310-WV-P

# INTERNATIONAL TRADE COMMISSION

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

### Citric Acid and Certain Citrate Salts From Canada and China

### Determination

On the basis of the record 1 developed in the subject five-year reviews, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930, that revocation of the countervailing duty order on citric acid and certain citrate salts from China and the antidumping duty orders on citric acid and certain citrate salts from China and Canada would be likely to lead to

continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

### Background

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

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

By order of the Commission.
Issued: June 12, 2015.
Lisa R, Barton,
Secretary to the Commission.
JFR Doc. 2015–14863 Filed 6–16–15; 8:45 am)
BILLING CODE 7620–02-P

# **DEPARTMENT OF JUSTICE**

Drug Enforcement Administration [Docket No. DEA-392]

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

ACTION: Notice of registration.

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

SUPPLEMENTARY INFORMATION: By notice dated January 9, 2015, and published in

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

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

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the basic classes of controlled substances listed:

Controlled substance	Schedule
Tetrahydrocannabinois (7370) Eogonine (9180) Morphine (9300) Thebaine (9333)	1)

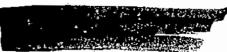
The company plans to produce the listed controlled substances in bulk to be used in the manufacture of reagents and drug calibrator controls which are DEA exempt products.

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

Dated: June 11, 2015.
Joseph T. Rannazzisi,
Deputy Assistant Administrator.
[FR Doc. 2015–14912 Filed 6–16–15; 8:45 am]
BILLING CODE 4410–09–P

### DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. DÉA-411F]



AGENCY: Drug Enforcement Administration, Department of Justice. ACTION: Final order.

<sup>&</sup>lt;sup>1</sup> The record is defined in sec, 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

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

DATES: This order is effective June 17, 2015.

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

### SUPPLEMENTARY INFORMATION:

### Legal Authority

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

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

### Background

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

#### Comments Received

Two companies, one institution of higher education, and five private citizens submitted timely comments in response to the proposed adjustment of these three controlled substances. The comments from the institution of higher education and one of the private citizens were in support of the proposed increases for these three controlled substances. The two companies and one private citizen supported the proposed adjustment and requested further increases to the APQs to support research, additional product development efforts, and increases in manufacturing demands. Further comments received from three private citizens were outside the scope of the proposed APQ notice. The DEA

appreciates the support for this adjusted 2015 aggregate production quota for difenoxin, diphenoxylate (for conversion), and marijuana, which is intended to provide for the estimated scientific, research, and industrial needs of the United States.

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

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

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

Basic class—schedule I	Previously established 2015 quota (g)	Adjusted 2015 quota (g)
Difenoxin	50 125,000	11,000 658,000
Basic classschedule II	Previously established 2015 quota (g)	Adjusted 2015 quota (g)
Diphenoxylate (for conversion)	0	75,000

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

## DEPARTMENT OF JUSTICE

#### **Drug Enforcement Administration**

[Docket No. DEA-410F]

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

AGENCY: Drug Enforcement Administration, Department of Justice. ACTION: Final order.

SUMMARY: This final order establishes the initial 2015 aggregate production quotas for three temporarily controlled synthetic cannabinoids: N-(1-amino-3-methyl-1-oxobutan-2-yl)-1- (cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA). N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA), and [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl]methanone (THJ-2201).

DATES: Effective June 17, 2015.

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

## Background

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

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

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

On March 20, 2015, the DEA published a notice titled, "Controlled Substances: 2015 Proposed Aggregate Production Quotas for Three Temporarily Controlled Synthetic Cannabinoids" in the Federal Register (80 FR 15034). That notice proposed the 2015 aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201. Interested persons were invited to comment on or object to the proposed aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201 on or before April 20, 2015. No comments were received.

## Analysis for 2015 Established Aggregate Production Quotas

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

Pursuant to 21 U.S.C. 526 and in accordance with 21 CFR 1303.11, the Acting Administrator hereby establishes the 2015 aggregate production quotes for AB-CHMINACA, AB-PINACA, and THJ-2201, expressed in grams of anhydrous acid or base, as follows:

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

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

Dated: June 11, 2015.
Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2015–14909 Filed 6-16-15; 8:45 am]

BILLING CODE 4410-09-P

## **DEPARTMENT OF JUSTICE**

## **Drug Enforcement Administration**

[Docket No. DEA-392]

Importer of Controlled Substances Registration: Mylan Technologies, Inc.

ACTION: Notice of registration.

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

SUPPLEMENTARY INFORMATION: By notice dated February 11, 2015, and published in the Federal Register on February 19, 2015, 80 FR 8902, Mylan Technologies. Inc., 110 Lake Street, Saint Albans, Vermont 05478 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Mylan Technologies, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under



#### COLORADO

#### Park County

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

#### San Juan County

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

#### MARYLAND

#### Baltimore Independent city

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

## Charles County

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

## MISSOURI

## St. Louis Independent city

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

## NEW HAMPSHIRE

#### Cops County

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

## NEW JERSEY

## Sussex County

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

## NEW YORK

#### **Brunx County**

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

### Suffolk County

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

#### NORTH CAROLINA

#### Ashe County

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

#### Beaufort County

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

#### **Guilford County**

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

#### Harnett County

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

## Macklenburg County

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

#### DIHO

#### Hamilton County

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

### Ottawa County

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

#### TENNESSEE

## Grundy County

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

### Shelby County

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

#### WEST VIRGINIA

#### Marion County

Dunbar School, 103 High St., Fairmont, 15000188

#### WISCONSIN

#### Sheboygan County

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

#### WYOMING

#### **Teton County**

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

[FR Doc. 2015-08007 Filed 4-7-15; 8:45 am]
BILLING CODE 4312-51-P

# INTERNATIONAL TRADE COMMISSION

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

AGENCY: U.S. International Trade Commission.

**ACTION:** Notice:

SUMMARY: In accordance with Section 743 of Division C of the Consolidated Appropriations Act of 2010 (Pub. L. 111-117), the U.S. International Trade Commission is publishing this notice to advise the public of the availability of the FY 2013 Service Contract Inventory Analysis, the FY 2014 Service Contract Inventory, and the FY 2014 Service Contract Inventory Planned Analysis. The FY 2013 inventory analysis provides information on specific service contract actions that were analyzed as part of the FY 2013 inventory. The 2014 inventory provides information on service contract actions over \$25,000

which were made in FY 2014. The inventory information is organized by function to show how contracted resources are distributed throughout the agency. The inventory has been developed in accordance with guidance issued on November 5, 2010 by the Office of Management and Budget's Office of Federal Procurement Policy (OFPP). OFPP's guidance is available at http://www.whitchouse.gov/sites/ defoult/files/omb/procurement/memo/ service-contract-inventories-guidance-11052010.pdf. The FY 2014 inventory planned analysis provides information on which functional areas will be reviewed by the agency. The United States International Trade Commission has posted its FY 2014 inventory, FY 2014 planned analysis, and FY 2013 inventory analysis at the following link: http://www.usitc.gov/procurement/. FOR FURTHER INFORMATION CONTACT: Questions regarding the service contract inventory should be directed to Debra Bridge, U.S. International Trade Commission, Office of Procurement, 500 E Street SW., Washington, DC 20436, or at 202-205-2004 or debra.bridge@

By order of the Commission.

Dated: April 3, 2015.

Lisa R. Barton,

Secretory to the Commission.

[FR Doc. 2015-06050 Filed 4-7-15: 8:45 am]

## DEPARTMENT OF JUSTICE

BILLING CODE 7020-02-P

Drug Enforcement Administration [Docket No: DEA-411N]

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

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

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

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

2015. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-411N" on all correspondence. including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to http://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia

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

## Posting of Public Comments

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

INFORMATION" in the first peragraph of your comment. You must also place all the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

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

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

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

## Legal Authority

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

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggragate production quotas for each basic class of controlled substance listed in schedules I and II each year. The Attorney General has delegated this function to the Administrator of the DEA, 28 CFR 0.100.

## Background

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

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

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

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

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

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

## Analysis for Adjusting the Established 2015 Aggregate Production Quota for Marijuana

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

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

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

Basic class- schedule !	Previously established 2015 quota	Adjusted 2015 quota
Difenoxin Marijuana	50 g 125,000 g	9,000 g 400,000 g
Basic class- schedule II	Previously established 2015 quota	Adjusted 2015 quota
Diphenoxylat- e (for con- version).	Zero	75,000 g

<sup>&</sup>lt;sup>1</sup> Difenoxin (schedule I) is the active pharmaceutical ingredient in the diarrhea preparation (schedule V).

Dated: April 1, 2015.

Michele M. Leonhart,

Administrator.

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

BILLING CODE 4410-09-P

# NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (15-026)]

# Notice of Intent To Grant a Partially Exclusive License

AGENCY: National Aeronautics and Space Administration.
ACTION: Notice of Intent to Grant Partially Exclusive License.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant a partially exclusive license in the United States to practice the invention described and claimed in U.S. Patent No. 7,086,593 B2 titled "Magnetic Field Response Measurement Acquisition System," NASA Case No. LAR-16908-1; U.S. Patent No. 7,159,774 B2 titled "Magnetic Field Response Measurement Acquisition System," NASA Case No. LAR-17280-1; U.S. Patent No. 7,075,295 B2 titled "Magnetic Field Response Sensor for Conductive Media," NASA Case No. LAR-16571-1; U.S. Patent No. 7,589,525 B2 titled "Magnetic Field Response Sensor for Conductive Media," NASA Case No. LAR-16571-2; U.S. Patent No. 7,759,932 B2 titled "Magnetic Field Response Sensor for Conductive Media," NASA Case No. LAR-16571-3; U.S. Patent No. 8,430,327 B2 titled "Wireless Sensing System Using Open-Circuit, Electrically-Conductive Spiral-Trace Sensor," NASA Case No. LAR-17294-1; U.S. Petent No. 7,683,797 B2 titled "Damage Detection/Locating System Providing Thermal Protection," NASA Case No. LAR-17295-1; U.S. Patent No. 7,902,815 B2 titled "Wireless System and Method for Collecting Motion and Non-Motion Related Data of a Rotating System," NASA Case No. LAR-17433-1; U.S. Patent No. 8,042,739 B2 titled "Wireless Tamper Detection Sensor and Sensing System," NASA Case No. LAR-17444-1; U.S. Patent No. 7,711,509 B2 titled "Method of Calibrating a Fluid-Level Measurement System," NASA Case No. LAR-17480-1; U.S. Patent No. 7,814,786 B2 titled "Wireless Sensing System for Non-Invasive Monitoring of Attributes of Contents in a Container,' NASA Case No. LAR-17488-1; U.S. Patent No. 8,673,649 B2 titled "Wireless

Chemical Sensor and Sensing Method for Use Therewith," NASA Case No. LAR-17579-1; U.S. Patent Application No. 14/215,793 titled "Wireless Chemical Sensor and Sensing Method for Use Therewith," NASA Case No. LAR-17579-2; U.S. Patent No. 8,167,204 B2 titled "Wireless Damage Location Sensing System," NASA Case No. LAR-17593-1; U.S. Patent No. 8,179,203 B2 titled "Wireless Electrical Device Using Open-Circuit Elements Having No Electrical Connections, NASA Case No. LAR-17711-1; U.S. Patent Application No. 14/193,861 titled "Wireless Temperature Sensing Having No Electrical Connections and Sensing Method for Use Therewith," NASA Case No. LAR-17747-1-CON; U.S. Patent Application No. 13/796,626 titled "Method of Mapping Anomalies in Homogonous Material," NASA Case No. LAR-17848-1 to GLSEQ, LLC having its principal place of business in Owens Cross Roads, Alabama. The fields of use may be limited to, but not necessarily be limited to, safety related and non-safety related instrumentation and control systems for nuclear facilities, including advanced safety related and non-safety related instrumentation systems for severe accident monitoring within nuclear power plants and nuclear storage facilities. The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective partially exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

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

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

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



Dated: June 11, 2015.
Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2015–14910 Filed 6–18–15; 8:45 am]
BILLING CODE 4410–05–P

#### **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

[Docket No. DEA-410F]

AGENCY: Drug Enforcement Administration, Department of Justice. ACTION: Final order.

SUMMARY: This final order establishes the initial 2015 aggregate production quotas for three temporarily controlled synthetic cannabinoids: N-(1-amino-3-methyl-1-oxobutan-2-yl)-1- (cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1- pentyl-1H-indazole-3-carboxamide (AB-PINACA), and [1-[5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201).

DATES: Effective June 17, 2015.
FOR FURTHER INFORMATION CONTACT: John R. Scherbenske, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.
SUPPLEMENTARY INFORMATION:

#### Background

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

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

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

On March 20, 2015, the DEA published a notice titled, "Controlled Substances: 2015 Proposed Aggregate Production Quotas for Three Temporarily Controlled Synthetic Cannabinoids" in the Federal Register (80 FR 15034). That notice proposed the 2015 aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201. Interested persons were invited to comment on or object to the proposed aggregate production quotas for AB-CHMINACA, AB-PINACA, and THJ-2201 on or before April 20, 2015. No comments were received.

## Analysis for 2015 Established Aggregate Production Quotas

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

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

. Basic class—schedule I	Eslablished 2015 quota (g)
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA) [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanono (THJ-2201)	15 15 15

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

Dated: June 11, 2015.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2015-14909 Filed 6-16-15; 8:45 am]

BILLING CODE 4410-09-P

#### DEPARTMENT OF JUSTICE

## **Drug Enforcement Administration**

[Docket No. DEA-392]

Importer of Controlled Substances Registration: Mylan Technologies, Inc.

ACTION: Notice of registration.

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

SUPPLEMENTARY INFORMATION: By notice dated February 11, 2015, and published in the Federal Register on February 19, 2015, 80 FR 8902, Mylan Technologies, Inc., 110 Lake Street, Saint Albans, Vermont 05478 applied to be registered as an importer of certain basic classes of controlled substances. No comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of Mylan Technologies, Inc. to import the basic classes of controlled substances is consistent with the public interest and with United States obligations under

15034

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to United States and the State of Indiana v. Exide Technologies, D.J. Ref. No. 90-5-2-1-11003. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

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

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: http://www.usdoj.gov/enrd/Consent\_Decrees.html. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs (at 25 cents per page). Please mail your request and a check or money order payable to the United States Treasury to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

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

## Randall M. Stone,

Acting Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division. [FR Doc. 2015–96369 Filed 3–19–15; 8:45 am] BILLING CODE 4410–15–P

## DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. DEA-410]

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

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

SUMMARY: Three synthetic cannabinoids: N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA), N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-

PINACA), and {1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201) were temporarily placed in schedule I of the Controlled Substances Act by a final order published by the Drug Enforcement Administration on January 30, 2015 (80 FR 5042). This means that any person that wishes to manufacture AB-CHMINACA, AB-PINACA, or THJ-2201 after January 30, 2015, must be registered with the Drug Enforcement Administration and have obtained a manufacturing quota pursuant to 21 CFR part 1303.

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

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c). Electronic comments must be submitted, and written comments must be postmarked, on or before April 20, 2015. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this Notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the Federal Register. After consideration of any comments and after a hearing, if one is held, the Administrator will publish in the Federal Register a final order establishing the 2015 aggregate production quotas for AB-CHMINACA, AB-FINACA, and THJ-2201.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-410" on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to http://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not

instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention; DEA Federal Register Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

## Posting of Public Comments

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

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

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket. Comments containing personal identifying information or confidential

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

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

## Legal Authority and Background

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II each year. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

The DEA established the 2015 aggregate production quotas for substances in schedules I and II on September 8, 2014 (79 FR 53216). Subsequently, on December 19, 2014, DEA published in the Federal Register a notice of intent to temporarily place 3

synthetic cannabinoids: N-(1-amino-3methyl-1-oxobutan-2-yl)-1 (cyclohexylmethyl)-1H-indazole-3carboxamide (AB-CHMINACA), N-(1amino-3-methyl-1-oxobutan-2-yl)-1pentyl-1H-indazole-3-carboxamide (AB-PINACA), and [1-(5-fluoropentyl)-1Hindazol-3-yl](naphthalen-1yl)methanone (THJ-2201) into schedule I of the CSA (79 FR 75767). On January 30, 2015, the DEA published in the Federal Register a final order to temporarily place these three synthetic cannabinoids in schedule I of the CSA (80 FR 5042), making all regulatory controls pertaining to schedule I controlled substances applicable to the manufacture of these three synthetic cannabinoids, including the requirement to establish an aggregate production quota pursuant to 21 U.S.C. 826 and 21 CFR part 1303.

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

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

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

Basic class—schedule I	Proposed 2015 quota (g)
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmothyi)-1H-indazole-3-carboxamide (AB-CHMINACA) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA) (1-(5-fluoropentyl)-1H-indazol-3-yl)(naphthalen-1-yl)methanone (THJ-2201)	15 · 15 15

Dated: March 12, 2015.

Michele M. Leonhart,

Administrator.

[FR Doc. 2015-00456 Filed 3-19-15; 8:45 am]

BILLING CODE 4410-09-P

# MORRIS K. UDALL AND STEWART L. UDALL FOUNDATION

#### Sunshine Act Meetings

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

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

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

MATTERS TO BE CONSIDERED: (1) Chair's Remarks; (2) Executive Director's Remarks; (3) Overview of Trustee Responsibilities; (4) Board Officers & Committee Elections; (5) Consent Agenda Approval, including program reports of the Education Programs, U.S.

Institute for Environmental Conflict Resolution, and Udall Center for Studies in Public Policy/Native Nations Institute for Leadership, Management, and Policy/Udall Archives, and resolutions related to the Operating Procedures of the Board of Trustees and the Parks in Focus Fund, Inc. (6) Financial and Internal Controls Update; (7) Ethics Briefing; (8) Program Panel & Discussion; and (9) Appropriations Update.

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

Dated: March 16, 2015.

Philip J. Lemanski,

Executive Director, Marris K. Udall and Stewart L. Udall Foundation, and Federal Register Llaison Officer.

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

# NUCLEAR REGULATORY COMMISSION

## [NRC-2015-0001]

## Sunshine Act Meetings

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

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

STATUS: Public and Closed.

## Week of March 23, 2015-Tentative

Thursday, March 26, 2015

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

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

Friday, March 27, 2015

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

2015 Nevtsed APQ Worksheets

PQ Total(CH+PD):

27,218,759.001

FDA Est: -.034 1M9 Est: -.289

Company DEA Num	2015 MQ Request	2015 MQ	2014 Sales	2014 Total Sales	% of 2014 Sales	Share of 2015 Total PO	2014 Inventory	2015 Projected Exports	Gale Valing CFR 20% Invent	Calc Using CFR 50% Invent	Finel MQ
(b)(4);(b)(7)(E)	5.000	5.000	0,000	25,605,542,319	0,000	0.000	1.600	0.000	·1.600	-1.600	0.000
	100.000	100,000	33,926	25,605,542,319	0.000	35,959	42.684	0.000	4.083	10.742	9,000
	628,000.000	626,000.000	0.000	25,606,542,319	0.900	0.000	0.000	0,000	0,000	0.000	0.003
	296,000.000	296,000.000	241,282.000	25,605,542,319	0.009	256,483.393	247,156,000	0.000	65,272.411	133,788.741	0.000
	18,400,000.000	11,600,000 000	8,778,025,000	25,805,542,919	0,343	9,332,128.380	3,913,299,000	2,088,849,000	10,406,314.295	12,133,484,228	0.000
	1,000.000	1,000,000	4.168	25,605,542,319	0.000	4.431	501.534	0.000	-495,774	-494.954	0.000
	25,501,000.000	18,774,000.000	15,885,650,000	25,605,542.319	0.620	16,888,487.216	4,380,520,000	0.000	17,571,913.381	20,699,001.520	0.000
	3,870,000.000	1,918,186,000	699,547.000	25,605,542.319	0.027	743,620.278	7,548.000	0.000	950,158.382	1,098,884.098	0.000
	'										
MQ Totale:	46,496,105.000	31,411,291.000	25,605,541.996				6,449,068.798	2,086,849.000	29,022,165,157		0.000

584,473,202

Final Initial APO:

39,600,000,000

Proposed Revised:

51,052,320,000 (IMS pct chg applied to current APQ then rounded up)

CFR 50%

Proposed Reviewd (with 25% buller):

63,815,400,000 (64,000,000 rounded up)

Final Revised APO:

0.000

MG NeedePG\* t.5 - Revised MG - Inventory:

967,777.203

35,900,000,000

IMS Est = 2014 APQ \* (1 + IMS Est);

35,630,640.000 47,571,480.000

Pending requests:

				2015 MG		
	* Company	DEA Num	current MQ	<b>Finquest</b>	Possible grant	difference
(	(b)(4);(b)(7)(E)		11,800,000,000	16,400,000,000	12,800,000,000	2,000,000.000
- 1			16,770,000,000	28,250,000.000	24,531,000.000	7,761,000.000
- 1			1,916,186.000	3,670,000.000	3,670,000.000	1,753,814.000
- 1			1			
-			J			11,514,814.000

CODEINE (FOR SALE)

(b)(4)					
(b)(4)					
		,			
				•	
May 14, 2015				÷	
Dr. Christine Sanne	end .	• .			
Drug Enforcement					
Office of Diversion					
8701 Morrisette Dri					
Springfield, VA 22					
Springred, TA 22	i <b>J</b> #				
Dear Dr. Sannerud:					
(b)(4);(b)(7)(E)		in increase in 201			PS
		ts additional 2015		ale (9300),	
morphine for conver	sion (9300), and codeine for sale (90	50) manufacturin	g quota.		
	, <del></del>				
			D	Increase	
Onote Category	Material Name	2015 Granted	Requested		
Quota Category	Material Name	Quota (kg)	Quota(kg)	(kg)	
	CPS-Morphine – 9670 NET				
Quota Category  Procurement		Quota (kg)	Quota(kg)	(kg)	
Procurement	CPS-Morphine – 9670 NET	Quota (kg) 38,999	Quota(kg) 80,000	(kg) 41,001	
	CPS-Morphine – 9670 NET CPS-Morphine – 9670 as kgB CPS-Codeine – 9670 NET	Quota (kg) 38,999 31,199 6,366	Quota(kg) 80,000 64,000 9,988	(kg) 41,001 32,801 3,622	
Procurement  Procurement	CPS-Morphine – 9670 NET CPS-Morphine – 9670 as kgB CPS-Codeine – 9670 NET CPS-Codeine – 9670 as kgB	Quota (kg) 38,999 31,199 6,366 5,417	Quota(kg) 80,000 64,000 9,988 8,500	(kg) 41,001 32,801 3,622 3,083	
Procurement	CPS-Morphine – 9670 NET  CPS-Morphine – 9670 as kgB  CPS-Codeine – 9670 NET  CPS-Codeine – 9670 as kgB  Total Morphine for Conversion	Quota (kg) 38,999 31,199 6,366	Quota(kg) 80,000 64,000 9,988	(kg) 41,001 32,801 3,622	
Procurement  Procurement	CPS-Morphine – 9670 NET CPS-Morphine – 9670 as kgB CPS-Codeine – 9670 NET CPS-Codeine – 9670 as kgB Total Morphine for Conversion - 9300	Quota (kg) 38,999 31,199 6,366 5,417 13,463	Quota(kg) 80,000 64,000 9,988 8,500 24,500	(kg) 41,001 32,801 3,622 3,083 11,037	
Procurement  Procurement	CPS-Morphine - 9670 NET CPS-Morphine - 9670 as kgB CPS-Codeine - 9670 NET CPS-Codeine - 9670 as kgB Total Morphine for Conversion - 9300 Morphine for Conversion for	Quota (kg) 38,999 31,199 6,366 5,417	Quota(kg) 80,000 64,000 9,988 8,500	(kg) 41,001 32,801 3,622 3,083	
Procurement  Procurement	CPS-Morphine - 9670 NET CPS-Morphine - 9670 as kgB CPS-Codeine - 9670 NET CPS-Codeine - 9670 as kgB Total Morphine for Conversion - 9300 Morphine for Conversion for Codeine	Quota (kg) 38,999 31,199 6,366 5,417 13,463	Quota(kg) 80,000 64,000 9,988 8,500 24,500	(kg) 41,001 32,801 3,622 3,083 11,037	
Procurement  Procurement	CPS-Morphine - 9670 NET CPS-Morphine - 9670 as kgB CPS-Codeine - 9670 NET CPS-Codeine - 9670 as kgB Total Morphine for Conversion - 9300 Morphine for Conversion for Codeine Morphine for Conversion for	Quota (kg) 38,999 31,199 6,366 5,417 13,463	Quota(kg) 80,000 64,000 9,988 8,500 24,500	(kg) 41,001 32,801 3,622 3,083 11,037	
Procurement Procurement Manufacturing	CPS-Morphine - 9670 NET CPS-Morphine - 9670 as kgB CPS-Codeine - 9670 NET CPS-Codeine - 9670 NET CPS-Codeine - 9670 as kgB Total Morphine for Conversion - 9300 Morphine for Conversion for Codeine Morphine for Conversion for oxymorphone	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403	(kg) 41,001 32,801 3,622 3,083 11,037 24,097	
Procurement Procurement Manufacturing Manufacturing	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  - 9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454	-
Procurement Procurement Manufacturing	CPS-Morphine - 9670 NET CPS-Morphine - 9670 as kgB CPS-Codeine - 9670 NET CPS-Codeine - 9670 NET CPS-Codeine - 9670 as kgB Total Morphine for Conversion - 9300 Morphine for Conversion for Codeine Morphine for Conversion for oxymorphone	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403	(kg) 41,001 32,801 3,622 3,083 11,037 24,097	, j
Procurement Procurement Manufacturing Manufacturing Manufacturing	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  - 9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454	, j
Procurement Procurement Manufacturing Manufacturing Manufacturing Current Situation	CPS-Morphine - 9670 NET CPS-Morphine - 9670 as kgB CPS-Codeine - 9670 NET CPS-Codeine - 9670 NET CPS-Codeine - 9670 as kgB Total Morphine for Conversion - 9300 Morphine for Conversion for Codeine Morphine for Conversion for oxymorphone Morphine for Sale - 9300 Codeine For Sale - 9050	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481	J.
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion - 9300  Morphine for Conversion for Codeine  Morphine for Conversion for oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  drug produ	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481	Ĺ.
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  - 9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  drug produ	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481	Ĺ.
Procurement Procurement Manufacturing Manufacturing Manufacturing Current Situation CPS Morph Codeine Pho	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  - 9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  ine is the starting material for two  oxymorphone for conversion	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769 drug producategory).	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250 (	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481	- Tand
Procurement Procurement Manufacturing Manufacturing Manufacturing Current Situation CPS Morph Codeine Pho	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  - 9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  ine is the starting material for two  oxphate (via morphine for conversion  dles have increased over 2014. [b)(4)	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  drug producategory). holds a contra	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250 cucts: Morphine	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481 Sulfate and	]and
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph Codeine Pho Morphine sa (b)(4);(b)(7)(E	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  - 9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  ine is the starting material for two  oxphate (via morphine for conversion  tles have increased over 2014. [b)(4)  requiring supply of 80% of their rec	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  (4) drug producategory). holds a contraquirements. As a requirements. As a requirements.	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250 cucts: Morphine	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481 Sulfate and	
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph Codeine Pho Morphine sa (b)(4),(b)(7)(E another supp	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  ine is the starting material for two oxymorphone (via morphine for conversion des have increased over 2014. (b)(4)  requiring supply of 80% of their recolier (b)(4) will require (b)(4) to b	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  (4) drug producategory).   holds a contrapuirements. As a regin supplying in	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250 cucts: Morphine act with (b)(4)(b) esult of exhaus 2015. (b)(4)	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481 Sulfate and ()(7)(E) ting inventory has already	from
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph Codeine Pho Morphine sa (b)(4),(b)(7)(E another supposspplied init	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  ine is the starting material for two osphate (via morphine for conversion des have increased over 2014. (b)(4)  requiring supply of 80% of their recoller (b)(4) will require (b)(4) to b in increased quantities. (b)(4) en	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  drug producategory). holds a contraquirements. As a regin supplying in spects demand to	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250 cucts: Morphine act with (b)(4);(b) esult of exhaus 2015. (b)(4) be approximate	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481 Sulfate and (x)(7)(E) thing inventory has already ely 4,000 to 6,	from
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph Codeine Pho Morphine sa (b)(4),(b)(7)(E another supplied initing kg salt due in	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  ine is the starting material for two osphate (via morphine for conversion des have increased over 2014. (b)(4)  requiring supply of 80% of their recoller (b)(4) will require (b)(4) to b ial, un-forecasted quantities. (b)(4) en part to base business not previously	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  drug producategory). holds a contraquirements. As a regin supplying in spects demand to	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250 cucts: Morphine act with (b)(4);(b) esult of exhaus 2015. (b)(4) be approximate	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481 Sulfate and ()(7)(E) ting inventory has already	from
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph Codeine Photo Morphine sa (b)(4),(b)(7)(E another supplied initing supplied initing supstitution	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 as kgB  Total Morphine for Conversion  9300  Morphine for Conversion for  Codeine  Morphine for Conversion for  oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  ine is the starting material for two osphate (via morphine for conversion des have increased over 2014. (b)(4)  requiring supply of 80% of their recoller (b)(4) will require (b)(4) to b in increased quantities. (b)(4) en	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  drug producategory). holds a contraquirements. As a regin supplying in spects demand to	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250 cucts: Morphine act with (b)(4);(b) esult of exhaus 2015. (b)(4) be approximate	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481 Sulfate and (x)(7)(E) thing inventory has already ely 4,000 to 6,	from
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph Codeine Photo Morphine sa (b)(4),(b)(7)(E another supplied initing salt due is substitution  (b)(4)  (b)(4)  Codeine Photo Cod	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  Codeine For Conversion for  Codeine  Morphine for Conversion for  Oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  ine is the starting material for two  posphate (via morphine for conversion  cles have increased over 2014. (b)(4)  requiring supply of 80% of their recoller. (b)(4) will require (b)(4) to b  in part to base business not previously for hydrocodone.  Odeine sales have increased significant	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  (4) drug producategory). Inolds a contrapairements. As a regin supplying in spects demand to a supplied by (b)(4) (atly compared to respect to the supplied by (b)(4)	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250  cucts: Morphine act with (b)(4),(b) esult of exhaus 2015. (b)(4) be approximate but also eccent years. Tr	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481 Sulfate and (0)(7)(E) sting inventory has already ly 4,000 to 6, driven by his may potential	from 000
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph Codeine Photo Morphine sa (b)(4),(b)(7)(E another supplied initing salt due is substitution  (b)(4)  (b)(4)  Codeine Photo Cod	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CODEINE - 9670 NET  CODEINE - 9300  Morphine for Conversion for  Oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  Inc is the starting material for two period on the starting supply of 80% of their recoller.  (b)(4) will require (b)(4) to be ital, un-forecasted quantities.  (b)(4) expression of the part to base business not previously for hydrocodone.  In part to base have increased significant to the rescheduling of hydrocodone.	Quota (kg) 38,999 31,199 6,366 5,417 13,463 24,097 403 19,546 16,769  (4) drug producategory). Inolds a contraguirements. As a regin supplying in spects demand to value supplied by (b)(4) atly compared to rand the movement	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250  cucts: Morphine act with (b)(4),(b) esult of exhaus 2015. (b)(4) be approximate but also eccent years. Tr	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481 Sulfate and (0)(7)(E) sting inventory has already ly 4,000 to 6, driven by his may potential	from 000
Procurement  Procurement  Manufacturing  Manufacturing  Manufacturing  Current Situation  CPS Morph Codeine Pho Morphine sa (b)(4);(b)(7)(E another supplied intit kg salt due is substitution  (b)(4)  Codeine Pho Codeine Ph	CPS-Morphine - 9670 NET  CPS-Morphine - 9670 as kgB  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  CPS-Codeine - 9670 NET  Codeine For Conversion for  Codeine  Morphine for Conversion for  Oxymorphone  Morphine for Sale - 9300  Codeine For Sale - 9050  ine is the starting material for two  posphate (via morphine for conversion  cles have increased over 2014. (b)(4)  requiring supply of 80% of their recoller. (b)(4) will require (b)(4) to b  in part to base business not previously for hydrocodone.  Odeine sales have increased significant	Quota (kg)  38,999  31,199  6,366  5,417  13,463  24,097  403  19,546  16,769  (4) drug producategory).  holds a contrapirements. As a regin supplying in spects demand to various supplied by (b)(4)  attly compared to read the movement stomer, (b)(4)	Quota(kg) 80,000 64,000 9,988 8,500 24,500 10,634 403 26,000 28,250  cucts: Morphine act with (b)(4).(b) esult of exhaus 2015. (b)(4) be approximate but also recent years. Trut of physicians has requested	(kg) 41,001 32,801 3,622 3,083 11,037 24,097 403 6,454 11,481 Sulfate and 0)(7)(E) sting inventory has already by 4,000 to 6, driven by his may potentiate other schedules.	from 000 ally

# Page 1 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request -(b)(4);(b)(7)(E)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

- Tasman codeine sales slowly increase as US customers on board and [b)(4) international sites consume the Tasman API.[b)(4) has supplied [b)(4) historically since the Tasman introduction. In 2014 [b)(4) received qualification samples with bulk API delivered in 2015.[b)(4) will be requiring qualification material in 2015 with commercial volume in 2016.
- The requested quota increases will provide adequate morphine and codeine inventory to support our first quarter 2015 sales and will be under the 50% year-end level requirement.
- With the recent change to reporting CPS as net and with the increase API demand, the initial CPS Morphine and CPS Codeine procurement quota grant does not provide enough material to support the (b)(4) 2015 production plan for both morphine for sale and codeine for sale while allowing for adequate year-end inventory to support IQ2016. The CPS needed to produce the planned volumes of morphine and codeine can be found in Appendix A.

## Timing

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

## Quota Justification - Process Losses, Morphine Sales

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

Page 2 of 20 CONFIDENTIAL BUSINESS INFORMATION Procurement and Manufacturing Quota Increase Request — (b)(4),(b)(7)(E) CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050) May 14, 2015

Table I: 2015 Codeine for Sale YTD Sales and Forecast

2015 Coc	leine from Moi	phine S	ales, kg	Base			]
Customer	Reg #	Jan - April	May - June	July- · Sept	Oct- Dec	2015 Total	
(b)(4);(b)(7)(E)		0.1	,		-	0.1	
		-	44,4	88.8	-	133.2	
		0.1			•	0.1	1
		50.1	166.5	111.0	134.7	462.3	S and tent
1		-	•	<u>-</u> .			- Use diameter
		372.2	370.0	1,462.2(	1,446.7	3,651.2	not granted yet
		42.3	421.8	252.3		716.5	]
		1.0	•	0.7		1.7	]
		101.9	11.8	44.4	96.2	254,3	]
		0.2	<u> </u>		-	0.2	
		858.2	606.1	966.4	•	2,430.7	]
		75.5	-	18.5		94.0	
		2.2	-	· -	-	2.2	
		<u> </u>		<u> </u>	<del>-</del>	<u> </u>	
			-			•	
		111.0	111.0.	481.0	1,342.4	2,045,4	(5.878,533 granted)
		692.6	865.8	1,858.9	2,516.0	5,933.3	(5,8,18,200 dianged)!
		<u> </u>	<del></del>	<del></del>		<u> </u>	i i
Total	<del> </del> -	2,307.4	2,597.4	5,284.3	5 525 0	*****	<b>{</b> .
Intercompany Movement for				3,284.3	5,535.9	15,725.1	
testing	(b)(4);(b)(7)(E)	0.8	-		•		
2015.0	<u> </u>						
(b)(4);(b)(7)(E)	deine from Tas	man Sal	es, kg B	ase	——- <sub>¬</sub>		<b>}</b>
(U)(4),(U)(1)(E)		1,110.0	1,184.0	740.0	1,480.0	4,514.0	
		37.7	•	-	-	37.7	
		107.3			<u> </u>	107.3	
		0.0	706.0		470.0	0.0	
			296.0	<u> </u>	370.0	666.0	
Total		1,255.1	1,480.0	740.0	1,850.0	5,325.1	
Intercompany Movement for testing	(b)(4);(b)(7)(E)	0.5	-			J-200.1	

Page 3 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request – (b)(4),(b)(7)(E) CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050) May 14, 2015

Table II: 2015 Morphine for Sale YTD Sales and Forecast

Customer	Reg#	Jen -	May	July-	Oct-	2015
(b)(4);(b)(7)(E)		April	June	Sept	Dec -	Total
b)(4),(b)(1)(E)		0.5	-	-		0.5
		<u> </u>	<u> </u>			
			<u> </u>	-		•
		0.2	-	<u> </u>		0.2
		657.3	1,630.5	•	1,687.5	3,975.3
		<u> </u>	-	-		•
			<u>-</u>	-	-	-
		7.5	-	14.3		21.8
		·				-
		233.3	36.8	-	298.5	568.5
			-	600.0		600.0
		0.7	-		•	0.7
		86.4	95,3	150.0	-	331.6
		-	-	-	-	-
		-		-		-
		1.5		0.8	0.8	3.0
		-	-	-	159.0	159.0
		-	-	198.8	-	198.8
		150.0	-	150.0	225.0	525.0
			18.8	-	37.5	56.3
		73.0	-	60.0	•	133.0
			-	-	-	
		-	_	-		•
			-	-		•
			300.0	300.0	300.0	900.0
		-	9.0	-	-	9.0
		-	-		-	•
		3,369.4	-	4,500.0	750.0	8,619.4
		-		51,0	-	51.0
		22.1		-	-	22.1
			257.3	198.0	-	455.3
		83.0	-	-	<b>-</b>	83.0
		481.9	360.3	543.8	915.0	2,301.0
		3.8	-	-		3.8
		116.6	749.7	-	-	866.3
	1	F 407 1	2 457 5	67665	4 271 2	10 004 7
Total Intercompany Movement for testing	(b)(4);(b)(7)(E)	5,287.1 1.0	3,457.5	6,766.5	4,373.3	19,884.3

Page 4 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request - (b)(4);(b)(7)(E) CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050) May 14, 2015

## Inventory

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

Table III: CPS-Morphine Procurement Quota Request

	kg	Base	kg NET		
2015 CPS-Morphine Inventory Calculations	With Current Quota	Additional 2015 Grant	With Current Quota	Additional 2015 Grant	
2014 Ending Inventory	8,101	8,101	10,107	10,107	
Non saleable material	2	2	2	2	
2014 Available End. Inv.	8,099	8,099	10,105	10,105	
2015 CPS Quota kgB	31,199	64,000	38,999	80,000	
2015 Dispositions:					
Converted to AMA for Sale	30,110	30,110	37,638	37,638	
Converted to AMA for Conv	28,024	28,024	35,030	35,030	
2015 Ending Inventory	-18,836	13,965	-23,5 <u>6</u> 4	17,437	
Converted to % Yearend	-41.1%	30.5%			

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

Page 5 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request — (b)(4)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

Table IV: Morphine for Conversion Manufacturing Quota Request

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

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

Page 6 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request — (b)(4);(b)(7)(E)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

Table V: Morphine for Sale Manufacturing Quota Request

	Initial 2015 Grant	Additional 2015 Grant
2014 Ending Inventory	6,951	6,951
Non saleable material	_56	56
2014 Available End. Inv.	6,895	6,895
2015 API Quota	19,546	26,000
2015 Dispositions:		
Sales	19,884	19,884
Processing Losses	-2(3.931) <u>.</u> \$	(5,468)
2015 Ending Inventory	2,626	7,543
Converted to % Yearend	14.6%	41.9%

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

Page 7 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request — (b)(4);(b)(7)(E) CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

Table VI: CPS-Codeine Procurement Quota Request

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

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

Table VII: Codeine from Morphine for Sale Manufacturing Quota Request

	With Current Quota	Additional 2015 Grant
2014 Ending Inventory	2,372	2,372
Non saleable material	28	28
2014 Available End. Inv.	2,344	2,344
2015 API Quota	12,581	21,500
2015 Dispositions:		
Sales	15,725	15,725
Processing Losses	道(939)的联	33(1569) <u>3</u>
2015 Ending Inventory	-1,738	6,550
Converted to % Yearend	-13.0%	.49.0%

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

Page 8 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request -[b)(4);(b)(7)(E)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

Table VIII: Codeine from Tasman for Sale Manufacturing Quota Request

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

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

	Thank you in advance for considering this not hesitate to contact me at (b)(6)	request.	If you require a	equire any additional informatio		
(h)(	Best recards.		-			
(6)(	),(o)					
	Director Controlled Substance Compliance		•	-		

Page 9 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request — (b)(4),(b)(7)(E)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

Appendix A Morphine and Codeine Process Loss Information

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

		PROCESS LOSSES BASED ON 2014 YIELDS FOR CURRENT GRANT				ESTIMATE WITH ADDITIONAL QUOTA		
Description	Input to Step	Process Yield	Net output of step	Loss by step	Input to Step	Output of Step	Loss by step	
CPS-AMA Requirements								
CPS-AMA to Morphine for Sale	22,636	86,35%	19,546		7,474	6,454		
CPS-AMA to Morphine for Conv	7,657	85.64%	6,557		20,367	17,443		
TOTAL CPS-AMA kgB	30,293				27,842			

<sup>1</sup> Standard processing yields are used to determine output.

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

,		ESS LOSSES DS FOR CUI				IMATE V	
Description	Input to Step	Process Yield	Net output of step	Loss by step	Input to Step	Output of Step	Loss by step
Morphine for Sale			1		•		,
Morphine to Morphine Sulfate	19,546	80.13%	15,662	(3,884)	7,642	6,124	(1,518)
Morphine Sulfate Finishing	15,662	99.70%	15,615	(47)	6,124	6,105	(18)
Total				(3,931)		· .	(1,537)

Page 10 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request - (b)(4);(b)(7)(E)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

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

	PROCESS	LOSSES BA	SED ON 20 INT GRAN		S FOR		TMATE W	
Description	Input to Step	Process Yield	MWC	Net output of step	Loss by step	Input to Step	Output of Step	Loss by
CPS-AMA to Morphine for Conv	15,720	85.64%		13,463		12,304	10,537	
Codeine for Sale			<u> </u>					
Morphine for Conv to Codeine for Sale	13,493	88.8%_	1.05	12,581		9,566	8,919	•
Codeine(fr Morph) to Codeine Phosphate	12,581	93.60%		11,776	(805)	9,422	8,819	(603)
Codeine Phosphate Finished	11,776	99.28%		11,691	(85)	8,903	8,839	(64)
Total				[	(890)			(667)

APPENDIX A-4

Codeine for Sale (Tasman) 2015 Production and Estimated Process Loss, kg BASE

	PROCESS LOSS FOR (	ESTIMATE WITH ADDITIONAL QUOTA					
Description	Input to Step	Process Yield	Net output of step	Loss by step	Input to Step	Output of Step	Loss by
CPS-ACA to Codeine for Sale	4,986	84.0%	4,188		3,050	2,562	
Codeine for Sale		<u>.</u>	<u> </u>	ļ ·		ļ ·	<u> </u>
Codeine(fr CPS) to Codeine Phosphate	4,188	87.8%	3,677	(511)	2,692	2,364	(328)
Codeine Phosphate Finished	3,677	99.3%	3,650	(26)	2,364	2,347	(17)
Total				(537)			(346)

Page 11 of 20 CONFIDENTIAL BUSINESS INFORMATION



Procurement and Manufacturing Quota Increase Request – (b)(4)(b)(7)(E) CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050) May 14, 2015 Appendix B Purchase Orders (b)(4);(b)(6)

## Page 12 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request - (b)(4),(b)(7)(E)
CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050) May 14, 2015 Appendix B Purchase Orders
(b)(4),(b)(6)

Page 13 of 20 CONFIDENTIAL BUSINESS INFORMATION

May 14, 2015 Appendix B Purchase Orders (b)(4);(b)(6)

Procurement and Manufacturing Quota Increase Request -(b)(4);(b)(7)(E) CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for

Sale (9300) and Codeine for Sale (9050)

Page 14 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request – (b)(4);(b)(7)(E)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050) May 14, 2015 Appendix B Purchase Orders (b)(4);(b)(6);(b)(7)(E)

Procurement and Manufacturing Quota Increase Request — (b)(4),(b)(7)(E) CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

Appendix B Purchase Orders

(b)(4);(b)(6);(b)(7)(E)	
(~/,·/,(~/,(~/,(~/, /, /, /, /, /, /, /, /, /, /, /, /, /	

CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request — (b)(4),(b)(7)(E)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

Appendix B Purchase Orders

Page 17 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request – (b)(4),(b)(7)(E)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050) May 14, 2015

Appendix B Purchase Orders

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

Page 18 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request – (b)(4),(b)(7)(E)

CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

Appendix B Purchase Orders

(b)(4);(b)(6);(b)(7)(E)	
N // N-N-N-N-/	

Page 19 of 20 CONFIDENTIAL BUSINESS INFORMATION

Procurement and Manufacturing Quota Increase Request — (b)(4),(b)(7)(E) CPS Morphine (9670), CPS Codeine (9670), Morphine for Conversion (9300), Morphine for Sale (9300) and Codeine for Sale (9050)

May 14, 2015

Appendix B Purchase Orders

(b)(4);(b)(7)(E)	٠,	
(D)(4),(D)(7)(E)		Т
		١
		- 1
		١
		١
		-
		-
		١
		- 1
		-
		-
		-
		-
		-
		1
		1
		1
		1
		1
		1
		1
		1
		1
		Т
		1
		ı
		ı
		ı
		ı
		ı
		ı
		ı
		ľ
		ı
		l

Page 20 of 20 CONFIDENTIAL BUSINESS INFORMATION ma: 9601-0

PO Tobal(CM+PD):

2015 Revised APQ Worksheets

FDA Est:

-.008 -.01

Company DE/	A Hum	2016 MQ Request	2015 MG	2014 Salou	2014 Yotal Sales	% of 2014 Sales	Share of 2015 Total PO	2014 Investory	2015 Projected Exports	Cate Using CFR 30% Invent	Calc Using CFR 50% Invent	Similar.
(b)(4);(b)(7)(E)		5.000	5.000	0.000	1,190,169,467	0,000	0.000		0.000	-0,100		
(3)(1),(3)(1)(2)		200,000.000	153,669.000	39,813,000		0 033	37,833.824	55.805.000	0.000	-8.621,029	1,440.530	-1000
		216,000,000	136,000,000	112,060,000	1,190,169,487	0.004	106,508,301	6,740,110	180,000,000	311,720.682		_
		2.000	2.000	0.487	1,190,189,467	0.000	0.444	2.282	0.000	-1,705	-1.811	
		13,330.000	10,690,000	10,174,000	1,190,189.467	0.009	9,668.232			10,065,702		
		600,000,000	518,885,000	273,105,000	1,190,199.467	0.229	259,528,459		0.000	-49,737.004	5,562,623	
		990,000,000	631,515,000	738,630,000		. 0.821	701,919,925			1,010,620,903		
	- 1	3,000,000	0.000	0.000	1,190,189,467	0.000	0.000			0.000	0.000	
		43,000,000	25,000,000	16,358,000		0.014	15,544,814			8,048,259	9,360,518	
	- 1	13,500,000	0.000	0,000	1,190,169,467	0.000	0.000	0.000	0.000	0.000	0.000	
					-44			0.000	0.000		0.000	0.000
NG Totafa:		2,077,637.000	1,675,746.000	1,190,169.467				699,090.492	511,081.000	1,282,295,706		0.000

Final Initial APQ: 1,720,000,000 Proposed Revised: 1,840,000.000 Proposed Revised (with 25% buffer): 2,500,000.000 Final Revised APQ: 0.000 MQ Need\_PCT 1,5 - Rayland MQ - Inventory: -676.330,492 2014 Initial APQ: 1,687,000,000 FDA Eet = 2014 APQ \* (t + FDA Eet): 1,676,540,600 IMS Eat = 2014 APO 1 (T + IMS Eat): 1,689,961.300

-883,539,125

CFR 50%:

Pending requests from:

| Company | DEA Num | 2915 MG Request | Current MG | possible grant | (b)(4);(b)(7)(E) | 290,000,000 | 637,615.000 | 990,000,000 | 3,000,000 | 0,000 | 400,000 |

1,131,004,000

difference

158.485.000 (ref # 123233; should be granted 158kg but limited to 40kg by APQ) 400.000 (ref # 123549; granted .4kg)

115,685,000 lctal

1,254.000 remaining APO



Basic Class: 9149-8
PG Total(CN4-PD):

2015 Revised APQ Worksheets

FOA Eat: MS Eat: -.018 .012

Company	DEAMorn	2015 MD Request	2015 MQ	2014 Sales	2014 Total Sales	% of 2014 Sales.	Share of 2015 Total PO	2014 Inventory	2015 Projected Exports	Cate Lieing CFR 30% Inwest	Calc Galog CFA 50% Invent	First MO
		10.000	10,000	0.000	75,172,840,417	0.000	9. <b>g</b> an	1.635	0.000	-1.635	-1.635	0.000
(b)(4);(b)(7)(E)		60,000	60.000	6.417	75,172,840.417	0.000	7.597	800,029	0.000	•790.153	-766.429	0.000
		6,425,000,000	4,842,015,000	263,725,000	75.172.640.417	0,004	235,019,231	118,390.000	0.000	191,035.000	245,065.268	0.000
		100,000,000	100,000,000	0.000	75,172,640,417	0.000	0.000	0.000	0.000	0.000	8.000	0,000
		5,100,000,000	1,350,000,000	9.000	76,172,840.417	0.000	0.000	0.000	0.000	9.000	9.000	0 000
		4.050.000.000	2.460,622,000			0.018	1,193,471.809	384,873.000	0.000	1,166,840.092	1,457,767.761	0.000
		15,900,000,000	18,900,000,000			0,103	•		0.000	-5,493,865,237	-3,913,367.363	0.000
		89.002.000.000	e5.470,000,000			0.627	42,660,740,995	19,579,710,000	0.000	35,749,253,293	45,410,527.743	0.000
		2,000.000	2,000,000	0.000	, -	0,000	0.000		0.000	0.000	0.000	0.000
		1 '				0.241	16,331,599,380		4,800,000.000	16,693,147.194	20,400,414.975	0.000
		18,536,000,000		619,760.000		0.000	559,296,681	822,934,000	0.000	104,151.688	231,111.852	0.000
		4,516,000,000	2,610,000.000	GI W, NOU.DOD	23,172,040,411	V	210,200,000			•		
HQ Yotals:		123,633,070.000	108,937,707.000	75,172,640.417				44,589,513.664	4,800,000.090	48,429,770.240		0.000

Firei Initial APQ:

110,000,000.000

Proposed Revised: 111,320,000,000 (IMS pct chg)

Proposed Revised (with 25% buffer): 139.150,000,000

Final Rayland APG: 0,000

MO NeedsPO\* 1.5 - Revised MQ - Inventory: 49,738,816,180

2014 Initial APO: 110,500,000.000
FDA Eat = 2014 APO \* (1 + FDA Eat): 117,349,000,000

FDA Eat = 2014 APO \* (1 + FDA Eat): 117.349,000,000

BIS Eat = 2014 APO \* (1 + Bis Eat): 120,934,000,000

Pending Requests:

| Company | DEA Num | 2015 MO Request | current MO | possible grant | difference | (b)(4);(b)(7)(E) | 5,100,000.000 | 1,350,000.000 | 17,270,000.000 | 3,750,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,000.000 | 2,987,0

67,845,603.003

6,717,000.000

-47,007,000,608

CFR 50%

3,062,293.000 current available APQ

3,654,707,000 difference

OXYCODONE (FOR SALE)

	Sum of Drug Amount 1 Current Quota
<b>Row Labels</b> (b)(4);(b)(7)(E)	Sum of Drug Amount 1 Current Crusta
	1,338.322
	18.184
	881,350.943
	102,201.000
	80,685,000 4,053,555
	2,273.000 - 5,910
	454,600
	37.922
	2.278
	181,525.113 874,312
	15,240.500 181,373
	6,705.350
	512.370 125,000
	7.465
	229.067
	40,923.092 574,200
	26.385
	27.462
	991.529 5,720
	290.035
Grand Total	1,314,839.617 5814,160

2015 Revised APQ Worksheets

Banic Class: 9739-0 PO Total(CHI+PDE

2,078,000

FDA Eac .057 BES Eet: .037

	ompany DEA Num	2015 MQ Request	2016 MQ	2014 Sales	2014 Total Gales	% of 2014 Sales	Share of 2015 Total PQ	2014 knyentory	2016 Projected Exports	Calc Using CFR 20% Invent	Calc Using CFR 50% Invent	Firet MO
(b)(4);(b)(7)(E)		5.000	5.000	0.000	450.789	0.000	0.000	G.000	0.000	0.000	0.000	0.000
1		1,300.000	1,156,000	D.000	459,789	<b>D.000</b>	0.000	0.000	0.000	0.000	0.000	0.000
1		5.000	5,000	0.000	459.789	0.000	0.000	0.000	0.000	9.000	0.000	0,000
l		1,620,000	1,620.000	459.000	459,789	0.996	2,074.434	2,055.000	0.000	<b>641,764</b>	652,793	0.000
		1,000.000	0.000	0.000	459.789	0.000	0.000	483.945	0.000	-483,945	-463.845	0.000
		5.000	5.000	0.769	459.789	0.002	3,568	4,016	0.000	4.618	4.637	0.000
MQ Totale:		4,135.000	2,990.000	459.769				2,538.963	0.000	162,437		0.000

Final Initial APQ: Proposed Revised: 3,000,000 3,350,400

Proposed Revised (with 25% buffer):

4,185,000 (4,200 rounding up)

Final Revised APQ:

0.000

MQ Noed:PQ\* 1.5 - Revised MQ - Invertory:

-2,411.983

2014 Initial APC:

3,000.000

FDA Est = 2014 APQ 1 (1 + FDA Est):

3,172,200

IMS Est = 2014 APQ \* (1 + IMS Est):

3,111.300

Pending Requests:

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

DEA Hum 2015 MO Request 2015 MG

1,300,000 1,155,000 quota granted was short 200g; ref P 121501

CFR 60%:

-2,816.516

# 2015 Proposed Adjusted Aggregate Production Quotas and Assessment of Annual Needs

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish
  limits on the production of schedules I and II controlled substances. This responsibility has since
  been delegated to the Administrator of the Drug Enforcement Administration (DEA), who has redelegated this responsibility to the Deputy Administrator of the DEA.
- The attached Federal Register notice, prepared for your signature, proposes to adjust the calendar
  year 2015 aggregate production quotas (APQ) for each basic class of schedule I and II controlled
  substances and assessment of annual needs (AAN) for the list I chemicals ephedrine,
  phenylpropanolamine, and pseudoephedrine for which the United States has medical, scientific,
  industrial, export, and reserve stock requirements.
- As stated in the 2013 Federal Register Notices, DEA continues to add an additional 25% to the APQ
  for schedule II substances and those schedule I substances that are used to produce drugs that have a
  medical need (specifically, GHB and tetrahydrocannabinols) to prevent potential drug shortage
  issues.
- The Federal Drug Administration (FDA) has responded to DEA's annual letter, which requests information on new, continuing, and discontinued drug products containing schedule II substances. Therefore, this information is considered in the analysis for the current proposed adjustments.
- Expeditious review and publication of this notice is necessary to ensure an uninterruptable supply of schedule I and II controlled substances as well as list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for the legitimate medical, scientific, industrial, and export requirements of the U.S.
- The following points provide brief explanations of the changes from the proposed initial AAN & APQ values:

## List i chemicals

No changes proposed.

## Schedule I substances

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

OD/ODO/ODEO

5/19/15

Page - 1 - of 2

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

- The APQ for Para-Fluorofentanyl, Parahexyl, and Pholodine were increased from zero due to requests to manufacture these substances for analytical standards, reference, and research material.
- The APQ for Tetrahydrocannabinols was increase due to increased product development efforts by DEA registered manufacturers.

## Schedule II substances

- The APQ for Dextropropoxyphene, Levomethorphan, Meperidine-Intermediate B, and Phencyclidine were increased due to increased registrant requirements. The manufacturing of these substances will be used for analytical standards, reference, and research material. New DEA registrant(s) entering the reference standard market at the bulk manufacturing level.
- The APQ for Codeine (for sale) is proposed to increase based on analysis of IMS Health Data, which shows an increase in prescription sales that appears to coincide with the rescheduling of FDA approved hydrocodone products from schedule III to schedule.
- The APQ for Fentanyl is proposed to increase based on a DEA registered bulk manufacturer's improvement of their synthesis route to manufacture fentanyl from ANPP.
- The APQ for Methylphenidate is proposed to increase based on the FDA downgrading the efficacy rating for two generic manufacturers of the brand Concerta®. This change is to allow the remaining authorized generic and brand manufacturers to supply the entire domestic market. This will avert a possible shortage due to APQ limitations.
- The APQ for Oxycodone (for sale) is proposed to increase based on additional product development efforts as dosage form manufacturers qualify a second supplier of API as required by the FDA.
- The APQ for Remifentanil was increased due to new applications from registrants conducting bulk API product development efforts or supporting dosage form manufacturers in dosage form product development efforts.

OD/ODQ/ODEQ

5/19/15

Page - 2 - of 2

## DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-411]

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II
Controlled Substances and Assessment of Annual Needs for the List I Chemicals
Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

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

**ACTION:** Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2015 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

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

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

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

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

## SUPPLEMENTARY INFORMATION:

## Posting of Public Comments

All comments received are considered part of the public record and will be made available for public inspection online at <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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

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

comment. You must also prominently identify the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

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

### Legal Authority

Section 306 of the Controlled Substances Act (CSA), 21 U.S.C. 826, requires the Attorney General to determine the total quantity and establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA pursuant to 28 CFR 0.100(b). The Administrator, in turn, has redelegated that authority to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

The DEA published the established aggregate production quotas for schedule I and II controlled substances and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine for 2015 in the *Federal Register* (79 FR 53216) on September 8, 2014. That notice stipulated that, in accordance with 21

CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

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

The DEA proposes to adjust the established 2015 aggregate production quotas for certain schedule I and II controlled substances to be manufactured in the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes. The DEA also proposes to adjust the established 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported to the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks.

In proposing the adjustment, the DEA has taken into account the criteria that the DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine by considering: (1) changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, and changes in the rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for the class; (2) whether any

increased demand for that class or chemical, the national and/or individual rates of net disposal of that class or chemical are temporary, short term, or long term; (3) whether any increased demand for that class or chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota; (4) whether any decreased demand for that class or chemical will result in excessive inventory accumulation by all persons registered to handle that class or chemical; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Deputy Administrator finds relevant.

The DEA also considered updated information obtained from 2014 year-end inventories, 2014 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to the DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed adjusted 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 established assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

As described in the previously published notice establishing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in

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

The Deputy Administrator, therefore, proposes to adjust the 2015 aggregate production quotas for certain schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudocphedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Established 2015 Quotas	Proposed Adjusted 2015 Quotas (g)
Schedule I	<u> </u>	(g)
(1-Pentyl-1 <i>H</i> -indol-3-yl)(2,2,3,3-		
tetramethylcyclopropyl)methanone (UR-144)	15	25
[1-(5-Fluoro-pentyl)-1 <i>H</i> -indol-3-yl](2,2,3,3-	15	25
tetramethylcyclopropyl)methanone (XLR11)		
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-	15	no change
yl)methanone (THJ-2201)		
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one	15	25
(butylone) 1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one		<u> </u>
(pentylone)	15	25
1-(1-Phenylcyclohexyl)pyrrolidine	10	no change
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	no change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	no change
!-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45	no change
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45	no change
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR- 18 and RCS-8)	45	no change
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45	no change
1-Methyl-4-phenyl-4-propionoxypiperidine	2	no change
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45	no change
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45	no change
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45	no change
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45	no change
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45	no change
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45	no change
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45	no change
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30	no change
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30	no change
2-(2,5-Directhoxy-4-methylphenyl)ethanamine (2C-D)	30	no change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30	no change
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30	no change
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe;	15	25

25B; Cimbi-36)		
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	no change
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30	no change
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2- methoxybenzyl)ethanamine (25I-NBOMe; 2C-I- NBOMe; 25I; Cimbi-5)	15	no change
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15	no change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change
2,5-Dimethoxy-4-n-propylthiophenethylamine	25	no change
2,5-Dimethoxyamphetamine	25	no change
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30	no change
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30	no change
3,4,5-Trimethoxyamphetamine	25	no change
3,4-Methylenedioxyamphetamine (MDA)	55	no change
3,4-Methylenedioxymethamphetamine (MDMA)	50	no change
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	no change
3,4-Methylenedioxy-N-methylcathinone (methylone)	50	no change
3,4-Methylenedioxypyrovalerone (MDPV)	35	no change
3-Fluoro-N-methylcathinone (3-FMC)	15	25
3-Methylfentanyl	2	no change
3-Methylthiofentanyl	2	no change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	no change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	no change
4-Fluoro-N-methylcathinone (4-FMC)	15	25
4-Methoxyamphetamine	100	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-Methyl-N-ethylcathinone (4-MEC)	15	25
4-Methyl-N-methylcathinone (mephedrone)	45 .	no change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	. 15	25
5-(1,1-Dimethylheptyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-3-hydroxycyclohexyl]-phenol	68	no change
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-	53	no change

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

Fenethylline	5	no change
gamma-Hydroxybutyric acid	70,250,000	no change
Heroin	25	50
Hydromorphinol	2	no change
Hydroxypethidine	2	no change
Ibogaine	5	no change
Lysergic acid diethylamide (LSD)	35	no change
Marihuana	658,000	no change
Mescaline	25	no change
Methaqualone	10	no change
Methcathinone	25	no change
Methyldesorphine	5	no change
Methyldihydromorphine	2	no change
Morphine methylbromide	5	no change
Morphine methylsulfonate	5	no change
Morphine-N-oxide	350	no change
N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4- fluorobenzyl)-1H-indazole-3-carboxamide (AB- FUBINACA)	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1- (cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA)	15	no change
N,N-Dimethylamphetamine	25	no change
Naphthylpyrovalerone (naphyrone)	15	25
N-Benzylpiperazine	25	no change
N-Ethyl-1-phenylcyclohexylamine	5	no change
N-Ethylamphetamine	24	no change
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Noracymethadol	2	no change
Norlevorphanol	52	no change
Normethadone	2	no change
Normorphine	18	40

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

Hydrocodone (for sale)	99,625,000	no change
Hydromorphone	7,000,000	no change
Isomethadone	5	no change
Levo-alphacetylmethadol (LAAM)		no change
Levomethorphan	5	30
Levorphanol	7,125	no change
Lisdexamfetamine	29,750,000	no change
Meperidine	6,250,000	no change
Meperidine Intermediate-A	. 6	no change
Meperidine Intermediate-B	. 11	32
Meperidine Intermediate-C	6	no change
Metazocine	19	no change
Methadone (for sale)	31,875,000	no change
Methadone Intermediate	34,375,000	no change
Methamphetamine	2,061,375	no change
[1,250,000 grams of <i>levo</i> -desoxyephedrine for use in 750,000 grams for methamphetamine mostly for congrams for methamphetamine (for sale)]	nversion to a schedule III produc	t; and 61,375
Methylphenidate	83,750,000	87,500,000
Morphine (for conversion)	91,250,000	no change
Morphine (for sale)	62,500,000	no change
Nabilone	18,750	no change
Noroxymorphone (for conversion)	17,500,000	no change
Noroxymorphone (for sale)	1,475,000	no change
Opium (powder)	112,500	no change
Opium (tincture)	687,500	no change
Oripavine	35,000,000	no change
Oxycodone (for conversion)	8,350,000	no change
Oxycodone (for salc)	137,500,000	139,150,000
Oxymorphone (for conversion)	29,000,000	no change
Oxymorphone (for sale)	7,750,000	no change
Pentobarbital	35,000,000	no change
		-
Phenazocine	6	no change
Phenazocine Phencyclidine	6 19	no change
<u> </u>		_ <del></del>

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

The Deputy Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2015 aggregate production quotas and assessment of annual needs as needed.

#### Comments

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

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

Dated:

John J. Riley, Acting Deputy Administrator.

OC:	
OD:	
OD/D:	
ODX:	
ODXS:	
ODW:	
ODW <sub>Analyst</sub> :	
ODQ:	
ODQ:(b)(6)	(date)
SBF-CM # ODEQ	
S:\ODQ\Federal Register\	



Dated: July 1, 2015. Robert W. Middleton,

Deputy Chief, Office of Offshare Regulatory Programs.

[FR Doc. 2015-16675 Filed 7-7-15: 8:45 am] BILLING CODE 4310-VH-P

#### **DEPARTMENT OF JUSTICE**

Drug Enforcement Administration [Docket No. DEA-418P]

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

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

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2015 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 7, 2015. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-418P" on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to http://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully

submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

#### SUPPLEMENTARY INFORMATION:

#### Posting of Public Comments

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

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

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made available in the public docket. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

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

#### Legal Authority and Background

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

The DEA established the 2015 aggregate production quotas for substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, and phenylpropanolamine on September 8, 2014 (79 FR 53216). That notice stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

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

The DEA proposes to adjust the established 2015 aggregate production quotas for certain schedule I and II controlled substances to be manufactured in the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes. The DEA is not proposing to adjust the established 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported into the United States in 2015 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks.

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

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

The DEA also considered updated information obtained from 2014 year-end inventories, 2014 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development,

and other information made available to the DEA after the initial aggregate production quotes and assessment of annual needs had been established. Other factors the DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed adjusted 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 established assessment of annual needs [74 FR 60294, Nov. 20, 2009, and 75 FR

79407, Dec. 20, 2010, respectively). As previously described in the published notice establishing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers, 21 CFR 1303.24, may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 626(a), as intended. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate

public need. As such, the DEA has included in all proposed adjusted schedule II controlled substance aggregate production quotas, and certain proposed adjusted schedule I controlled substance aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting adjusted established aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Acting Administrator, therefore, proposes to adjust the 2015 aggregate production quotas for certain schedule I and II controlled substances expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2015 Quotas	Proposed Adjusted 2015 Quotas
(9)		(g)
Schedule I		
1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15	25
1-(5-Fluoro-pentyl)-1/Findol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15	25
1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15	no change
-[1,3-Benzodioxol-5-yl]-2-(methylamino)butan-1-one (bulylone)	15	25
-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15	25
-(1-Phenylcyclohexyl)pyrrolidine	10	no change
-(5-Fluoropentyl)-3-(1-naphthoyl)indote (AM2201)	45	no change
-(5-Fluoropentyl)-3-(2-lodobenzoyl)indole (AM694)	45	no change
-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change
-[2-(4-Morpholinyl)ethyl)-3-(1-naphthoyl)indole (JWH-200)	45	no change
-Butyl-3-(1-naphthoyf)indole (JWH-073)	45	no change
-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indote (SR-18 and RCS-8)	45	no change
-Hexyl-3-(1-naphthoyi)indole (JWH-019)	45	no change
-Methyl-4-phenyl-4-propionoxypiperidine	2	no change
-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45	no change
-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45	no change
-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45	no change
-Pentyl-3-(4-chlorg-1-naphthoyl)indole (JWH-398)	45	no change
-Pentyl-3-{4-methyl-1-naphthoyl)lincole (JWH-122)	.45	no change
-Pentyl-3-[(4-melhoxy)-benzoyi]indole (\$R-19, RCS-4)	45	по спалде
-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45	no change
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30	no change
-(2.5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30	no change
-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30	no change
-(2,5-Dimethoxy 4-nitro-phenyl)ethanamine (2C-N)	30	no change
-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30	no change
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-N8OMe; 2C-B-N8OMe; 25B: Cimbi-36).	15	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	no change

Basic class	Established 2015 Quotas	Proposed Adjusted 2015 Quotas
במשוע עומשט	(g)	. (g)
(4-Chtoro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe;	15	25
acc. Cimbi 49)	<b>an</b>	
to be de the complete of the c	30	no change
(4-lodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (251-NBOMe; 2C-I-NBOMe; 251;	15	no change
Cimbi-5	15	no change
Methylamino)-1-phenylpentan-1-one (pentedrone)	25	no change
5-Dimethoxy-4-enyramphetamina (BOE1)	25	no change
E Dimothaviamohatamina	25	no change
ta /Ethylikio\-0 6-dimethery/henyllelhagamige (2C−1−2)	30	no change
A. decoropylithiol-2 5-dimethoxyohenvilethanamine (2C-T-4)	30 25	no change no change
K.Trimethorusmnhetamine	55 55	no change
Methylenedioxyamphetamine (MDA) Methylenedioxymethamphetamine (MDMA)	50	no change
4-Methylenedioxymethamphetamine (MDMA) 4-Methylenedioxy-A-ethylamphetamine (MDEA)	40	no change
4-Methylenedioxy-A-methylcathinche (methylone)	50	no change
Mathulanadiovernerouglerone (MDPV)	35	no change
Stuare Al methylesthinese (3-FMC)	15	25
Mothulfentany	2	no change
Methylthjofontanyl	2 25	no change no change
Promo 2 5 dimethoryamphetamine (ROB)	25 25	no change
Bromo-2,5-dimethoxyphenethylamine (2–CB)	15	25
Fluoro-N-methylcathinone (4–FMC)	100	no change
Methoxyamphetamine	25	no change
Methyl-2,5-dimethoxyamphetamine (DOM) Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
Methylaminorex  Methyl-N-ethylcathinone (4-MEC)	15	25
Market At mathebrathings (monhadrons)	45	no change
Mothyll a pyrolidingsroploshegge (4-MePPP)	15	25 .
read the second of the DOCA Substitution of the DOCA Substitution of the State of t	68	no change
(1,1-Dimotrlyinephyl-2-[[17,35]-3-hydroxycyclohexyl]-phenol (cannabicyclohaxanol or CP-47,497	53	no change
C0 homology	25	no change
Methoxy-3,4-methylenedioxyamphetamine	25 25	no change
Methoxy-N,A-diisopropythyptamine	25	no change
Methoxy-N,N-dimethyltryptamine	2	no change
atyl-afphe-methyllentanyl	2	no change
petylmethadal	2	no change
t dans diese	2	no change
phacehimethadol	2	no change
aha. Ethultootamine	25	no change
shamastadina	2	no change no change
shamothadol	2	no change
pha-Methylfentanyl	2	no change
pha-Methylthiofentanyl	25	
pha-Methyltryptamine (AMT) pha-Pyrrolidinobutiophenone (α-PBF)	15	
aba Digeolidingnantinghanga (a-PVP)	15	
minorex	25	
annimornina	2	
etacety/methadol	2	
ata. Hydroxy. 3-methylfediany	2	
ota Hudzovidonianul	. 2	
etamentotine		no change
etamethadol	2	no change
etaprodine	3	
ufotenina	70	
odeine methylbromide	· 5	
adeine Maride	305	Y
accomombine	5	1
inthidinatemina	25	
ifonavia	11,000 3,990,000	
in demonstrate	3,990,000	
imethyltryptamine	ا ا	
TEL PORADA		no change
phanote		
emma-Hydroxybutyric acid	70,250,000	_

Basic class	Established 2015 Quotas	Proposed Adjusted 2015 Quotas
	(9)	· (g)
lydroxypethidine	. 2	no change
bogaine	5	no change
ysergic acid diethylamide (LSD)	35	no change
Aarihuana	658,000	no change
Aescaline	25	no change
delhaqualone	10	no change
Melhoathinone	25	no change
Methyldesorphine	5	no change
Aethyldihydromorphine	2	no change
Morphine methylbromide	5	no change
Morphine methylsulfonate	5	no change
Morphine-M-exide ,	350	no change
V-(1-Acamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15	25
v-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1#-indazole-3-carboxamida (ADB-PINACA)	15	25
V-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamide (A8–	15	25
	,,,	
FUBINACA). v.(1-Amino-3-methyl-1-oyohutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-	15	no change
A (1 Autume o them). I expected a 1) I (a) and a state of the state of	10	110 ottarige
CHMINACA).	15	no change
v-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA)	25	no change
V,N-Dimethylamphetamine	15	
Naphthylpyrovalerone (naphyrone)		
Y-Benzylpiperazine	25	no change
V-Eihyl-1-phenylcyclohexylamine	. 5	no change
V-Ethylamphetamine	24	no change
V-Hydroxy-3.4-methylenedioxyamphetamine	24	no change
Noracymethadol	2	no change
Norleyorphanol	52	no change
Normathadone	2	no change
Nomorphine	· 18	40
Para-fluorolenianyi	zero	5
Parahexyl	zero	5
Phenomorphan	2	no change
Photocodine	zero	5
Psilocybin	30	no change
Psilocyn	30	no change
Quinolin-8-yl 1-(5-fluoropentyl)-1/Hindole-3-carboxylate (5-fluoro-PB-22; 5F-P8-22)	15	
Quinolin-8-yi 1-pentyl-11-indole-3-carboxylate (P8-22; QUPIC)	15	25
Tetrahydrocannabinois	497,500	h .
Thiofentany	2	no change
Iniorentanyi	10	25
Tilidhe	l ž	
Frimeperidine		The stidings
Schedule II	<del></del>	<del></del>
I-Phonylcyclohexylamine	5	
f-Piperidinocyclohexanecarbonitrile	5	
1-Aniting-W-phenethyl-4-piperidine (ANPP)	2,687,500	
Alfentanil	17,750	
Nohaprodine		no change
Amobarbital	25,125	
Amphetamine (for conversion)	21,875,000	no change
Amphetamine (for sale)	37,500,000	no change
Cartentanii	19	no change
Cocaine	275,000	no change
Codeine (for conversion)	50,000,000	
Codeina (for sale)	49,500,000	l <del></del> -
Dextropropoxyphene	19	45
Ditydrocodeine	226,375	no change
Diphenoxylate (for conversion)	75,000	no change
Diphenoxylate (for sale)	1,337,500	no change
Ecgonine	174,375	no change
Ethylmorphine	3	
	2,150,000	
Fentanyl	2,,50,500	no change
Clarke National Re	137,500	no change
Hydrocodone (for conversion)		no change
Glutethimide	99,625,000	I no obcome
-tydrocodone (for conversion)	7,000,000	
Hydrocodone (for conversion) Hydrocodone (for sale) Hydromorphone Somethadone	7,000,000 5	no change
hydrocodone (for conversion) Hydrocodone (for sale) Hydrocodone (for	7,000,000 5 4	no change no change
lydrocodone (lor conversion)	7,000,000 5 4 5	no change

	Established	Proposed
	2015 Quotas	Adjusted 2015
Basic class		Quolas
·	(g) .	(9)
isdexamfetamine	29,750,000	no change
Meperidine	6,250,000	no change
Aeperidine Intermediate-A	6	no change
Reperidine Intermediate-8	11	32
Apperidine Intermediate-C	6	no change
Metazocine	19	no change
Nethadone (for sale)	31,875,000	no change
Methadone Intermediate	34,375,000	no change
Melhamphetamine	2,061,375	no change
1,250,000 grams of <i>levo</i> -desoxyephedrine for use in a non-controlled, non-prescription product; 750, conversion to a schedule III product; and 61,375 grams for methamphete	,000 grams for metha amine (for sale)]	imphetamine mostly t
Methylphenidate	83,750,000	87,500,000
Morphine (for conversion) ,	91,250,000	no change
Morphine (for sale)	62,500,000	no change
labilone	18,750	no change
Voroxymorphone (for conversion)	17,500,000	no change
COOXYMOLETIONE (IOI CONVESION)	1,475,000	no change
Voroxymorphone (for sale)	112,500	no change
pour (powder)	687.500	no change
Dium (tincture)	35,000,000	no change
Pripavine	8,350,000	no change
Dxycodone (for conversion)	137,500,000	139,150,000
Oxycodone (for sale)	29,000,000	no change
Oxymorphone (for conversion)	7,750,000	no change
Oxymorphone (for sale)		
Pentobarbital	35,000,000	no change
Phonazocine	6	no change 38
Phancyclidine	19	
Phenmetrazine	3	no change
Phenylacetone	9,375,000	no change
Pacemelhorphan	3	no change
Remifentanii	3,750	4,200
Secobarbital	215,003	no change
Sufentanii	6,255	no change
Fapentadol	12,500,000	no change
Thebaine	125,000,000	no change
List I Chemicals		•
Ephedrine (for conversion)	1,000,000	no change
-Digginic (or Contended) Administration of the contended	4,000,000	
Inhadring (for cala)		
phedrine (for sale)	I 44.800.000	
Ephedrine (for sale)	44,800,000 8,500,000	no change no change
Ephedrine (for sale)	44,800,000 8,500,000 7,000	no change no change no change

The Acting Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Acting Administrator may further adjust the 2015 aggregate production quotas and assessment of annual needs as needed.

### Comments

In accordance with 21 CFR 1303.13(c) and 1315.13(d), any interested person may submit written comments on or objections to these proposed determinations. Based on comments

received in response to this notice, the Acting Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.13(c) and 1315.13(e). In the event the Acting Administrator decides to hold such a hearing, the Acting Administrator will publish a notice of the hearing in the Federal Register. After consideration of any comments or objections, or after a hearing, if one is held, the Acting Administrator will issue and publish in the Federal Register a final order establishing any adjustment of the 2015 aggregate production quota for each basic class of controlled substance and established assessment of annual needs for the list I chemicals ephedrine. pseudoephedrine, and

phenylpropanolamine. 21 CFR 1303.13(c) and 1315.13(f).

Dated: July 1, 2015.
Chuck Rosenberg,
Acting Administrator.
(FR Doc. 2015–16699 Filed 7–7–15; 8:45 am)
BILLING CODE P

Drug	Company	Comment	Amount `	Response	Proposed APO	Davis d 4 DO	
codeine (for sale)	(b)(4)	increase APO	5,484,000	sufficient APO available	63,900,000	Revised APO 63.900,000	Change
codeine (for sale)		increase APO	6,636,000	sufficient APO available	see above	see above	
codeine (for sale)		increase APO	3,884,067	sufficient APO available	see above	see above	see above
fentanyl	<u>`</u>	increase APO	38,485	sufficient APO available	2,300,000		300 20040
gamma hydroxybutric acid	]	increase APO	_ 7.500	sufficient APO available	70,250,000		
hydrocodone (for sale)		increase_APO	1,830,000	sufficient APO available	99,625,000		
methadone	<b>」</b>	_increase APO	2,718,159	sufficient APQ available	31,875,000		
methadone intermediate		increase APO	1,800,634	sufficient APQ available	34,375,000		
methylphenidate		increase APQ	9,186,236	adjust APO	87,500,000		9,250,000
morphine (for conversion)		increase APO	4,499,987	sufficient APQ available	91,500,000		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
oripavine		increase APO	1,823,038	sufficient APQ available	35,000,000	35,000,000	
oxycodone (for sale)	.]	increase APO	2,510,000	adjust APO	139,150,000		2,225,000
oxymorphone (for conversion)		increase APO	3,190,000	sufficient APQ available	29,000,000		2,225,000
oxymorphone (for sale)		increase APO	150,000	sufficient APQ available	7.750,000		

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

5 12

12

CMEA Chemical	- Company	Comment	Amount	Response	Proposed AAN	Revised AAN	CL
	92:00:-11	. Comment	Alliegat	лесаронае	TTUDOSEG AAN	Revisco AAIN	Change
		_			1		

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

Additional Drug Considerations:

Drite	Response	Proposed	Revised	Change
dihydroetorphine	(b)(4) no available APQ drug code 9334	- 11070	3	CHAREC
ethylmorphine etorphine HCl	no available APQ, drug code 9190	3		
	no available APQ drug code 9059			
racemethorphan	ng available APQ drug code 9732			
racemorphan	no available APQ drug code 9733	<del></del>		
fentanyl	(b)(4) bending application # 123706, 123955	2,300,000	see above	see above
<del></del>				

#### Additional Chemical Considerations:

Drug	Response	Proposed	Revised	Change
				<del></del> -

<sup>.\*\*</sup> the proposed and revised values include 25% buffer for CII substances

AUG 1 0 2015

August 6, 2015

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

Subject: Docket No. DEA-418P

Dear Sirs:

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

We feel the proposed quantities for the material mentioned above are not sufficient to provide for adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements, and that the quotas should be increased to cover our needs. For these items an appropriate Electronic DEA Quota Application Form 189 will be submitted shortly pertaining to the items for which we are submitting comments.

Very truly yours

# **PUBLIC SUBMISSION**

As of: 8/7/15 10:21 AM Received: August 04, 2015 Status: DoNotPost

Tracking No. 1jz-8kda-10sr Comments Due: August 07, 2015 Submission Type: Web

Docket: DEA-2015-0011

Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List 1 Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

Comment On: DEA-2015-0011-0001

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

Document: DEA-2015-0011-DRAFT-0005

Comment on FR Doc # N/A

# **Submitter Information**

Name: [	(b)(6)		'ty
. L		<b>\</b>	

## General Comment

Re: Comments on Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015 on behalf of the following registrant:

(b)(4)	

Attachments

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

(b)(4)
August 4, 2015
Deputy Administrator Drug Enforcement Administration Washington, D.C. 20537
Attn: DEA Federal Register Representative [Docket No. DEA-418P]
This letter constitutes (b)(4) comments on the Proposed Revised Aggregat Production Quotas for 2015, as published in Federal Register on July 8, 2015, FR Volum 80, No. 130, pages 39156-39160. It should be considered to be Confidential Business Information.
In light of the fact that (b)(4) has no knowledge of either the amounts of any available aggregate quotas or DEA's planned allocation of any aggregate (b)(4) requests that DEA make any adjustments to the aggregate quotas sufficient to satisfy our requests for increased manufacturing quotas, which are outlined below. Because this comment contains proprietary information on our manufacturing quota needs, (b)(4) also requests that DEA treat this entire document as confidential.
All requests below are stated in grams anhydrous base ("AA").
9050 Codeine (for Sale)  (b)(4) requests that the revised aggregate be sufficient to include (b)(4)  request for 6,636,000 grams AA of codeine (for Sale) manufacturing quota for 2015, reference DEA online submission number 123843.
9801 Fentanyl  [b)(4)  requests that the revised aggregate be sufficient to include (b)(4)  request for 38,485 grams AA of fentanyl manufacturing quota for 2015, reference DEA online submission number 124116.
2010 Gamma Hydroxybutyric Acid  (b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 7,500 grams AA of gamma hydroxybutyric acid manufacturing quota for 2015 reference DEA online submission number 124113.

Contains Confidential and Proprietary Business Information

9250 Methadone  (b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 2,718,159 grams AA of methadone manufacturing quota for 2015, reference DEA online submission number 124112.
9170 Methadone Intermediate  (b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 1,800,634 grams AA of Methadone Intermediate manufacturing quota for 2015 reference DEA online submission number 124111.
9330 Oripavine  (b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 1,823,038 grams AA of oripavine manufacturing quota for 2015, reference DEA online submission number 124115.
All other quota requests remain unchanged from original request.
Sincerely,
(b)(6)
Supervisor, Controlled Substance Compliance
(b)(4) (b)(6)
(b)(4);(b)(6)

Supports

(b)(4)

Page 1 of 1

# **PUBLIC SUBMISSION**

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

Docket: DEA-2015-0011

Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

Comment On: DEA-2015-0011-0001

Proposed Adjustments to the Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015

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

# Submitter Information

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

General Comment

See attached file(s)

# Attachments

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



### **Confidential Business Information**

August 4, 2015

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

Docket No. DEA-418P Teva Pharmaceuticals Comment

Dear DEA Federal Register Representative,

Confidential	aggregate production quota for codeine (for sale), CSA code 9050. (b)(4) believes the proposed new level of 63.9 metric tons may not be adequate for the medical, scientific, research and industrial needs of the United States.
Business Information	Since the rescheduling of hydrocodone combination products from schedule III to schedule II in October 2015, the codeine combination products market has observed a significant increase in sales, specifically in sales of APAP/codeine combination tablets, which remain schedule III.
Confidential Business	(in terms of codeine base content). Our market share, per IMS, has remained relatively steady, indicating all manufacturers are observing similar increases in

Information

sales. Reference Table 1 for year-by-year APAP/Codelne tablet sales (kg codeine base).

is requesting DEA take into account our sales data (in kg codeine base),

Confidential **Business** Information

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

Administrative Offices:	•	•
(b)(4)		

# Confidential Business Information

	Table 1. (b)(4)	Codeine/APAP Co kg codeine base	mbination Tablet I kg codeine base	Historical and Projetics kg  codeine base	cted Sales in Terr kg codelne base	ns of Codeine Base Content kg codeine base	
	Year	2011 (actual)	2012 (actual)	2013 (actual)	2014 (actual)	2015 (Projected)	
Confidential Business Information	Sales	4556.151	4638.916	4633.833	4499.778	7822.236*	
	Notes		2011-2014 (b)(4) yearly codeine/APAP combination products sales average, in terms of codeine base content = 4582.169 kg.				
	*Projected sales	= 2015 sales (as of 30.	June2015) x 365 / day	of year = 3878.972 kg	x 365/181 = 7822.236		

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

# **Confidential Business Information**

# Docket No. DEA-418P

# 2014 and Projected 2015 Acetominophen/Codeine Tablet Sales

(b)(4)	
(D)(4)	
1	

	2014 54100		!	I			
		Polency	unita/bottle	Day of Year	Unit Sold	salt (kg)	base (kg)
	ACETAMINOPHEN & COOPINE TB 300/15KG 100	15	100	365	2,231	40.158	29.71
	ACETAMINOPHEN & CODEINE TB 300/30MG 100	. 30	100	365	18,133	580.779	429.770
	ACETAMINOPHEN & CODEINE TO 300/JOMG 1000	30	1000	385	8,842	3470.94	2568.496
	ACETAMINOPHEN & CODEINE TO 300/60MG 100	. 60		385	18,263	1314.924	<u>973.04</u>
	ACETAMINOPHEN & CODEINE TB 300/60MG S00	- 60	500	385	1,895	610.2	451.548
	ACETAMINOPHEN & CODEINE TO 300/60MG 1000	60	1000	385	89	63.78	47,197
	·—·				Total	6080.761	4499,771
al i	,						
	2015 Proj Salos (Jan-Jun Avg)						
		Polenty	units/bottle			satt	base
	ACETAMINOPHEN & CODEINE TB 300/15MG 100	15	100	Day of Year	18,750	50.668	bese
	ACETAMINOPHEN & CODEINE TB 300/15MG 100 ACETAMINOPHEN & CODEINE TB 300/30MG 100	15	100 100	Day of Year 181	18,750 183,638	50.668 1110.959	5858 37.493 822.110
	ACETAMINOPHEN & CODEINE TB 300/15MG 100 ACETAMINOPHEN & CODEINE TB 300/30MG 100 ACETAMINOPHEN & CODEINE TB 300/30MG 1000	15 - 30 30	100 100 1000	Day of Year 181 181 181	18,750 183,638 81,092	50,668 1110,959 4906,842	37.493 622.110 3830.32
	ACETAMINOPHEN & CODEINE TB 300/15MG 100 ACETAMINOPHEN & CODEINE TB 300/30HG 100 ACETAMINOPHEN & CODEINE TB 300/30HG 1000 ACETAMINOPHEN & CODEINE TB 300/60HG 100	15 - 30 30 60	100 100 1000 1000	Day of Year 181 181 181	18,750 183,638 81,092 228,516	50.668 1110.859 4906.842 2740.718	37.493 622.110 3830.32 2028.137
•	ACETAMINOPHEN & CODEINE TB 300/15MG 100 ACETAMINOPHEN & CODEINE TB 300/30MG 100 ACETAMINOPHEN & CODEINE TB 300/30MG 1000 ACETAMINOPHEN & CODEINE TB 300/60MG 100 ACETAMINOPHEN & CODEINE TB 300/60MG 500	15 - 30 30 60	100 100 1000 1000 500	Day of Year 191 181 181 181	18,750 183,638 81,092 228,516 19,352	50,668 1110,859 4906,842 2740,718 1170,743	37.493 822.110 3830.32 2028 137 868 349
••	ACETAMINOPHEN & CODEINE TB 300/15MG 100 ACETAMINOPHEN & CODEINE TB 300/30HG 100 ACETAMINOPHEN & CODEINE TB 300/30HG 1000 ACETAMINOPHEN & CODEINE TB 300/60HG 100	15 - 30 30 60	100 100 1000 1000 500	Day of Year 191 181 181 181	18,750 183,638 81,092 228,516	50,668 1110,859 4906,842 2740,718 1170,743	37.493 622.110 3830.32 2028.137

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

July 31, 2015

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

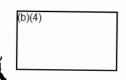
RE: Docket No. DEA-418P

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

Dear DEA Federal Register Representative:
herewith comment to a portion of the
above referenced Federal Register proposal. Specifically, (b)(4) believes that 2015 Proposed
Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of
Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine
for the listed drug codes below may not be adequate for the medical, scientific, research and
industrial needs of the United States.

Drug	Drug Code
Methylphenidate	1724
Codeine	9050
Morphine for Conversion	9300
Oxymorphone for Conversion	9652
Oxymorphone	9652

Regards,		
(b)(6)		
	'	
Director, Controlled Subst		



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

(b)(4)·(b)(6)		
(b)(4);(b)(6)		

July 15, 2015

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

Dear Federal Register Representative,

"PERSONAL IDENTIFYING INFORMATION" to be redacted is (b)(4) registration number (b)(4),(b)(7)(E) "CONFIDENTIAL BUSINESS (NFORMATION" to be redacted includes increased sales volumes from 694 kg (624 kg as base) in 2014 to 2,469 kg (2,222 kg as base) in 2015 and a 33% manufacturing loss. lis a registered manufacturer (b)(4);(b)(7)(E) of Oxycodone (for sale). (b)(4) providing comment to the Proposed Adjustments to the Aggregate Production Quota for 2015 for Oxycodone (for sale) based on the information provided below. On June 12, 2015. (b)(4) requested an increase of 3,514 kg in its 2015 Oxycodone (for sale) manufacturing quota over its then granted quota of 2,510 kg. On June 29, 2015, (b)(4) was only granted an increase of 1,004 kg "due to the limitations of the currently established aggregate production quota, no additional oxycodone (for sale) can be authorized at this time." was granted 502 kg for a new high ABUK process and 502 kg for our regular low impurity material. One batch of Oxycodone Base which consumes 502 kg of quota will yield ~375 kg (337.5 kg as base) of saleable Oxycodone HCl, Low Impurity material. (b)(4) 545 kg (490.5 kg as base) of low impurity sales for fourth quarter 2015 and currently has no saleable low impurity inventory. is requesting that the aggregate production quota for Oxycodone (for sale) be increased by 1,506 kg to allow (b)(4) to make three additional batches. These batches will

A table detailing customers' registration numbers, their actual year to date purchases, their open 2015 purchase orders and their forecasts for the balance of 2015 was provided to DEA with our quota request Reference # 123773.

be used to meet the balance of 2015 sales plus January through April 2016 sales of 1040 kg

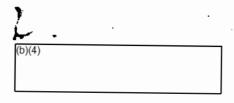
Santa de grande specielada

(936 kg as base).

(b)(4)

• •			
between the point the saleable product. The	at DEA requires (b)(4) nerefore, the additional	to count quota as	33% manufacturing loss consumed and the final be requested will only yield
		15 aggregate production rams to allow for its re	on quota for Oxycodone (fo quest,
If you have any ques directly.	tions or require addit	ional information, pleas	se feel free to contact me
Sincerely,			
(b)(4)			
(b)(6)			
DEA Compliance Manager		1	
(b)(6)			
(b)(6)			

7		
(b)(4)		
_	AUG 0 7 RECTO	•
	Drug Enforcement Administration Attn: DEA Federal Register Representative/ODL 8701 Morrissette Drive Springfield, VA 22152	(b)(4);(b)(6)
	August 5, 2015	
	Subject: Docket No. DEA-418P - Oxycodone (for sale) AM	IENDED
	Dear Federal Register Representative,	
<b>-</b>	"PERSONAL IDENTIFYING INFORMATION" to be redacted egistration number (b)(4),(6)  BUSINESS INFORMATION" to be redacted includes increase (624 kg as base) in 2014 to 3,862 kg (3,476 kg as base)	b)(7)(E) "CONFIDENTIAL" ed sales volumes from 694 kg 15 and a 33% manufacturing loss.
	providing comment to the Proposed Adjustments to the Aggreg for Oxycodone (for sale) based on the information provided be	gate Production Quota for 2015
	On June 12, 2015, (b)(4) requested an increase of 3,5 sale) manufacturing quota over its then granted quota of 2,510 was only granted an increase of 1,004 kg "due to the limitation aggregate production quota, no additional oxycodone (for sale)	s of the currently established
	was granted 502 kg for a new high ABUK process an impurity material. It is important to remember that there is an the point that DEA requires bid to count quota as consumproduct. Therefore, one batch of Oxycodone Base consumes 375 kg (337.5 kg as base) of saleable Oxycodone Hydrochlor	33% manufacturing loss between ned and the final saleable 502 kg of quota but yields only
	On July 27, (b)(4) received a purchase order for 1500 kg for quarter 2015. A copy will be provided to DEA with the quota a fourth quarter total 1,540 kg (1,386 kg as base) for low impurity has no saleable low impurity inventory.	pplication. Purchase orders for
	is requesting that the aggregate production quota for increased by 2,510 kg to allow (b)(4) to make five additional	Oxycodone (for sale) be al batches. These batches plus



the one batch granted at the end of June will yield ~2,250 kg of saleable product. See table below for inventory numbers.

Low Impl	rity	52
Open 2015 PO's	1540	kg
2015 Forecast	205	kg
2016 Q1 Sales	500	kg
Total Sales	2245	kg
Make 6 batches	2250	kg
Balance	5	kg

High/ABUK			
Make	375	kg_	
Sell	160	kg	
Available	215	kg	

A table detailing customers' registration numbers, their actual year to date purchases, their open 2015 purchase orders and their forecasts for the balance of 2015 was provided to DEA with quota request Reference # 123773. An updated version will be provided with the next quota request.

respectfully requests that the 2015 aggregate production quota for Oxycodone (for sale) be increased by at least 2,510,000 grams to allow for its request.

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

Sincerely,

	•
(b)(4)	
(b)(6)	
<b>DEA Compliance Manager</b>	1

(b)(6)

· Re	quest ID Status			DEA Number (b)(4);(b)(7)(E)	Соптрапу	Grug Name  4-ANILINO-N-PHENETHYL-4-	Orug Code	Quọta Year	Requested Quota		
	123712 Pending	U2-JUN-15	MAN			PIPERIDINE (ANPP)	8333-0	2015	235,400.000	215,000.000	28,400.000
	123843 New 124044 New	25-JUN-15 22-JUL-15				CODEINE (FOR SALE) CODEINE (FOR SALE)	9050-B 9050-B		20,000,000.000 27,251,000.000	13,363,697.000 21,767,000.000	6,636,303.000 5,484,000.000 12,120,303.000
	124116 New	04-AUG-15	MAN _			FENTANYL	9801-0	2015	910,000.000	871,515,000	38,485.000
o seen }		, ,		(b) (4) (b) (7) (F)			,				•
	123955 New	09-JUL-15	MAN	(b)(4);(b)(7)(E)		FENTANYC.	9801-0	2015	195,800.000	136,000.000	59,800.000 98,285.000
	124113 New	04-AUG-15	MAN			GAMMA HYDROXYBUTYRIC ACID	2010-0	2015	7,500.000	. 0.000	7,500.000
	104044 Dandina	10 00 15				International Control of the				·	
	124014 Pending					HYDROCODONE (FOR SALE)	9193-8		5,900.000	5,900.000	0.000
	124163 New	08-AUG-15	MAN			HYDROCODONE (FOR SALE)	9193-B	2015	2,461,653.000	1,241,653.000	1,220,000.000
	124112 New	04-AUG-15	MAN			METHADONE	9250-0	2015	14,100,000.000	11,381,841.000	2,718,159.000
	124111 New	04-AUG-15	MAN			METHADONE-INTERMEDIATE	9254-0	2015	16,000,000.000	14,199,366.000	1,800,634.000
										0	
۸ 💊	124036 Pending	22-JUL-15	MAN			METHYLPHENIDATE	1724-0	2015	28,187,000.000		237,236.000 237,236.000
	124042 New	22-JUL-15	MAN			MORPHINE (FOR CONVERSION)	9300-A	2015	23,501,000.000	19,001,013.000	4,499,987.000
	124961 New	23-JUL-15	MAN			NOROXYMORPHONE (FOR CONVERSION)	9658-A	2015	1,329,265.000	729,265.000	600,000.000
				b)(4);(b)(7)(E)		,					
•	124126 New	05-AUG-15		U,\T,\U)(1)(L)		ORIPAVINE	9330-0	2015	12,300,000.000	10,476,962.000	1,823,038.000
	124161 New	07-AUG-15	MAN			OXYCODONE (FOR SALE)	9143-B	2015	6,024,000.000	3,514,000.000	2,510,000,000 2,510,000.000
	124049 Pending	22-JUL-15	MAN			OXYMORPHONE (FOR CONVERSION)	9652-A	2015	5,456,000.000	2,268,000.000	3,190,000,000

Molecule	2012 KG	2013 KG	2014 KG	6months 2015 KG	est year 2015 KG	
CODEINE	22,756.7281	21,747.8088	21,719.2066	13,853.5453	27,707.0906	
HYDROCODONE	63,179.5151	61,711.0281	56,376.7266	24,594.5385	49,189.077	
HYDROMORPHONE	1,913.0402	1,927.6179	1,834.5971	852.8523	1705.7046	
MORPHINE	28,706.4431	26,272.7352	24,604.3908	11,924.7271	23,849.4542	
OXYCODONE	<b>66,7</b> 04.849	60,357.3128	58,914.83	29,802.5075	59,605.015	
OXYMORPHONE	1,958.2805	1,863,4005	1,930.5344	980.6512	1961.3024	
•	100 mg	••			;:	
with c.f.		•		.'		
Molecule	2012 KG	2013 KG	201 <i>4</i> KG	2015 KG	2015 est. KG	% chg
CODEINE	16,839.9788	16,093.3785	16,072.2129	10,251.6235	20,503.247	27.6%
HYDROCODONE	38,539.5042	37,643.7271	34,389.8032	15,002,6685	30,005.337	-12.7%
HYDROMORPHONE	1,702.6058	1,715.5799	1,632.7914	759,0385	1,518.0771	-7.0%
MORPHINE	21,529.8323	19,704.5514	18,453.2931	8,943.5453	17,887.0907	-3.1%
OXYCODONE	60,034.364	54,321.582	53,023.347	26,822.257	53,644.514	1.2%
OXYMORPHONE	1,742,8696	1,658,4264	1,718.1756	872.7796	1,745.5591	1.6%

KG Audit from July 2009 to June 2015.

A. Includes all available columns.

itle NSP KG

oub Title

Audit NSPKG

--- Report Filters ---

Molecule Codeine, Hydrocodone, Hydromorphone, Morphine, Oxycodone, Oxymorphone, restricted to: 4Hydroxybutyric acid, Alfentanil, Alprazolam, Amobarbital, Atomoxetine, Belladona, Benzphetamine, Buprenorphine,
Bupropion, Butabarbital, Butalbital, Butorphanol, Carbinoxamine, Carisoprodol, Chloral Hydrate,
Chlordiazepoxide, Clonazepam, Clorazepate, Cocaine, Codeine, Cyclobenzaprine, Dexmethylphenidate,
Dextroamphetamine, Dextromethorphan, Diazepam, Dichloralphenazone, Diethylpropion, Difenoxin,
Dihydrocodeine, Diphenhydramine, Diphenoxylate, Dronabinol, Ephedrine, Estazolam, Eszopiclone, Fentanyl,
Fluoxetine, Fluoxymesterone, Flurazepam, Fospropofol, Gabapentin, Hydrocodone, Hydromorphone, Ketamine,
Lacosamide, Levorphanol, Lisdexamfetamine, Lorazepam, Lorcaserin, Meperidine, Meprobamate, Methadone,
Methamphetamine, Methohexital, Methylphenidate, Methylphenobarbital, Methyltestosterone, Midazolam,
Modafinil, Morphine, Nabilone, Nalbuphine, Naloxone, Naltrexone, Nandrolone, Opium, Oxandrolone, Oxazepam,
Oxycodone, Oxymetholone, Oxymorphone, Pemoline, Pentazocine, Pentobarbital, Perampanel, Phendimetrazine,
Phenobarbital, Phentermine, Phenylephrine, Phenylpropanolamine, Pregabalin, Propofol, Propoxyphene,
Pseudoephedrine, Quazepam, Remifentanil, Retigabine, Secobarbital, Sibutramine, Stanozolol, Sufentanil,
Suvorexant, Tapentadol, Temazepam, Testosterone, Thiopental, Tramadol, Triazolam, Zaleplon, Zolpidem
Month 2012, 2013, 2014, 2015

### 2015 Final Adjusted Aggregate Production Quotas and Annual Assessment of Needs

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish the
  production amount of each basic class of Schedule I and II controlled substances and for the List I
  chemicals ephedrine, pseudocphedrine, and phenylpropanolamine. This responsibility has been
  delegated to the Administrator of the Drug Enforcement Administration (DEA).
- DEA regulations allow the Administrator to revise the established annual aggregate production quota (APQ) and assessment of annual needs (AAN) after review of pertinent information provided from various sources including DEA-registered manufacturers and the Food and Drug Administration (FDA).
- The attached Federal Register notice, prepared for your signature, reflects the calendar year 2015
  final adjusted aggregate production quotas (APQ) for schedules I and II controlled substances and
  assessment of annual needs (AAN) for the list I chemicals ephedrine, phenylpropanolamine, and
  pseudoephedrine for which the United States has medical, scientific, industrial, export and reserve
  stock requirements.
- As stated in the 2013 Federal Register Notices, DEA continues to add an additional 25% to the APQ
  for schedule II substances and those schedule I substances that are used to produce drugs that have a
  medical need (specifically, GHB and tetrahydrocannabinols) to prevent potential drug shortage issues.
- Expeditious review and publication of this notice is necessary to ensure an uninterruptable supply of schedule I and II controlled substances as well as list I chemicals ephedrine, phenylpropanolamine, and pseudoephedrine for the legitimate medical, scientific, industrial, and export requirements of the U.S.
- The following points provide brief explanations of the changes from the proposed revised AAN & APQ values:

#### List 1 Chemicals:

No further adjustments

### Controlled Substances:

- OD is recommending an increase in the APQs for Dihydroetorphine, Ethylmorphine, Etorphine HCl, Racemethorphan, Racemorphan. The increase is based on registrant applications and projected demand for reference standards.
- OD is recommending an increase in the APQ for Methylphenidate based on the FDA downgrading
  the efficacy rating for two generic manufacturers of the brand Concerta®. This change is to allow
  the remaining authorized generic and brand manufacturers to supply the entire domestic market. This
  will avert a possible shortage due to APQ limitations.
- OD is recommending an increase in the APQ for Oxycodone (for sale). The increase is based on additional new purchase orders and batch size requirements at the bulk manufacturer level.

OD/ODQ/ODEQ 8/17/15 Page 1 of 1

### DEPARTMENT OF JUSTICE

**Drug Enforcement Administration** 

[Docket No. DEA-418F]

Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled

Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine,

Pseudoephedrine, and Phenylpropanolamine for 2015

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order,

**SUMMARY:** This final order establishes the final adjusted 2015 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

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

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

### SUPPLEMENTARY INFORMATION:

### Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended.

21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act"

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

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

# Background

The DEA established the initial 2015 aggregate production quotas for controlled substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on September 8, 2014. 79 FR 53216. That notice stated that the DEA could adjust, as needed, the established aggregate production quotas and assessment of annual needs in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The proposed adjusted 2015 aggregate production quotas for controlled substances in schedules I and II and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the *Federal Register* on July 8, 2015, 80 FR 39156, in consideration of the

outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted 2015 aggregate production quotas and assessment of annual needs on or before August 7, 2015.

Analysis for Final Adjusted 2015 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the July 8, 2015, notice of proposed adjusted aggregate production quotas and assessment of annual needs, 80 FR 39156, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Five companies submitted timely comments regarding twelve schedule I and II controlled substances. These comments suggested that the proposed adjusted aggregate production quotas for codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate, methylphenidate, morphine (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), and oxymorphone (for sale) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks. The DEA did not receive any comments related to the proposal not to adjust the 2015 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

In accordance with 21 CFR 1303.13, the DEA has taken into consideration the above comments along with the relevant 2014 year-end inventories, initial 2015 manufacturing and import quotas, 2015 export requirements, actual and projected 2015 sales, research and product development requirements, and the additional quota applications received.

Upon consideration of the above, the Administrator determined that the proposed

adjusted 2015 aggregate production quotas for dihydroetorphine, ethylmorphine, etorphine HCl, racemethorphan, racemorphan, methylphenidate, and oxycodone (for sale) required additional consideration and hereby further adjusts the proposed 2015 aggregate production quotas for these substances. Regarding codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate, morphine (for conversion), oripavine, oxymorphone (for conversion), and oxymorphone (for sale) the Administrator hereby determines that the proposed adjusted 2015 aggregate production quotas for these substances as published in the *Federal Register* on July 8, 2015, 80 FR 39156, are sufficient to meet the current 2015 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock.

As described in the previously published notice establishing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. See 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA included in all schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The final established aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to

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

Pursuant to the above, the Administrator hereby finalizes the 2015 aggregate production quotas for the following schedule I and II controlled substances and the 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Final Adjusted 2015 Quotas (g)	
Schedule I		
(1-Pentyl-1FI-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanonc (UR-144)	25	
[1-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	25	
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15	
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	25	
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	25 ~	
1-(1-Phenylcyclohexyl)pyrrolidine	10	
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45	
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45	
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45	
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45	
l-Methyl-4-phenyl-4-propionoxypiperidine	2	

1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-N-methylcathinone (3-FMC)	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-N-methylcathinone (4-FMC)	25
4-Methoxyamphetamine	100

4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-ethylcathinone (4-MEC)	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	. 2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-N-oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	11,000

Dihydromorphine	3,990,000	7/
Dimethyltryptamine	35	$\checkmark$
Dipipanone	5	1
Fenethylline	- 5	<u> </u>
gamma-Hydroxybutyric acid	70,250,000	
Heroin	50	ľ
Hydromorphinol	2	
Hydroxypethidine	2	
Ibogaine	5	سا
Lysergic acid diethylamide (LSD)	35	
Marihuana	658,000	Ĭ
Mescaline	25	Ĺ
	10	1~
Methaqualone	25	┨,
Methcathinone	5	1.
Methyldesorphine	<u> </u>	۱,
Methyldihydromorphine	2	انا. ا
Morphine methylbromide	5	-  ′
Morphine methylsulfonate	5	ļ∼
Morphine-N-oxide	350	\ٰ
N-(I-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	25	_ ~
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	25	<u>سا</u>
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	25	]
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15	]· <b>\</b>
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA)	15	-
N,N-Dimethylamphetamine	25	-
Naphthylpyrovalerone (naphyrone)	25	
N-Benzylpiperazine	25	<b></b> √
N-Ethyl-1-phenylcyclohexylamine	5	٦,
N-Ethylamphetamine	24	٦,
N-Hydroxy-3,4-methylenedioxyamphetamine	24	
Noracymethadol	2	7
Norlevorphanol	52	ا ا
Normethadone	2	٦,
Normorphine	40	<b>⊣</b>
Para-fluorofentanyl	5	٦-

Parahexyl	5	1/
Phenomorphan	2	سا
Pholcodine	5	$\overline{}$
Psilocybin	30	<u> </u>
Psilocyn	. 30	سنا
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	25	با
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	25	]~
Tetrahydrocannabinols	511,250	$] \lor $
Thiofentanyl	2	
Tilidine	25	را
Trimeperidine	2	r
Schedule II		
1-Phenylcyclohexylamine	5	]_
1-Piperidinocyclohexanecarbonitrile	5	V
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500	]~
Alfentanil	17,750	]/
Alphaprodine	3	]~
Amobarbital	25,125	]~
Amphetamine (for conversion)	21,875,000	$\mathbf{Y}$
Amphetamine (for sale)	37,500,000	\ <u>\</u>
Carfentanil	19	Y
Cocaine	275,000	
Codeine (for conversion)	50,000,000	а.
Codeine (for sale)	63,900,000	Y
Dextropropoxyphene	45	ľ
Dihydrocodeine	226,375	₩
Dihydroetorphine	3	1
Diphenoxylate (for conversion)	75,000	سا
Diphenoxylate (for sale)	1,337,500	_
Ecgonine	174,375	] <u>.                                    </u>
Ethylmorphine	5	]₩
Etorphine hydrochloride	3	1.5
Fentanyl	2,300,000	<u> </u> ~
Glutethimide	3	٧.
Hydrocodone (for conversion)	137,500	\v
Hydrocodone (for sale)	99,625,000	
Hydromorphone	7,000,000	1
Isomethadone	5	レ
Levo-alphacetylmethadol (LAAM)	4	J٧

	·
Levomethorphan	30
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	6,250,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	32
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine/	2,061,375
[1,250,000 grams of levo-desoxyephedrine for use in a non product; 750,000 grams for methamphetamine mostly for eproduct; and 61,375 grams for methamphetamine (for sale)	onversion to a schedule III ]
Methylphenidate	96,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	35,000,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	141,375,000
Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	38
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	5
Racemorphan	3
Remifentanil	4,200
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000 125,000,000

List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

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

Dated:

Chuck Rosenberg, Acting Administrator.

A:
AX:
OC:
OD:
CCR:CCO:CC:
ODX:
ODXL:
ODW:
ODW <sub>analyst</sub> :
ODQ:
ODEQ_(b)(6)

DFN: 630-07-Federal Register

SBF-CM # ODEQ-15-841



Jean Sonneman.

Bureau of Land Management, Information Collection Clearance Officer, Bureau of Land Management.

[FR Doc. 2015-23257 Filed 9-15-15; 8:45 am] BILLING CODE 4310-84-P

#### DEPARTMENT OF JUSTICE

Drug Enforcement Administration [Docket No. DEA-418F]

Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudosphedrine, and Phenylpropanolamine for 2015

AGENCY: Drug Enforcement Administration, Department of Justice. ACTION: Final order.

summary: This final order establishes the final adjusted 2015 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the essessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: This order is effective September 16, 2015.

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

# SUPPLEMENTARY INFORMATION:

### Legal Authority

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

substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Section 306 of the CSA [21 U.S.C. 826] requires the Attorney General to establish aggregate production quotes for each basic class of controlled substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA, 28 CFR 0.100(b).

## Background

The DEA established the initial 2015 aggregate production quotas for controlled substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on September 8. 2014. 79 FR 53216. That notice stated that the DEA could adjust, as needed. the established aggregate production quotas and assessment of annual needs in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The proposed adjusted 2015 aggregate production quotas for controlled substances in schedules I and II and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the Federal Register on July 8, 2015, 80 FR 39156, in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted 2015 aggregate production quotas and assessment of annual needs on or before August 7, 2015.

#### Analysis for Final Adjusted 2015 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the July 8, 2015, notice of proposed adjusted aggregate production quotas and assessment of annual needs, 80 FR 39156, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Five companies submitted timely comments regarding twelve schedule I and II controlled substances. These comments suggested that the proposed adjusted aggregate production quotas for codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate. methylphenidate, morphine (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), and oxymorphone (for sale) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the

establishment and maintenance of reserve stocks. The DEA did not receive any comments related to the proposal not to adjust the 2015 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

In accordance with 21 CFR 1303.13, the DEA has taken into consideration the above comments along with the relevant 2014 year-end inventories, initial 2015 manufacturing and import quotas, 2015 export requirements, actual and projected 2015 sales, research and product development requirements, and the additional quota applications received. Upon consideration of the above, the Administrator determined that the proposed adjusted 2015 aggregate production quotas for dihydroetorphine, ethylmorphine, etorphine HCl, recemethorphan, racemorphan, methylphenidate, and oxycodone (for sale) required additional consideration and hereby further adjusts the proposed 2015 aggregate production quotas for these substances, Regarding codeine (for sale), fentanyl, gamma hydroxybutric acid, hydrocodone (for sale), methadone, methadone intermediate, morphine (for conversion), oripavine, oxymorphone (for conversion), and axymorphone (for sale) the Administrator hereby determines that the proposed adjusted 2015 aggregate production quotas for these substances as published in the Federal Register on July 8, 2015, 80 FR 39156, are sufficient to meet the current 2015 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock.

As described in the previously published notice establishing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended, See 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA included in all schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The final established aggregate production quotas will reflect these included

amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in substantial

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

Pursuant to the above, the Administrator hereby finalizes the 2015

aggragate production quotas for the following schedule I and II controlled substances and the 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Final adjusts 2015 quotas (g)
Schedule I	
1-Pentyl-1H-indol-3-yl)(2,2,3,3-letramethylcyclopropyl)methanone (UR-144)	
-(5-Fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-teframethyloyolopropyl)methanone (XLR11)	
-(5-fluoropentyl)-1H-indazol-3-yi)(naphthalen-1-yi)methanone (THJ-2201)	,
(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	.
(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	
(1-Phenylcyclohexyl)pyrrolidine	
(5-Fluoropentyl)-3-(1-naphthoyl)indale (AM2201)	.
(5-Fluoropentyl)-3-(2-jodobenzoyl)indole (AM694)	•
1-(2-Thlenyl)cyclobexylloiperidine	.
[2-(4-Morpholinyl)ethy(I-3-(1-naphthoyl)indole (JWH-200)	.
Butyl-3-(1-nachthoyl)indole (JWH-073)	,
Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	.
Hexyl-3-(1-naphthoyl)indole (JWH-019)	.
Methyl-4-phenyl-4-propionaxypiperidine	.
Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	.
Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	. l
Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	.
Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-396)	. l
Penlyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	.1
Pentyl-3-(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	` <b> </b>
Pentyl-3-[(4-methoxy)-benzoyn]indole (JWH-081)	, I
Peniyi-3-[1-(4-meinoxynapninoxyn)jindoie (JWI)-051)	·
(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	' <b> </b>
(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	<i>'</i>
(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	•
(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	•
(2,5: Dimethoxyphenyl)ethanamine (2C-H)	•
(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (258–NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	•
/4.Chloro-2 5.dimethoxyohenyl)elhanamine (2C=C)	.
ta. Chloro 2 5. dimethoxyohenvi) N-/2-methoxybenzvi)ethanaming (25C-NBOMe; 2C-C-NBOMe; 25C; Clmb+82)	. [
/A-Indo-2 5-dimetharyophenyl)ethanamine (2C-I)	. [
(4. jodg-2 5. dimethoxyohenyt)-N-(2-methoxybenzyt)ethanamine (25[-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5]	.
(Methylaming)-1-phenylpentan-1-one (pentedrone)	•
5-Dimethoxy-4-ethylamohetamine (DOET)	.
5-Dimethoxy-4-n-propylthicphenethylamine	.
5-Dimelhoxyamphetamine	
(4-/Fthylthio)-2 5-dimethoxyphenyllethanamine (2C-T-2)	.
4-(Isopropylthio)-2.5-dimethoxyohenyllethanamine (2C-T-4)	.
4.5-Trimethoxyamphetamine	·
4-Methylenedioxyamphetamine (MDA)	,
4-Malhylenedioxymethamphetamine (MDMA)	.
4-Methylenedioxy-N-ethylamphetamine (MDEA)	
4-Methylenedioxy-N-methylcathinone (methylone)	, [
4-Methylenedioxypyrovalerona (MDPV)	. ]
Fluoro-N-methylcathinone (3-FMC)	.1
Methylfontanyl	
Mathylihiofenianyi	]
Memphinistry (Control of the Control	·
Bromo-2,5-dimethoxyamphetamine (DOB) Bromo-2,5-dimethoxyphenethylamine (2-CB)	1
Bromo-2,5-dimethoxyphenethylamine (2–CB)	1
ruore-n-metriykarınınone (4-FMC)	
Methoxyamphetamine	.
Methyl-2,5-oinetroxyamphetamine (UOM)	.
Melnylaminorex	. 1
Methyl-N-ethylcathinone (4-MEC)	'
Methyl-N-mathylcathinone (mephedrone)	-
Methyl-a-pyrrolidinopropiophenone (4-MePPF)	1
(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	•
(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannablcyclohexanol or CP-47,497 C8-homolog)	1
-Methoxy-3.4-methylegedjoxyamphetamine	.
-Methoxy-N.N-dijsooropyitryplamine	.
-Methoxy-N.N-dimethyltryotamine	
cetyl-alpha-methylfentanyl	1

Basic class	Final adjusted 2015 quotas (g)
cetyldihydrocodeine	
cetylmethadol	
lylorodine	
ohacelylmethadol	
cha-Ethyltryolamine	
ohameprodine	
phamethadol	
ha-Methylfentany	
cha-Methylthiofentanyl	
oha-Methytryptamine (AMT)	
pha-Pyrrolldinobultophenone (α-PBP)	
pha-Pyrrolldinopentiophenone (α-PVP)	
TITOTAY	
anzylmorphine	
etacetylmethadol	
eta-Hydroxy-3-methylfentanyl	
ta-Hydroxyfentanyl	
etamaorodine	
stamethadol	
daprorline	
ufolepine	
athingne	
odaine methylbromide	
orleine-N-oxide	
esomorphine	
ielbyllovolarnine	
ifenoxin	11,
inveromorphine	3,990,
imethylmydamine	
ininanane	
anethyline	
acoma. Hydroxybutyric acld	70,250,
efold	
ydromorphinol ,	
ydroxypethidine	
ogaine (	
ysergic acid diethytamide (LSD)	
arihuana	659,
escaline	
escalineethaqualone	
ethcathinone	
ethodation ethodation	
etryldesorphineethyldihydromorphine	
orphine methylbromide	
orphine methylsulfonate	
orphine methylsuronate	
orphine-N-oxide	
(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (ANDA)	
-(1-Amino-3,3-dimethyl-1-oxcbutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	
-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	
-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmothyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	
-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA)	
,N-Dimethylamphetamine	
aphthylpyrovalerone (naphyrone)	
-Benzylpiperazine	
-Ethyl-1-phenylcyclohexylamine	
-Ethylamphetamine	i
-Hydroxy-3.4-methylenedioxyamphetamine	
oracymethadol	
oviewamband	I
ormelhadone	1
ormorphine	
ara-fluorolantanyl	
arahayul	
henomorphan	
holondina	Į
reincyhin	į
ciloren	Ĭ
himolin-8-vt 1-(5-fluoropentyl)-1H-indola-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	
Vigorin-B-vi 1-pentyl-1)-Indole-3-carboxylate (PB-22; QUPIC)	
etrahydrocannabinois	511
etranydrocannatinois	

Basic class	Final adjusted 2015 quotas (g)
rimeperidine	
Schedule II	
Phenylcyclohexylamine	
Piperidinocyclohexanecarbonitrile	
-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,5
fentanii	17,7
Iphaprodine	25,12
mphetamine (for conversion)	21,875,0
mphetamine (for sale)	37,500,0
arfentanii	
ocalne	275,0
odelne (for conversion)	50,000,00 63,900,00
odeine (for sale)	, 65,800,0
extrapropoxyphene	226,3
ihydroetorphine	
ighenoxylate (for conversion)	75,0
ohenovylate (for sale)	1,337,5
conine	174,3
thylmorphine	
torphine hydrochloride	2,300,0
entanyl	2,000,0
ydrocodone (lor conversion)	137,5
vdrocodone (lor sale)	99,625.0
ydromorphone	7,000,0
omethadone	
evo-alphacetylmethadol (LAAM)	- '
evomethorphan evorphanei	7,1
evorpnanci isdexamfetamine	29,750,0
leneridine	6,250,0
Ignoridize Intermediate-A	
Separationa Intermediate-8	
Apportation Intermediate-C	
letazocine letnadone (for sale)	31,875,0
tethadone Intermediate	34,375,0
lethamphetamine	2,061,3
(1,250,000 grams of levo-desoxyephedrine for use in a non-centrelied, non-prescription product; 750,000 grams for mostly for conversion to a schedule fil product; and 61,375 grams for methamphetamine (for sale)	
lethylphenidate	96, <b>75</b> 0,0 91,250,0
forphine (for conversion)	62,500,0
forphine (for sale)	18,7
loraxymorphone (for conversion)	17,500,0
OF CONVENIENCE (OF CONVERSION)	1,475,0
loroxymorphone (for sale)	112,5
oroxymorphone (for sale)	5,786 25,000 (
loroxymorphone (for sale)	35,000,0
ioraxymorphone (for sale)	ם ያደብ (
loraxymorphone (for sale)	
loraxymorphone (for sale)	141,375,0
oraxymorphone (for sale)  pium (pawder)  pium (tinclure)  ripavine  ixycodone (for conversion)  ixycodone (for conversion)  ixymorphone (for conversion)	141,375,0 29,000,0 7,750,0
loroxymorphone (for sale)  pium (powder)  pium (tinclure)  piyone (for conversion)  pixycodone (for sale)  pixymorphone (for conversion)  pixymorphone (for sale)	141,375,0 29,000,0 7,750,0
loroxymorphone (for sale)  pium (powder)  pium (tincture)  piyone (for conversion)  pixycodone (for conversion)  pixymorphone (for conversion)  pixymorphone (for sale)  pixymorphone (for sale)	141,375,0 29,000,0 7,750,0
oraxymorphone (for sale)  pium (powder)  pium (tincture)  pripavine  lxycodone (for conversion)  lxycodone (for sale)  lxymorphone (for conversion)  lxymorphone (for sale)  entobarbital  thenazocine  thenazocine	141,375,0 29,000,0 7,750,0
loraxymorphone (for sale)  pium (powder)  pium (tincture)  pripavine  bxycodone (for conversion)  bxycodone (for sale)  bxymorphone (for conversion)  cymorphone (for sale)  henazocine  thenazocine	141,375,0 29,000,0 7,750,0 35,000,0
loraxymorphone (for sale)  plum (powder)  plum (tincture)  pripavine  (xycodone (for conversion)  (xycodone (for sale)  (xymorphone (for conversion)  (xymorphone (for sale)  entobarbital  thenazocine  thencyclidine  thenulacetone	141,375,0 29,000,0 7,750,0 35,000,0
loraxymorphone (for sale)  pium (powder)  pium (tincture)  pixycodone (for conversion)  pixycodone (for sale)  pixymorphone (for conversion)  pixymorphone (for sale)  entobarbital  henazocine  thenyloidene  thenyloidene  thenyloidene  thenyloidene  thenyloidene  thenyloidene  thenyloidene	141,375,0 29,000,0 7,750,0 35,000,0
loroxymorphone (for sale)  pium (powder)  pium (tincture)  pripavine  pxycodone (for conversion)  pxymorphone (for conversion)  pxymorphone (for sale)  entobarbital  Phenazocine  Phenazocine  Phenylacetone  lacemethorphan  lacemorphan  lacemorphan  lacemorphan	141,375,0 29,000,0 7,750,0 35,000,0 9,375,0
loraxymorphone (for sale)  pium (powder)  pipum (inclure)  pripavine  Dxycodone (for conversion)  Dxycodone (for sale)  Dxymorphone (for sale)  entobarbital  Phenazocine  Phenazocine  Phenyciidine  Phenylacetone  Racemethorphan  Racemorphan  Recopartital	8,350,0 141,375,0 29,000,0 7,750,0 35,000,0 9,375,0
loraxymorphone (for sale)  pium (powder)  pium (tincture)  Dixycodone (for conversion)  Dixycodone (for sale)  Dixymorphone (for conversion)  Dixymorphone (for sale)  Pentobarbital  Phenazocine  Phenazocine  Phenazocine  Phenylacetone  Jacemethorphan  Jacemethorphan  Jacemorphan	141,375,0 29,000,0 7,750,0 35,000,0 9,375,0

Basic class	Final adjusted 2015 quotas (g)
List I Chemicals	_
Ephedrine (for conversion)  Ephedrine (for sale)  Phenylpropanolamine (for conversion)  Phenylpropanolamine (for sale)  Pseudoephedrine (for sale)  Pseudoephedrine (for sale)	1,000,000 4,000,000 44,800,000 8,500,000 7,000 224,500,000

Aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308,12 remain at zero.

Dated: September 10, 2015. Chuck Rosenberg, Acting Administrator. [FR Doc. 2015-23199 Filed 9-15-15; 8:45 am] BILLING CODE 4410-09-P

## DEPARTMENT OF LABOR

## Office of the Secretary

Establishing a Minimum Wage for Contractors, Notice of Rate Change in Effect as of January 1, 2016

AGENCY: Wage and Hour Division, Department of Labor. ACTION: Notice.

**SUMMARY: The Wage and Hour Division** (WHD) of the U.S. Department of Labor (the Department) is issuing this notice to announce the applicable minimum wage rate to be paid to workers performing work on or in connection with Federal contracts covered by Executive Order 13658, beginning

January 1, 2016. Executive Order 13658, Establishing a Minimum Wage for Contractors (the Executive Order or the Order), was signed by President Barack Ohama on February 12, 2014, and raised the hourly minimum wage paid by contractors to workers performing work on covered Federal contracts to: \$10.10 per hour, beginning January 1, 2015; and beginning January 1, 2016, and annually thereafter, an amount determined by the Secretary of Labor (the Secretary) in accordance with the methodology set forth in the Order, See 79 FR 9851. The Secretary's determination of the Executive Order minimum wage rate also affects the minimum hourly cash wage that must be paid to tipped employees performing work on or in connection with covered contracts beginning January 1, 2016. See 79 FR 9851-52. The Secretary is required to provide notice to the public of the new minimum wage rate at least 90 days

before such rate is to take effect. Scc 79

Pursuant to Executive Order 13658 and its implementing regulations at 29 CFR part 10, notice is hereby given that beginning January 1, 2016, the Executive Order minimum wage rate that generally must be paid to workers performing work on or in connection with covered contracts is \$10.15 per hour. Notice is also hereby given that, beginning January 1, 2016, the required minimum cash wage that generally must be paid to tipped employees performing work on or in connection with covered contracts is \$5.85 per hour.

DATES: This notice is effective on September 16, 2015.

FOR FURTHER INFORMATION CONTACT: Robert Waterman, Acting Director, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S-3502, 200 Constitution Avenue NW. Washington, DC 20210; telephone: (202) 693-0406 (this is not a toll-free number). Copies of this notice may be obtained in alternative formats (Large Print, Braille, Audio Tape, or Disc) upon request, by calling (202) 693–0023 (not a toll-free number). TTY/TTD callers may dial toll-free (877) 889-5627 to obtain information or request materials in alternative formats. SUPPLEMENTARY INFORMATION:

I, Executive Order 13658 Background and Requirements for Determining Annual Increases to the Minimum Wage Rate

Executive Order 13658 was signed by President Barack Obama on February 12, 2014, and raised the hourly minimum wage paid by contractors to workers performing work on or in connection with covered Federal contracts to \$10.10 per hour, beginning January 1, 2015; and beginning January 1, 2016, and annually thereafter, an amount determined by the Secretary pursuant to the Order. See 79 FR 9851. The Executive Order directed the Secretary to issue regulations to implement the Order's requirements. See 79 FR 9852. Accordingly, after

engaging in notice-and-comment rulemaking, the Department published a Final Rule on October 7, 2014 to implement the Executive Order. See 79 FR 60634. The final regulations, set forth at 29 CFR part 10, established standards and procedures for implementing and enforcing the minimum wage protections of the Order.

The Executive,Order and its implementing regulations require the Secretary to determine the applicable minimum wage rate to be paid to workers performing work on or in connection with covered contracts on an annual basis, beginning January 1, 2016. See 79 FR 9851; 29 CFR 10.1(a)(2), 10.5(a)(2), 10.12(a). Sections 2(a) and (b) of the Order establish the methodology that the Secretary must use to determine the annual inflation-based increases to the minimum wage rate. See 79 FR 9851. These provisions, which are implemented in 29 CFR 10.5(b), explain that the applicable minimum wage determined by the Secretary for each calendar year shall be:

(i) Not less than the amount in effect on the date of such determination;

(ii) Increased from such amount by the annual percentage increase in the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI-W) (United States city average, all items, not seasonally adjusted), or its successor publication, as determined by the Bureau of Labor Statistics (BLS); and

(iii) Rounded to the nearest multiple of \$0.05.

Section 2(b) of the Executive Order further provides that, in calculating the annual percentage increase in the CPI for purposes of determining the new minimum wage rate, the Secretary shall compare such CPI for the most recent month, quarter, or year available (as selected by the Secretary prior to the first year for which a minimum wage is in effect) with the CPI for the same month in the preceding year, the same quarter in the preceding year, or the preceding year, respectively. See 79 FR 9851. In order to calculate the annual percentage increase in the CPI, the Department elected in its Final Rule