Basic Class: 9040-A

2014 Initial APQ Worksheets

Total PQ Requested: 3,903,000.000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Inventory Adj.	MQ
(b)(4);(b)(7)(E)		14,500,000.000	19,280,990.000	12,133,621.000	53,520,189.000	0.227	884,858.014	5,113,094.000	0.000	13,370,611.000	0.000	5,397,404.000	16,282,722.667	5.000
		34,000,000.000	21,799,868.000	29,770,268.000	53,520,189.000	0.556	2,171,049.164	10,875,598.000	0.000	33,462,533.000	0.000	11,857,568.000	21,783,644.000	28,000,000.000
MQ Totals:		48,500,000.000	41,080,858.000											28,000,005.000

2013 Final Initial APQ: 69,000,000.000

2013 Final Revised APQ: 0.000

FDA Est: (2013 Initial APQ * FDA Est): 0.000

IMS Est: (2013 Initial APQ * IMS Est): 0.000

2014 Proposed Initial APQ: 55,000,000.000 lowered to 2012 granted levels

Note:			PQ requested	c.f.	Needed
(b)(4)	will convert to	hydrocodone (for sale)	7,100,000.000	0.742	9,568,733.154
(b)(4)	will convert to	dihydrocodeine	80,000.000	0.750	106,666.667
		hydrocodone (for sale)	30,000,000.000	0.875	34,285,714.286

Basic Class: 9050-B

2014 Initial APQ Worksheets

Total PQ Requested: 25,736,256.849

FDA Est: n/a

IMS Est: -05

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		100.000	100.000	1.788	23,368,255.978	0.000	1.989	32.739	0.000	10.000	0.000	130.739	-95.278	5.000
		148,000.000	445,000.000	106,619.000	23,368,255.978	0.005	117,423.185	137,364.000	0.000	148,000.000	0.000	72,644.000	-176,335.019	148,000.000
		13,500,000.000	12,610,843.000	12,167,512.000	23,368,255.978	0.521	13,400,580.820	4,918,642.000	8,140.000	12,749,580.000	0.000	4,650,420.000	16,133,571.899	13,500,000.000
		1,000.000	5,000.000	4,199.140	23,368,255.978	0.000	4,614.748	0.000	0.000	5.000.000	0.000	10,000.000	7,018.432	1,000.000
		14,210,000.000	15,730,716.000	9,786,650.000	23,368,255.978	0.419	10,780,796.361	7,244,704.000	0.000	12,260,000.000	0.000	8,098,000.000	8,893,256.951	14,210,000.000
		5,280,000.000	2,700,000.000	1,301,083.000	23,368,255.978	0.056	1,432,927.614	705,552.000	0.000	4,070,000.000	0.000	185,000.000	3,129,607.517	3,129,607.517
MQ Totals:		33,139,100.000	31,491,659.000											30,968,612.517

2013 Final Initial APQ:	39,605,000.000
2013 Final Revised APQ:	0.000
Est):	39,605,000.000
IMS Est: (2013 Initial APQ * IMS Est):	37,644,552.500

2014 Proposed Initial APQ: 36,900,000.000 lowered to total granted in 2012

Basic Class: 9273-0

Total PQ Requested: 82.000

2014 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		10.000	10.000	0.298	12,612,070.298	0.000	0.000	0.810	0.000	2.000	0.000	9.810	-8.310	10.000
MQ Totals:		10.000	10.000											10.000

2013 Final Initial APQ: 15.000

2013 Final Revised APQ: 0.000

FDA Est: (2013 Initial APQ * FDA Est): 0.000

IMS Est: (2013 Initial APQ * IMS Est): 0.000

2014 Proposed Initial APQ: 15.000

19.000 with 25% buffer

Basic Class: 9120-0

2014 Initial APQ Worksheets

Total PQ Requested: 5,007.000

FDA Est: -.714

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 53% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.530	23,835,010	0.000	0.111	10.616	0.000	3.000	0.000	15.616	-11.429	5.000
		80,000.000	80,000.000	23,785.000	23,835,010	0.998	4,996.454	210,562.000	0.000	57,000.000	0.000	173,000.000	-197,316.362	80,000.000
		250.000	370.000	49.480	23,835,010	0.002	10.394	139.270	0.000	250.000	0.000	130.000	-153.777	250.000
MQ Totals:		80,255.000	80,375.000											80,255.000

2013 Final Initial APQ:	200,000.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	57,200.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000
2014 Proposed Initial APQ:	80,600.000

Basic Class: 9190-0

2014 Initial APQ Worksheets

Total PQ Requested: 4.000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.200	0.200	1.000	4.000	0.990	0.000	1.000	0.000	1.990	3.510	2.000
MQ Totals:		2.000	2.000											2.000

2013 Final Initial APQ:	2.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000
2014 Proposed Initial APQ:	2.000

Basic Class: 9801-0

Total PQ Requested: 970,558.531

2014 Initial APQ Worksheets

FDA Est: 072

MS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		200,000.000	137,147.000	43,779.000	1,178,096.780	0.037	36,066.716	63,246.000	0.000	200,000.000	0.000	50,000.000	78,977.145	167,000.000
		210,000.000	47,699.000	49,344.780	1,178,096.780	0.042	40,652.006	5,739.406	60,000.000	210,000.000	0.000	3,500.000	278,301.356	123,000.000
		2.000	2.000	0.000	1,178,096.780	0.000	0.000	0.223	0.000	1.000	0.000	2.223	-0.723	2.000
		31,760.000	6,800.000	5,148.000	1,178,096.780	0.004	4,241.108	1,216.000	0.000	33,760.000	0.000	500.000	30,670.385	30,670.385
		350,000.000	474,000.000	279,461.000	1,178,096.780	0.237	230,230.031	141,028.000	0.000	335,840.000	0.000	179,188.000	127,099.538	350,000.000
		610,000.000	852,247.000	600,364.000	1,178,096.780	0.509	559,368.671	308,901.000	95,600.000	615,320.000	0.000	314,868.000	787,044.589	787,044.589
		1,640.000	0.000	0.000	1,178,096.780	0.000	0.000	0.000	0.000	1,640.000	0.000	0.000	1,640.000	1,640.000
		1,000.000	45,000.000	0.000	1,178,096.780	0.000	0.000	0.000	0.000	1,000.000	0.000	15,000.000	-32,750.000	1,000.000
MQ Totals:			1,604,422.000	1,562,995.000										1,460,356.973

2013 Final Initial APQ: 1,687,000.000

2013 Final Revised APQ: 0.000

FDA Est: (2013 Initial APQ * FDA Est): 1,808,464.000

MS Est: (2013 Initial APQ * MS Est): 1,687,000.000

2014 Proposed Initial APQ: 1,687,000.000

2,108,750.000 with 25% buffer

Basic Class: 9200-0

Total PQ Requested: 4,003.000

2014 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	0.000	0.000	3.270	0.000	0.000	0.000	0.250	2.500	0.000	2.500	2.750	5.000
		5.000	5.000	0.020	3.270	0.006	24.483	9.300	0.000	3.000	0.000	11.101	20.554	5.000
MQ Totals:		10.000	5.000											10.000

2013 Final Initial APQ:	25.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000
2014 Proposed Initial APQ:	25.000

Basic Class: 9193-B

2014 Initial APQ Worksheets

Total PQ Requested: 70,108,722,142

FDA Est: 015

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		266,000	132,500	0	56,999,043	0	0	0	0	200,000	0	90,000	199,625	192,500
		20	20	5	56,999,043	0	7	63	0	10	0	64	-60	20
		231,000	186,451	17,696	56,999,043	0	21,766	44,888	0	231,000	0	5,000	71,661	203,000
		7,100,000	5,722,000	0	56,999,043	0	0	0	0	3,551,433	0	3,548,567	-740,067	2,178,567
		30,000,000	16,873,086	24,410,383	56,999,043	0	30,024,728	6,825,793	12,200	28,147,608	0	8,962,477	44,710,110	30,000,000
		24,000,000	24,451,038	23,305,815	56,999,043	0	28,666,111	5,160,117	0	14,830,000	0	9,657,000	26,164,243	24,000,000
		3,600,000	0	365,549	56,999,043	0	449,588	2,514,546	0	1,000,000	0	4,463,000	-952,561	1,954,134
		5,310,000	1,269,659	0	56,999,043	0	0	1,643,300	0	2,600,000	0	5,000,000	4,456	3,750,000
		9,000,000	7,613,000	5,580,064	56,999,043	0	8,462,467	1,695,730	0	6,557,500	0	943,700	9,730,123	9,000,000
MQ Totals:		79,527,020	58,249,754											71,280,221

2013 Final Initial APQ:	79,700,000
2013 Final Revised APQ:	0.000
FDA Est (2013 Initial APQ * FDA Est):	60,695,500
IMS Est (2013 Initial APQ * IMS Est):	79,700,000

2014 Proposed Initial APQ: 79,700,000

99,625,000 w/25% buffer

Basic Class: 9160-0

Total PQ Requested: 2,460,372.507

2014 Initial APQ Worksheets

FDA Est: .106

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		100,000.000	102,353.000	0.000	3,509,088.484	0.000	0.000	0.000	0.000	50,000.000	0.000	50,000.000	-26,762.500	100,000.000
		30.000	25.000	18.725	3,509,088.484	0.000	11.727	29.438	0.000	22.000	0.000	52.438	-11.530	30.000
		156,000.000	78,000.000	0.000	3,509,088.484	0.000	0.000	0.000	0.000	156,000.000	0.000	3,000.000	97,500.000	97,500.000
		535,998.000	549,743.000	575,362.609	3,509,088.484	0.164	403,411.413	215,808.822	0.000	417,999.000	0.000	117,999.000	294,146.195	535,995.000
		445,000.000	447,529.000	343,962.000	3,509,088.484	0.098	241,166.517	166,258.000	0.000	445,000.000	0.000	257,885.000	244,553.397	445,000.000
		1,870,000.000	958,463.000	901,186.000	3,509,088.484	0.257	631,861.576	166,583.000	1,760.000	967,450.000	0.000	477,186.000	851,108.720	1,408,907.576
		1,565,000.000	1,534,093.000	1,444,815.450	3,509,088.484	0.412	1,013,022.107	225,161.938	0.000	1,547,000.000	0.000	775,000.000	1,406,525.934	1,565,000.000
		220,000.000	93,000.000	43,567.000	3,509,088.484	0.012	30,545.693	37,282.000	0.000	142,400.000	0.000	20,772.000	73,551.366	133,300.000
MQ Totals:		4,192,028.000	3,793,203.000											4,305,995.576

2013 Final Initial APQ: 4,775,000.000

2013 Final Revised APQ: 0.000

FDA Est: (2013 Initial APQ * FDA Est): 5,281,150.000

IMS Est: (2013 Initial APQ * IMS Est): 0.000

2014 Proposed Initial APQ: 4,775,000.000

5,968,750 w/25% buffer

Basic Class: 9226-0

2014 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	0.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	-1.000	2.000
MQ Totals:		2.000	2.000											2.000

2013 Final Initial APQ:	4.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000
2014 Proposed Initial APQ:	2.000

Basic Class: 9648-0

2014 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	0.000	0.000	0.000	0.012	0.000	0.500	0.000	1.512	-1.012	2.000
MQ Totals:		2.000	2.000											2.000

2013 Final Initial APQ: 3.000
2013 Final Revised APQ: 0.000
FDA Est: (2013 Initial APQ * FDA Est): 0.000
IMS Est: (2013 Initial APQ * IMS Est): 0.000

2014 Proposed Initial APQ: 3.000 with 25% buffer = 4g

Basic Class: 9210-0

2014 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 80% Invent	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.120	0.120	1.000	0.000	2.747	0.000	1.500	0.000	2.247	-2.747	2.000
MQ Totals:		2.000	2.000											2.000

2013 Final Initial APQ:	5.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000
2014 Proposed Initial APQ:	5.000

Basic Class: 9220-0

Total PQ Requested: 4,488.000

2014 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	1,060.000	0.000	0.000	0.000	0.000	0.500	0.000	1.500	-1.000	2.000
		1,500.000	3,100.000	1,060.000	1,060.000	1.000	4,488.000	171.000	41.000	1,433.000	0.000	688.000	4,585.500	1,500.000
MQ Totals:		1,502.000	3,102.000											1,502.000

2013 Final Initial APQ:	3,600.000	
2013 Final Revised APQ:	0.000	
FDA Est: (2013 Initial APQ * FDA Est):	0.000	
IMS Est: (2013 Initial APQ * IMS Est):	0.000	
2014 Proposed Initial APQ:	1,600.000	
	2,000.000	with 25% buffer

Basic Class: 9230-0

2014 Initial APQ Worksheets

Total PQ Requested: 2,405,714.411

FDA Est: -.26

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		4,000,000.000	3,109,000.000	1,735,789.000	2,174,619.396	0.798	1,922,644.480	1,344,899.000	500,000.000	4,000,000.000	0.000	1,250,000.000	3,227,356.601	3,227,356.601
		5.000	7.000	0.396	2,174,619.396	0.000	0.439	1.532	0.000	6.000	0.000	10.532	-5.734	5.000
		710,000.000	740,000.000	438,830.000	2,174,619.396	0.202	486,069.492	436,153.000	95,700.000	522,000.000	0.000	236,503.000	234,133.665	710,000.000
MQ Totals:		4,710,005.000	3,849,007.000											3,937,361.601

2013 Final Initial APQ:	5,500,000.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	4,070,000.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000

2014 Proposed Initial APQ: 5,000,000.000

4,250,000 w/25% buffer

Basic Class: 9232-0

2014 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:
IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		3.000	3.000	0.000	0.000	0.000	0.000	0.000	0.000	0.200	0.000	2.800	-2.050	3.000
MQ Totals:		3.000	3.000											3.000

2013 Final Initial APQ:	5.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000
2014 Proposed Initial APQ:	3.000

Basic Class: 9193-B

2014 Initial APQ Worksheets

Total PQ Requested: 2,000

FDA Est:
IMS Est:

Company	DEA Num	2014 Forecasted MQ	MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2013 Projected Exports	2013 Projected Inventory	2013 DEA Projected Inventory	Inventory Adj	Calc Using Company Invent	Calc Using Dist Invent	Calc Using CSR 50% Invent	MQ
(b)(4);(b)(7)(E)		7,000	7,000	1,085	1,085	1.000	2.000	7,757	0.000	3,000	0.000	11,253	12,757	9,478	13,257	14,757	48,507	*****
MQ Totals:		7,000	7,000															*****

2013 Final Initial APQ: 9,000
2013 Final Revised APQ: 0.000
FDA Est (2013 Initial APQ * FDA Est): 0.000
IMS Est (2013 Initial APQ * IMS Est): 0.000

2014 Proposed Initial APQ: 7,000

Basic Class: 9234-0

2014 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		3.000	3.000	0.000	0.000	0.000	0.000	0.000	0.000	0.200	0.000	2.800	-2.050	3.000
MQ Totals:		3.000	3.000											3.000

2013 Final Initial APQ:	5.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000
2014 Proposed Initial APQ:	3.000

Basic Class: 9250-0

Total PQ Requested: 21,563,028.000

2014 Initial APQ Worksheets

FDA Est:

IMS Est: -- 087

Company	DEA Num	2014 Requested MQ	MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		6,375,000.000	6,321,000.000	4,976,800.000	17,835,768.583	0.279	6,016,635.061	3,016,884.000	0.000	6,544,000.000	0.000	3,272,000.000	6,007,409.826	6,007,409.826
		10.000	10.000	2,583	17,835,768.583	0.000	3.123	6.536	0.000	8.000	0.000	9.236	-1.133	10.000
		1,052,000.000	223,333.000	26,872.000	17,835,768.583	0.002	32,487.621	62,133.000	0.000	1,052,000.000	0.000	5,000.000	862,931.776	862,931.776
		13,000,000.000	9,904,525.000	9,774,716.000	17,835,768.583	0.548	11,817,403.540	3,635,734.000	41,833.000	11,153,190.000	0.000	4,864,208.000	14,902,648.676	13,000,000.000
		4,950,000.000	3,551,000.000	3,057,378.000	17,835,768.583	0.171	3,696,298.555	652,225.000	0.000	3,827,000.000	0.000	1,234,070.000	5,131,698.318	4,950,000.000
MQ Totals:			25,378,810.000	19,999,929.000										24,620,351.602

2013 Final Initial APQ:	20,000,000.000
2013 Final Revised APQ:	0.000
Est):	20,000,000.000
IMS Est: (2013 Initial APQ * IMS Est):	24,237,600.000
2014 Proposed Initial APQ:	25,500,000.000
	31,875,000.000 wit 25% buffer

Basic Class: 9254-0

Total PQ Requested: 7,745,400.000

2014 Initial APQ Worksheets

FDA Est: -

INB Est: -

Company	DEA Num	2014 Requested IMQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	2013 DEA Projected Inventory	Inventory Adj.	Calc Using Company Invent	Calc Using Ord Invent	Calc Using CPR 50% Invent	MQ
(b)(4);(b)(7)(E)		10.000	10.000	0.000	23,804,359.000	0.000	0.000	0.000	0.000	5.000	0.000	5.000	5.000	6.667	5.000	5.000	-2.500	5.000
		2,298,000.000	877,000.000	139,508.000	23,804,359.000	0.006	45,202.643	0.000	0.000	2,286,000.000	0.000	0.000	-1,414,000.000	564,666.667	45,202.643	-1,372,797.357	1,663,753.679	1,663,753.679
		14,000,000.000	10,781,334.000	10,214,405.000	23,804,359.000	0.427	3,309,630.372	656,064.000	0.000	12,575,292.000	0.000	2,345,437.000	-475,887.000	7,766,263.333	8,668,678.372	2,433,742.372	7,710,778.995	7,710,778.995
		5,780,000.000	4,234,860.000	4,621,808.000	23,804,359.000	0.183	1,487,449.834	803,879.000	0.000	5,834,000.000	0.000	264,300.000	-692,027.000	3,361,316.333	1,761,445.834	906,418.834	3,625,334.250	3,625,334.250
MQ Totals:		22,084,010.000	15,808,341.000															12,927,811.937

2013 Final Initial APQ:	26,000,000.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000

2014 Proposed Initial APQ:	31,100,000.000	
	38,875,000.000	with 25% buffer

METHADONE-INTERMEDIATE

Basic Class: 9300-A

Total PQ Requested: 6,200,016.000

2014 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		3,500,000.000	3,500,000.000	1,433,653.000	47,831,774.800	0.030	185,831.941	950.000	3,420,950.000	3,420,950.000	0.000	0.000	4,448,239.926	3,500,000.000
		44,000,000.000	42,285,090.000	34,704,093.000	47,831,774.800	0.726	4,498,389.047	99,670,020.000	0.000	45,356,940.000	0.000	13,746,150.000	404,903.191	44,000,000.000
		5,000.000	1,000.000	0.000	47,831,774.800	0.000	0.000	0.000	0.000	5,000.000	0.000	0.000	4,250.000	4,250.000
		9,151,000.000	12,798,000.000	11,170,137.000	47,831,774.800	0.234	1,447,887.485	1,111,683.000	0.000	9,151,000.000	0.000	4,609,950.000	262,176.356	6,204,570.486
		5,260,000.000	1,599,975.000	449,600.000	47,831,774.800	0.009	57,268.663	0.000	0.000	5,260,000.000	0.000	0.000	4,151,602.103	4,151,602.103
MQ Totals:		61,936,000.000	60,182,065.000											57,860,422.568

2013 Final Initial APQ:	83,000,000.000
2013 Final Revised APQ:	73,000,000.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000

2014 Proposed Initial APQ: 73,000,000.000

91,250,000.000 with 25% buffer

methylphenidate not complete

Basic Class: 9300-B

Total PQ Requested: 42,497,706.328

2014 Initial APQ Worksheets

FDA Est: .019

IMS Est: -.021

Company	DEA Num	2014 Requested MQ	MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		100.000	100.000	6.577	39,610,997.717	0.000	7.056	129.749	0.000	10.000	0.000	217.949	-185.929	100.000
		162,630.000	0.000	0.000	39,610,997.717	0.000	0.000	0.000	0.000	121,973.000	0.000	0.000	121,973.000	162,630.000
		6,500,000.000	4,512,500.000	2,888,583.000	39,610,997.717	0.073	3,100,169.907	0.000	0.000	6,032,085.000	0.000	547,915.000	5,522,922.384	5,600,000.000
		14,600,000.000	14,825,855.000	15,310,761.000	39,610,997.717	0.462	19,645,947.491	4,166,053.000	225,000.000	13,697,160.000	0.000	6,904,820.000	23,193,095.113	14,600,000.000
		26,550,000.000	21,698,101.000	15,447,446.000	39,610,997.717	0.390	16,573,224.314	3,880,000.000	0.000	20,250,000.000	0.000	8,997,000.000	20,662,954.643	21,698,101.000
		1,000.000	5,000.000	1,762.700	39,610,997.717	0.000	1,891.182	0.000	0.000	1,000.000	0.000	500.000	-356.048	1,000.000
		1,600,000.000	937,500.000	480,551.000	39,610,997.717	0.012	$15,572.575	0.000	0.000	1,500,000.000	0.000	0.000	1,541,340.719	937,500.000
		5,400,000.000	4,000,000.000	0.000	39,610,997.717	0.000	0.000	0.000	0.000	2,000,000.000	0.000	5,400,000.000	-1,000,000.000	3,000,000.000
MQ Totals:		54,913,730.000	48,179,156.000	37,130,050.277						43,702,248.000				47,199,331.000

2013 Final Initial APQ: 46,200,000.000

2013 Final Revised APQ: 0.000

Est: 49,115,880.000

IMS Est (2013 Initial APQ * IMS Est): 47,197,440.000

2014 Proposed Initial APQ: 50,000,000.000

62,500,000.000 with 25% buffer

Basic Class: 9668-A

2014 Initial APQ Worksheets

Total PQ Requested: 1,000 000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		6,800,000.000	5,371,701.000	[redacted]	3,713,022.000	1.000	1.000 000	1,585,894.000	0.000	5,947,428.000	0.000	1,597,484.000	334,006.250	6,800,000.000
		3,000,000.000	832,273.000	0.000	3,713,022.000	0.000	0.000	444,132.000	0.000	3,000,000.000	0.000	0.000	1,931,663.250	3,000,000.000
MQ Totals:		9,800,000.000	6,203,974.000											9,800,000.000

2013 Final Initial APQ:	7,200,000.000
2013 Final Revised APQ:	0.000
FDA Est: [2013 Initial APQ * FDA Est]:	0.000
IMS Est: [2013 Initial APQ * IMS Est]:	0.000

2014 Proposed Initial APQ:	9,800,000.000	
	12,250,000.000	with 25% buffer

(b)(4) will be converting the API to Nalbuphine, Naltrexone, and Naloxone, yields were provided but all are non-controlled substances

(b)(4) will be converting the API to naloxone (non-controlled substance), no conversion factor given with MQ request

Basic Class: 9668-B

2014 Initial APQ Worksheets

Total PQ Requested: 4,067,500

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% invent	MQ
(b)(4);(b)(7)(E)		1,000,000.000	400,000.000	166,804.000	166,807.382	1.000	4,087.417	374,296.000	1,000,000.000	1,000,000.000	0.000	0.000	1,330,813.271	1,000,000.000
		10.000	10.000	0.242	166,807.382	0.000	0.006	261.541	0.000	3.000	0.000	266.547	-268.034	10.000
		3,000.000	2,618.000	0.000	166,807.382	0.000	0.000	534.000	5.000	3,025.000	0.000	509.000	532.500	3,000.000
		2,000.000	1,000.000	3.140	166,807.382	0.000	0.077	0.000	0.000	2,000.000	0.000	700.000	1,250.096	2,000.000
MQ Totals:		6,005,010.000	403,628.000											1,005,010.000

2013 Final Initial APQ:	407,000.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000

2014 Proposed Initial APQ: 1,010,000.000

1,262,500.000 with 25% buffer

Basic Class: 9639-0

2014 Initial APQ Worksheets

Total PQ Requested: 1,015,421.000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		52,800.000	32,400.000	2,000.000	449,600.000	0.004	4,521.445	0.000	0.000	41,600.000	0.000	11,000.000	23,151.807	52,800.000
		430,000.000	854,054.000	447,600.000	449,600.000	0.996	1,010,899.554	155,553.000	0.000	431,400.000	0.000	214,301.000	900,180.943	430,000.000
MQ Totals:		482,800.000	886,454.000				-							482,800.000

2013 Final Initial APQ:	1,030,000.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000

2014 Proposed Initial APQ: 500,000.000

625,000.000 with 25% buffer

Basic Class: 9639-0

2014 Initial APQ Workshools

Total PQ Requested: 53,170,000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 60% Invent	MQ
(b)(4);(b)(7)(E)		90,000.000	53,360.000	55,750.000	55,750.000	1.000	53,170.000	4,911.000	0.000	56,000.000	0.000	34,000.000	77,531.500	77,531.500
MQ Totals:		90,000.000	53,360.000											77,531.500

2013 Final Initial APQ:	73,000.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000

2014 Proposed Initial APQ:	90,000.000
	112,500.000 with 25% buffer

Basic Class: 9150-0

Total PQ Requested: 5,977,000.000

2014 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		1,000,000.000	1,000,000.000	0.000	7,456,837.370	0.000	0.000	0.000	0.000	1,000,000.000	0.000	0.000	250,000.000	667,000.000
		1,674,000.000	1,467,039.000	845,573.000	7,456,837.370	0.113	677,765.864	277,547.000	0.000	1,674,000.000	0.000	105,000.000	1,143,381.080	1,163,057.333
		10,700,000.000	8,444,444.000	4,532,217.000	7,456,837.370	0.608	3,632,781.522	570,621.000	0.000	10,666,667.000	0.000	533,333.000	8,303,689.902	8,444,444.000
		4,235,000.000	3,126,162.000	1,457,204.370	7,456,837.370	0.197	1,176,032.155	1,252,200.000	0.000	2,857,000.000	0.000	1,415,000.000	730,218.693	2,918,808.000
		480,000.000	462,716.000	611,843.000	7,456,837.370	0.082	490,420.460	0.000	0.000	476,000.000	0.000	4,000.000	741,566.575	480,000.000
		700,000.000	700,000.000	0.000	7,456,837.370	0.000	0.000	0.000	0.000	700,000.000	0.000	0.000	175,000.000	700,000.000
MQ Totals:		18,789,000.000	15,200,361.000											14,373,409.333

2013 Final Initial APQ:	18,200,000.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000

2014 Proposed Initial APQ: 18,200,000.000

22,750,000.000 with 25% buffer

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 115535		Date Submitted	15-APR-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
ORIPAVINE		Schedule/List Number	2
Name and Address of Registrant		Drug Code	9330-0
(b)(4)		Quota Year	2014
		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)		Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

	Quotas Previously Issued by DEA			
Quota History	2012	2013	2014	Quota Requested
	3,684,000.0	3,126,000.0	0.0	4,235,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	0.0	0.0	1,415,000.0	1,415,000.0
b.In-Process Material.....	1,252,200.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	1,252,200.0	0.0	1,415,000.0	1,415,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	2,504.92	0.0	2,857,000.0	2,857,000.0
b Exports.....	0.85	0.0	0.0	0.0
	2,505.77	0.0	2,857,000.0	2,857,000.0
Acquisition/Production				
a.Domestic Sources.....	3,184,006.7	0.0	4,235,000.0	4,235,000.0
	3,184,006.7	0.0	4,235,000.0	4,235,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2011	2012	2014	
HYDROMORPHONE	9150-0	874,020	1,140,220	1,827,000	85.70

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 115756		Date Submitted	25-APR-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)		Schedule/List Number	2
ORIPAVINE		Drug Code	9330-0
Name and Address of Registrant		Quota Year	2014
(b)(4)		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)		Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

	Quotas Previously Issued by DEA			
Quota History	2012	2013	2014	Quota Requested
	1,630,000.0	1,467,039.0	0.0	1,674,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	277,547.0	0.0	105,000.0	105,000.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	277,547.0	0.0	105,000.0	105,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	798,775.0	0.0	1,674,000.0	1,674,000.0
b Exports.....	0.0	0.0	0.0	0.0
	798,775.0	0.0	1,674,000.0	1,674,000.0
Acquisition/Production				
a.Domestic Sources.....	797,922.0	0.0	1,674,000.0	1,674,000.0
	797,922.0	0.0	1,674,000.0	1,674,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2011	2012	2014	
HYDROMORPHONE	9150-0	0	0	156,000	45.00
OXYMORPHONE (FOR SALE)	9652-B	0	35,053	143,000	45.00

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

Quota is for supply of 1,000Kg to (b)(4);(b)(7)(E) will also use Oripavine for internal conversion to Oxymorphone and Hydromorphone for sale to (b)(4);(b)(7)(E) and (b)(4)

APPLICATION FOR PROCUREMENT QUOTA

Request ID	115204	Date Submitted	01-APR-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-250)			
ORIPAVINE		Drug Schedule/List	2
Name and Address of Registrant		Drug Code	9330-0
(b)(4)		Quota Year	2014
		DEA Registration	(b)(4);(b)(7)(E)
Contact Person	(b)(4);(b)(6)	Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

Quota History	Quotas Previously Issued by DEA			
	2012	2013	2014	Quota Requested
	615,000.0	668,000.0	0.0	476,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Current Year Estimates	Quota Year Estimates
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	89,060.0	0.0	52,000.0	52,000.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	89,060.0	0.0	52,000.0	52,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	647.0	0.0	476,000.0	476,000.0
b Exports.....	0.0	0.0	0.0	0.0
	647.0	0.0	476,000.0	476,000.0
Acquisition/Production				
a.Domestic Sources.....	610,324.0	0.0	476,000.0	476,000.0
b.Importation.....	0.0	0.0	0.0	0.0
	610,324.0	0.0	476,000.0	476,000.0

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

Name of New Substance	Drug Code	Amount Used for this Purpose			% Yield
		2011	2012	2014	
HYDROMORPHONE	9150-0	62,824	66,774	133,500	80.00
OXYMORPHONE (FOR SALE)	9652-8		475,610	127,500	85.00

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

Name of Dosage Form (include product form, i.e., tablets, patches, etc. and strengths)	Authority to Market	Drug Sched	Amount Used for this Purpose		Estimate for 2014	Estimate for Year Quota is Requested
			2011	2012		

Transfer Registrant	Explanation of Transfer

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

Date of Destruction	Explanation

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

Remarks

Hydromorphone production requires 256,000 grams and Oxymorphone production requires 220,000 grams in 2014. Due to equipment constraints it is possible not all 2013 quota will be consumed. If this is the case, quota will be surrendered later this year

Basic Class: 9143-A

2014 Initial APQ Worksheets

Total PQ Requested: 0.000

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		7,400,000.000	5,840,045.000	6,646,859.000	6,646,859.000	1.000	0.000	2,370,141.000	0.000	7,017,544.000	0.000	2,575,098.000	267,369.250	7,400,000.000
MQ Totals:		7,400,000.000	5,840,045.000											7,400,000.000

2013 Final Initial APQ:	8,200,000.000
2013 Final Revised APQ:	0.000
FDA Est (2013 Initial APQ * FDA Est):	0.000
IMS Est (2013 Initial APQ * IMS Est):	0.000

2014 Proposed Initial APQ:	7,400,000.000
	9,250,000.000 with 25% buffer

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 116051	Date Submitted: 30-APR-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189): OXYCODONE (FOR CONVERSION)	Schedule/List Number: 0
	Drug Code: 9143-A
Name and Address of Registrant: (b)(4)	Quota Year: 2014
	DEA Registration Number: (b)(4);(b)(7)(E)
Contact Person: (b)(4);(b)(6)	Fax. No: (b)(4);(b)(6)
Email Address:	Phone No.

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

Quota History	Quotas Previously Issued by DEA 2012	2013	2014	Quota Requested
	7,542,000.0	5,840,045.0	0.0	7,400,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	1,150,621.0	0.0	625,098.0	625,098.0
b.In-Process Material.....	1,219,520.0	0.0	1,950,000.0	1,950,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	2,370,141.0	0.0	2,575,098.0	2,575,098.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	7,017,544.0	7,017,544.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	7,017,544.0	7,017,544.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	7,400,000.0	7,400,000.0
	0.0	0.0	7,400,000.0	7,400,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2011	2012	2014	% Yield
OXYMORPHONE (FOR SALE)	9652-B	4,167,525	5,036,613	7,017,544	57.00

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 116052		Date Submitted	30-APR-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
OXYMORPHONE (FOR SALE)		Schedule/List Number	0
Name and Address of Registrant		Drug Code	9652-B
(b)(4)		Quota Year	2014
		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)		Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

Quota History	Quotas Previously Issued by DEA 2012	2013	2014	Quota Requested
	3,548,263.0	2,861,622.0	0.0	4,000,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	325,061.0	0.0	1,273,450.0	1,273,450.0
b.In-Process Material.....	560,781.0	0.0	250,000.0	250,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	885,842.0	0.0	1,523,450.0	1,523,450.0
Disposition(Sale)/Utilization				
a.Domestic.....	2,864,919.0	0.0	3,277,692.0	3,277,692.0
b Exports.....	0.0	0.0	0.0	0.0
	2,864,919.0	0.0	3,277,692.0	3,277,692.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	4,000,000.0	4,000,000.0
	0.0	0.0	4,000,000.0	4,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2011	2012	2014	% Yield

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

Basic Class: 9143-B

2014 Initial APQ Worksheets

Total PQ Requested: 98,744,757.717

FDA Est:

IMS Est: - 045

Company	DEA Num	2014 Requested MQ	MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		200,000.000	0.000	0.000	78,672,122.708	0.000	0.000	0.000	0.000	100,000.000	0.000	100,000.000	100,000.000	100,000.000
		60.000	60.000	3.998	78,672,122.708	0.000	5.018	303.439	0.000	20.000	0.000	333.440	60.000	60.000
		875,500.000	115,835.000	2,936.000	78,672,122.708	0.000	3,685.100	12,187.000	0.000	875,500.000	0.000	20,000.000	761,043.125	761,043.125
		2,880,000.000	900,000.000	365,669.000	78,672,122.708	0.005	458,666.856	899,207.000	0.000	2,916,000.000	0.000	1,482,995.000	1,924,501.570	1,924,501.570
		24,000,000.000	22,000,000.000	18,099,868.000	78,672,122.708	0.230	22,717,918.640	18,073,590.000	88,954.000	23,257,329.000	0.000	8,147,670.000	19,170,091.299	19,170,091.299
		64,500,000.000	43,326,873.000	39,262,449.000	78,672,122.708	0.499	49,279,884.834	12,240,264.000	0.000	53,820,000.000	0.000	16,050,000.000	70,684,562.292	64,500,000.000
		1,000.000	5,000.000	11,190.710	78,672,122.708	0.000	14,045.940	29,325.000	0.000	1,000.000	0.000	35,000.000	1,000.000	1,000.000
		24,000,000.000	26,000,000.000	20,490,277.000	78,672,122.708	0.260	25,738,226.079	15,657,708.000	6,000,000.000	23,000,000.000	0.000	10,000,000.000	25,990,074.599	24,000,000.000
		875,000.000	565,000.000	439,731.000	78,672,122.708	0.006	551,925.251	148,704.000	0.000	639,000.000	0.000	148,500.000	764,452.563	764,452.563
MQ Totals:		117,331,560.000	92,912,768.000										119,415,785.448	111,241,148.557

2013 Final Initial APQ:	105,200,000.000
2013 Final Revised APQ:	0.000
Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	117,489,500.000
2014 Proposed Initial APQ:	119,500,000.000
	149,375,000.000 with 25% buffer

Basic Class: 9652-A

Total PQ Requested: 4,001,000.000

2014 Initial APQ Worksheets

FDA Est:

IMS Est: 4,129

Company	DEA Num	2014 Requested MQ	MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory
(b)(4);(b)(7)(E)		8,600,000.000	7,600,000.000	4,318,079.000	5,766,249.000	0.749	2,996,130.418	25,000.000
		1,898,000.000	2,600,000.000	1,448,770.000	5,766,249.000	0.251	1,004,869.582	446,079.000
		2,300,300.000	1,762,600.000	0.000	5,766,249.000	0.000	0.000	0.000
MQ Totals:		13,798,300.000	11,962,600.000					

Company	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	2013 DEA Projected Inventory	Inventory Adj.	Calc Using Company Month	Calc Using Drawdown	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)	0.000	5,447,068.000	0.000	1,052,932.000	-1,818,458.000	3,065,733.333	4,047,062.418	1,177,652.418	7,465,851.029	8,000,000.000
	0.000	1,710,000.000	0.000	865,000.000	1,336,079.000	2,730,866.000	1,859,869.582	2,340,869.582	370,357.977	1,699,000.000
	0.000	0.000	0.000	2,500,000.000	1,762,600.000	1,388,400.000	2,500,000.000	1,762,600.000	-1,336,850.000	1,762,600.000
MQ Totals:										12,061,600.000

2013 Final Initial APQ:	14,700,000.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	12,606,840.000

2014 Proposed Initial APQ:	13,800,000.000	
	17,250,000.000	with 25% buffer

OXYMORPHONE (FOR CONVERSION)

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 115798		Date Submitted	26-APR-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
OXYMORPHONE (FOR CONVERSION)		Schedule/List Number	0
Name and Address of Registrant		Drug Code	9652-A
(b)(4)		Quota Year	2014
		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)		Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

Quota History	Quotas Previously Issued by DEA 2012	2013	2014	Quota Requested
	7,766,000.0	7,600,000.0	0.0	9,600,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	28,600.0	0.0	1,052,932.0	1,052,932.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	28,600.0	0.0	1,052,932.0	1,052,932.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	9,447,068.0	9,447,068.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	9,447,068.0	9,447,068.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	9,600,000.0	9,600,000.0
	0.0	0.0	9,600,000.0	9,600,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2011	2012	2014	% Yield
NOROXYMORPHONE (FOR CONVERSION)	9668-A	4,319,604	3,328,952	9,440,362	63.00
NOROXYMORPHONE (FOR SALE)	9668-B	0	0	6,707	63.00

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

Basic Class: 9739-0

2014 Initial APQ Worksheets

Total PQ Requested: 3,174.500

FDA Est: .074

IMS Est: .

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		1,000.000	5.000	0.000	0.225	0.000	0.000	0.000	0.000	1,000.000	0.000	1,000.000	996.250	1,000.000
		5.000	0.000	0.000	0.225	0.000	0.000	0.000	0.000	1.000	0.000	4.000	1.000	5.000
		1,820.000	1,820.000	0.000	0.225	0.000	0.000	1,938.000	0.000	1,820.000	0.000	1,026.000	-1,483.000	1,820.000
		5.000	5.000	0.225	0.225	1.000	3,174.500	0.000	0.000	4.000	0.000	1.000	3,968.375	5.000
MQ Totals:		2,830.000	1,830.000											2,830.000

2013 Final Initial APQ:	3,000.000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	3,222.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000
2014 Proposed Initial APQ:	3,000.000

3,750 w/25% buffer

Basic Class: 9740-8

Total APQ Requested: 774,136

2014 Initial APQ Worksheets

FDA Est:

Bdt Est:

Company	DEA Form	2014 Requested APQ	2013 Revised APQ	2012 Sales	2012 DEA APQ Sales	% of 2012 Sales	Share of 2014 Total PC	2011 Inventory	2014 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	2013 DEA Projected Inventory	Inventory Adj.	Calc Using Company Invent	Calc Using Dist Invent	Calc Using CFR 80% Invent	APQ
(b)(4);(b)(7)(E)		1,000,000	2,000,000	256,300	3,062,300	0.124	96,834	1,020,000	0.000	800,000	0.000	200,000	2,220,000	2,015,233	296,834	3,315,834	-1,800,208	1,500,000
		2,000	3,500	0.000	3,062,300	0.000	0.000	0.000	0.000	0.000	0.000	0.000	1,500	1,383	1,500	1,500	-1,000	2,000
		650,000	600,000	321,000	3,062,300	0.158	120,496	501,000	100,000	645,000	0.000	260,000	525,000	734,000	360,496	475,496	-54,360	650,000
		710,000	2,394,000	1,466,000	3,062,300	0.721	557,808	2,351,000	1,200,000	1,700,000	0.000	1,210,000	1,710,000	3,121,333	2,275,808	2,297,808	-425,808	710,000
																		2,362,000

2013 Final Initial APQ:	5,004,000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
Bdt Est: (2013 Initial APQ * Bdt Est):	0.000
2014 Proposed Initial APQ:	5,004.000

Basic Class: 9780-0

Total PQ Requested: 22,048,809,000

2014 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Num	2014 Requested PQ	2013 Revised PQ	2013 Sales	2012 DEA PQ Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	2013 DEA Projected Inventory	Inventory Adj.	Calc Using Company Invent	Calc Using Est Invent	Calc Using CFR 50% Invent	PQ
(b)(4);(b)(7)(E)		387,600,000	344,000,000	0.000	13,428,272,854	0.000	0.000	0.000	0.000	400,000,000	0.000	4,000,000	-96,000,000	229,333,333	4,000,000	-96,000,000	142,000,000	142,000,000
		10,000	10,000	0.504	13,428,272,804	0.000	0.457	3,987	0.000	1,000	0.000	12,987	12,987	8,325	13,814	13,814	48,453	13,814
		392,000,000	0.000	0.000	13,428,272,804	0.000	0.000	0.000	0.000	392,000,000	0.000	5,000,000	-392,000,000	0.000	5,000,000	-392,000,000	392,000,000	392,000,000
		15,000,000,000	2,350,000,000	##########	13,428,272,804	0.206	4,544,050,477	20,245,000	0.000	13,600,000,000	0.000	21,000,000	-10,728,705,000	1,513,530,000	4,370,058,427	-6,140,654,573	10,679,518,087	##########
MQ Totals:		13,779,010,000	2,364,010,000															##########

2013 Final Initial APQ:	11,000,000,000
2013 Final Revised APQ:	0.000
FDA Est: (2013 Initial APQ * FDA Est):	0.000
IMS Est: (2013 Initial APQ * IMS Est):	0.000

2014 Proposed Initial APQ:	11,000,000,000
	12,600,000,000 with 25% buffer

Basic Class: 9333
Total PQ Requested: = 31,831,208,000

2014 Initial APQ Worksheets

FDA Est:
IMS Est:

Company	DEA Num	2014 Requested MQ	MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	2013 DEA Projected Inventory	Inventory Adj.	Calc Using Company Invent	Calc Using Dea Invent	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		870,000,000	653,500,000	62,790,000	74,267,648.667	0.001	29,911.473	518,696,000	0.000	870,000,000	0.000	0.000	301,198,000	780,797,333	29,911.473	321,107,473	-104,431.136	870,000,000
		25,000	25,000	4,187	74,267,648.667	0.000	1.837	57,000	0.000	10,000	0.000	71,000	72,000	56,333	73.436	74,833	-44,451	25,000
		1,544,000,000	388,000,000	39,682,000	74,267,648.667	0.001	17,093.476	92,718,000	0.000	1,344,000,000	0.000	50,000,000	-1,083,782,000	320,145,333	67,093,476	-1,046,668,524	1,152,140,844	1,544,000,000
		1,200,000,000	1,200,000,000	941,400,000	74,267,648.667	0.013	412,087,254	5,090,000	0.000	1,200,000,000	0.000	0.000	5,090,000	803,393,333	412,087,254	417,147,254	909,901,546	1,200,000,000
		45,000,000,000	45,000,000,000	############	74,267,648.667	0.501	15,855,061.452	############	0.000	43,808,996,000	0.000	13,170,207,000	13,491,088,000	############	38,175,266.452	29,436,156,452	17,712,788,676	45,000,000,000
		2,000,000	4,167,000	19,300	74,267,648.667	0.000	8.308	0.000	0.000	8,000,000	0.000	1,500,000	-833,000	2,778,000	1,508.308	-824,694	1,656,133	2,000,000
		8,100,000,000	11,084,700,000	8,002,791,800	74,267,648.667	0.108	3,430,008.578	2,344,851,000	0.000	8,000,000,000	0.000	4,262,000,000	5,429,351,000	6,953,800,667	7,712,008,324	8,858,353,578	1,679,331,810	8,100,000,000
		20,000,000,000	7,498,513,000	9,374,830,000	74,267,648.667	0.126	4,017,876.256	1,655,850,000	0.000	20,300,000,000	0.000	1,505,609,000	-16,697,837,000	6,066,742,000	5,022,878,256	4,878,454,744	17,794,256,070	20,000,000,000
		18,500,000,000	21,700,000,000	############	74,267,648.667	0.230	7,912,089.207	3,725,400,000	0.000	19,500,000,000	0.000	15,000,000,000	5,923,400,000	############	16,973,089.207	13,837,469,707	8,464,658,549	18,500,000,000
MQ Totals:		98,218,675,000	87,525,906,000															98,218,025,000

2013 Final Initial APQ: 116,000,000.000
2013 Final Revised APQ: 0.000
Est2: 0.000
IMS Est: (2013 Initial APQ * IMS Est): 0.000

2014 Proposed Initial APQ: 115,000,000.000
145,000,000.000 with 25% buffer

THEBAINE

2014 Proposed Established 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 2014 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.

- 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 changes from the 2013 proposed revised AAN & APQ values:

Schedule I substances

- DEA is proposing to establish the APQ for 1-(1-phenylcyclohexyl)pyrrolidine, codeine methylbromide, dipipanone, fenethylline, morphine methylbromide, morphine methylsulfonate, n-ethyl-1-phenylcyclohexylamine, parahexyl for the first time in this FR. In previous years these substances have been established at zero. The change is based on receiving requests from bulk manufacturers for these substances. The manufacturing of these substances will be used for analytical standards, reference, and research material.

- DEA is proposing to establish the APQ for betamethadol at zero, although a quota was established in 2013. This is based on receiving zero requests for this substance for the 2014 calendar year.

- The APQ for gamma-hydroxybutyric acid (GHB) is proposed to accommodate a new bulk manufacturer that will supply a dosage form manufacturer bringing the first generic GHB product to market. FDA approval for the generic product is expected in late 2013.

- The APQ for 2-(2,5-dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P), 2-(2,5-dimethoxy-4-ethylphenyl)ethanamine (2C–E), 2-(2,5-dimethoxy-4-methylphenyl)ethanamine (2C–D), 2-(2,5-dimethoxy-4-nitro-phenyl)ethanamine (2C–N), 2-(2,5-dimethoxyphenyl)ethanamine (2C–H), 2-(4-chloro-2,5-dimethoxyphenyl)ethanamine (2C–C), 2-(4-iodo-2,5-dimethoxyphenyl)ethanamine (2C–I), 2,5-dimethoxy-4-ethylamphetamine (DOET), 2,5-dimethoxy-4-n-propylthiophenethylamine, 2,5-dimethoxyamphetamine, 2-[4-(ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2), 2-[4-

(isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4), 3,4-methylenedioxyamphetamine (MDA), 3,4-methylenedioxy-n-methylcathinone (methylone), 3,4-methylenedioxy-n-ethylamphetamine (MDEA), 3,4-methylenedioxypyrovalerone (MDPV), 3,4,5-trimethoxyamphetamine, 4-bromo-2,5-dimethoxyamphetamine (DOB), 4-bromo-2,5-dimethoxyphenethylamine (2-CB), 4-methoxyamphetamine, 4-methylaminorex, 4-methyl-2,5-dimethoxyamphetamine (DOM), 4-methyl-n-methylcathinone (mephedrone), 5-methoxy-3,4-methylenedioxyamphetamine, 5-methoxy-n,n-diisopropyltryptamine, 5-methoxy-n,n-dimethyltryptamine, alpha-ethyltryptamine, alpha-methyltryptamine (AMT), aminorex, diethyltryptamine, dimethyltryptamine, mescaline, methcathinone, n-benzylpiperazine, n,n-dimethylamphetamine, n-ethylamphetamine, n-hydroxy-3,4-methylenedioxyamphetamine, psilocybin, and psilocyn were increased. The manufacturing of these substances will be used for analytical standards, reference, and research material. There are new DEA registrant(s) entering the reference standard market at the bulk manufacturing level and caused increased requests for research material.

- The APQ for codeine-n-oxide, hydromorphinol, and morphine-n-oxide were decreased. The decrease is due to lower quantities being requested from the bulk manufacturers who require this material for analytical and reference standards.

Schedule II substances

- The APQ for amphetamine (for sale), lisdexamfetamine, morphine (for sale), nabilone, opium (powder), oxymorphone (for sale), and tapentadol are proposed to accommodate increased registrants' requirements based on FDA granting new generic manufacturers access to market, registrants exporting to new markets overseas, and changes in domestic market demands. Amphetamine (for sale) manufacturing has high losses due to the isomer isolation, i.e., d-amphetamine from the racemic (d,l-amphetamine) mixture.

- The APQ for 1-piperdinocyclohexanecarbonitrile (PCC), alfentanil, codeine (for conversion), codeine (for sale), dihydrocodeine, levorphanol, meperidine, methadone (for sale), methadone intermediate, methamphetamine, opium (tincture), oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), pentobarbital, and phencyclidine were decreased. The proposed values are determined from a review of the requested API quantities and subsequent registrant requests.

- The APQ for 4-anilino-n-phenethyl-4-piperidine (ANPP), noroxymorphone (for conversion), and phenylacetone were increased due to the increased sales of the controlled substances that utilize them as the starting material. These controlled substances include: amphetamine (for conversion), amphetamine (for sale), fentanyl, lisdexamfetamine, and nal-based non-controlled drugs.

List I Chemicals

- Pseudoephedrine (for conversion), for which DEA does not typically establish an AAN, was added to the 2014 AAN because a registrant requested small amounts for product development efforts for a feasibility study for the conversion of pseudoephedrine to methamphetamine.

- The proposed AAN for ephedrine (for sale), phenylpropanolamine (for sale), and pseudoephedrine (for sale) have decreased based on registrant demand.

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-378]

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 2014

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes initial year 2014 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*. 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-378" on all electronic and written correspondence. DEA encourages that all comments be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at http://www.regulations.gov for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to www.regulations.gov will be posted for public review and are part of the official docket record. Written comments submitted via

regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

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

Background

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The proposed year 2014 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 2014 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes.

In determining the proposed 2014 aggregate production quotas and assessment of annual needs, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 U.S.C. 826(a), 21 CFR 1303.11 (aggregate production quotas for controlled substances), and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). DEA proposes the aggregate production quotas and assessment of annual needs for 2014 by considering (1) total net disposal of the class or chemical by all manufacturers

and chemical importers during the current and two preceding years; (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for such class or chemical as indicated by procurement and chemical import quotas requested pursuant to 21 CFR 1303.12, 1315.32, and 1315.34; and (5) other factors affecting the medical, scientific, research, and industrial needs in the United States, lawful export requirements, and reserve stocks, as the Deputy Administrator finds relevant. Other factors DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed 2014 assessment of annual needs, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407, respectively).

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

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

The Deputy Administrator, therefore, proposes that the year 2014 aggregate production quotas and assessment of annual needs for the following schedule I and II controlled substances and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Proposed 2014 Quotas
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15 g
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15 g
1-(1-Phenylcyclohexyl)pyrrolidine	10 g
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	30 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30 g
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	30 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25 g

2,5-Dimethoxy-4-n-propylthiophenethylamine	25 g
2,5-Dimethoxyamphetamine	25 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30 g
3,4,5-Trimethoxyamphetamine	25 g
3,4-Methylenedioxyamphetamine (MDA)	55 g
3,4-Methylenedioxymethamphetamine (MDMA)	50 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	50 g
3,4-Methylenedioxypyrovalerone (MDPV)	35 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25 g
4-Methoxyamphetamine	100 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25 g
4-Methylaminorex	25 g
4-Methyl-N-methylcathinone (mephedrone)	45 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	25 g
5-Methoxy-N,N-diisopropyltryptamine	25 g
5-Methoxy-N,N-dimethyltryptamine	25 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	25 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	25 g
Aminorex	25 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g

Betaprodine	2 g
Bufotenine	3 g
Cathinone	26 g
Codeine Methylbromide	5 g
Codeine-N-oxide	200 g
Desomorphine	5 g
Diethyltryptamine	25 g
Difenoxin	50 g
Dihydromorphine	3,300,000 g
Dimethyltryptamine	25 g
Dipipanone	5 g
Fenethylline	5 g
Gamma-hydroxybutyric acid	70,250,000 g
Heroin	25 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	25 g
Methaqualone	10 g
Methcathinone	25 g
Methyldihydromorphine	2 g
Morphine Methylbromide	5 g
Morphine Methylsulfonate	5 g
Morphine-N-oxide	175 g
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15 g
N-Benzylpiperazine	25 g
N,N-Dimethylamphetamine	25 g
N-Ethyl-1-phenylcyclohexylamine	5 g
N-Ethylamphetamine	24 g
N-Hydroxy-3,4-methylenedioxyamphetamine	24 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Parahexyl	5 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g

Psilocybin	30 g
Psilocyn	30 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Proposed 2014 Quotas
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile (PCC)	3 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500 g
Alfentanil	17,625 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	18,375,000 g
Amphetamine (for sale)	49,000,000 g
Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	68,750,000 g
Codeine (for sale)	46,125,000 g
Dextropropoxyphene	19 g
Dihydrocodeine	100,750 g
Diphenoxylate	750,000 g
Ecgonine	127,500 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	5,968,750 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	6 g
Levorphanol	2,000 g
Lisdexamfetamine	23,750,000 g
Meperidine	6,250,000 g
Meperidine Intermediate-A	6 g
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	6 g
Methadone (for sale)	31,875,000 g

Methadone Intermediate	38,875,000 g
Methamphetamine	3,911,375 g
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,600,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000 g
Morphine (for conversion)	91,250,000 g
Morphine (for sale)	62,500,000 g
Nabilone	30,375 g
Noroxymorphone (for conversion)	12,250,000 g
Noroxymorphone (for sale)	1,262,500 g
Opium (powder)	112,500 g
Opium (tincture)	625,000 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	9,250,000 g
Oxycodone (for sale)	149,375,000 g
Oxymorphone (for conversion)	17,250,000 g
Oxymorphone (for sale)	7,750,000 g
Pentobarbital	35,000,000 g
Phenazocine	6 g
Phencyclidine	6 g
Phenmetrazine	3 g
Phenylacetone	29,980,050 g
Racemethorphan	3 g
Remifentanil	3,750 g
Secobarbital	215,003 g
Sufentanil	6,255 g
Tapentadol	17,500,000 g
Thebaine	145,000,000 g

Basic Class – List I Chemicals	Proposed 2014 Quotas
Ephedrine (for conversion)	15,100,000 g
Ephedrine (for sale)	2,900,000 g
Phenylpropanolamine (for conversion)	25,700,000 g
Phenylpropanolamine (for sale)	5,300,000 g
Pseudoephedrine (for conversion)	5,000 g
Pseudoephedrine (for sale)	156,000,000 g

The Deputy Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 be established at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2014 aggregate production quotas and assessment of annual needs as needed.

Comments

Pursuant to 21 CFR 1303.11 and 21 CFR 1315.11, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Deputy Administrator may hold a public hearing on one or more issues raised. In the event the Deputy Administrator decides in his sole discretion to hold such a hearing, the Deputy Administrator will publish a notice of any such hearing in the Federal Register. After consideration of any comments and after a hearing, if one is held, the Deputy Administrator will publish in the Federal Register a Final Order establishing the 2014 aggregate production quota for each basic class of controlled substance and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Dated:

Thomas M. Harrigan
Deputy Administrator

OC:_____

OD:_____

OD/D:_____

ODX:_____

ODXS:_____

ODW: _____

ODQ:_____

ODQ:(b)(6) _____:(b)(6) 06-25-13

Webcims #ODEQ-13-408

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

1308.24(a). All other requirements of the CSA and the CFR apply, including, but not limited to, registration as an importer as required by 21 U.S.C. 957.

Chemical Preparations Containing Newly Controlled Substances

The statutory authority for exempt chemical preparations is based on the control status of substances contained within a preparation, the intended administration of a preparation, and the packaged form of a preparation. DEA conducts a case-by-case analysis of each application for exemption to determine whether exemption of a preparation from certain provisions of the CSA is appropriate pursuant to the specified statutory and regulatory requirements.

Most exempt chemical preparations have remained effective until the holder of a specific exempt chemical preparation specifically requested that the exemption be terminated. The CSA allows for modifications to the controlled substances schedules to add, remove, or change the schedule of substances thus resulting in periodic modifications to the control status of various substances. 21 U.S.C. 811(a). Since the CSA was enacted in 1970, DEA has on several occasions added to, removed from, or modified the schedules of controlled substances in accordance with the CSA. Such changes may result in the non-compliance of exempt chemical preparations with current statutes or regulations if chemical preparations that have already obtained exempt status contain newly controlled substances. For example, although an exempt chemical preparation may continue to be packaged in the same manner as when it was approved, non-controlled substances in the preparation may become controlled, thus prompting the need for a new application for exemption of the chemical preparation to ensure continued compliance. Other preparations that previously contained no controlled substances may contain newly controlled substances and thus would require an application for exemption.

DEA reviews applications for chemical preparation exemptions based on the statutes and regulations that are in place at the time of the application, including the control status of substances included in the preparation. DEA must remain vigilant to ensure that exempt chemical preparations remain consistent with the standards set forth in the CSA and its implementing regulations. As such, DEA reminds the public that any chemical preparation, regardless of whether it was previously exempt, that contains a newly controlled substance will require a new application for exemption pursuant to 21 U.S.C. 811(g)(3)(B) and 21 CFR 1308.23–1308.24.

Review of Exemptions Pursuant to 21 U.S.C. 811(g)(3)

Based on inquiries received from industry, DEA is conducting a comprehensive review of the exempt chemical preparation regulations. DEA's regulations at 21 CFR 1308.24(a) state that approved chemical preparations are exempt from certain provisions of both Subchapter I and Subchapter II of the CSA: "The chemical preparations and mixtures approved pursuant to 1308.23 are exempt from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and 1301.74 of this chapter, to the extent described in paragraphs (b) to (h) of this section." Pursuant to its regulations, DEA has provided exemptions from the application of section 302, 303, 305, 306, 307, 308, 309, 1002, 1003, and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and 21 CFR 1301.74 since the implementation of the regulations in the early 1970s. Until DEA's analysis of the exemption regulations is complete, DEA will continue to review and provide exemptions to chemical preparations consistent with the implementing regulations, when warranted. DEA will publish a future notice regarding the outcome of DEA's review of its regulations with respect to the exemption of chemical preparations.

Opportunity for Comment

Pursuant to 21 CFR 1308.23, any interested person may submit written comments on or objections to any chemical preparation in this order that has been approved or denied as exempt. If any comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which this order is based, the Deputy Assistant Administrator will immediately suspend the effectiveness of any applicable part of this order until he may reconsider the application in light of the comments and objections filed.

Approved Exempt Chemical Preparations Are Posted on DEA's Web Site

A list of all current exemptions, including those listed in this order, is available on DEA's Web site at *http://www.DEAdiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf*. The dates of applications of all current exemptions are posted for easy reference.

Dated: June 17, 2013.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2013–16010 Filed 7–2–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–378]

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 2014

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes initial year 2014 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before August 2, 2013. The electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–378" on all electronic and written correspondence. DEA encourages that all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at *http://www.regulations.gov* for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *www.regulations.gov* will be posted for public review and are part of the official docket record. Written comments submitted via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive,

Springfield, VA 22152, Telephone: (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

Background

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The proposed year 2014 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 2014 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes.

In determining the proposed 2014 aggregate production quotas and assessment of annual needs, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 U.S.C. 826(a), 21 CFR 1303.11 (aggregate production quotas for controlled substances), and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). DEA proposes the aggregate production quotas and assessment of annual needs for 2014 by considering (1) total net disposal of the class or chemical by all manufacturers and chemical importers during the current and two preceding years; (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for such class or chemical as indicated by procurement and chemical import quotas requested pursuant to 21 CFR 1303.12, 1315.32, and 1315.34; and (5) other factors affecting the medical, scientific, research, and industrial needs in the United States, lawful export requirements, and reserve stocks, as the Deputy Administrator finds relevant. Other factors DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed 2014 assessment of annual needs, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294 and 75 FR 79407, respectively).

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

The Deputy Administrator, therefore, proposes that the year 2014 aggregate production quotas and assessment of annual needs for the following Schedule I and II controlled substances and for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, be established as follows:

Basic class—schedule I	Proposed 2014 quotas
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144)	15 g
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15 g
1-(1-Phenylcyclohexyl)pyrrolidine	10 g
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	5 g

Basic class—schedule I	Proposed 2014 quotas
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	30 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30 g
2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C-N)	30 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	25 g
2,5-Dimethoxyamphetamine	25 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30 g
3,4,5-Trimethoxyamphetamine	25 g
3,4-Methylenedioxyamphetamine (MDA)	55 g
3,4-Methylenedioxymethamphetamine (MDMA)	50 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	50 g
3,4-Methylenedioxypyrovalerone (MDPV)	35 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25 g
4-Methoxyamphetamine	100 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25 g
4-Methylaminorex	25 g
4-Methyl-N-methylcathinone (mephedrone)	45 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	25 g
5-Methoxy-N,N-diisopropyltryptamine	25 g
5-Methoxy-N,N-dimethyltryptamine	25 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	25 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	25 g
Aminorex	25 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betaprodine	2 g
Bulotenine	3 g
Cathinone	26 g
Codeine Methylbromide	5 g
Codeine-N-oxide	200 g
Desomorphine	5 g
Diethyltryptamine	25 g
Difenoxin	50 g
Dihydromorphine	3,300,000 g
Dimethyltryptamine	25 g
Dipipanone	5g
Fenethylline	5 g
Gamma-hydroxybutyric acid	70,250,000 g
Heroin	25 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	30 g
Marihuana	21,000 g
Mescaline	25 g
Methaqualone	10 g
Methcathinone	25 g
Methyldihydromorphine	2 g
Morphine Methylbromide	5 g
Morphine Methylsulfonate	5 g
Morphine-N-oxide	175 g
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15 g
N-Benzylpiperazine	25 g
N,N-Dimethylamphetamine	25 g
N-Ethyl-1-phenylcyclohexylamine	5 g
N-Ethylamphetamine	24 g
N-Hydroxy-3,4-methylenedioxyamphetamine	24 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Parahexyl	5 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	30 g
Psilocyn	30 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic class—schedule II	Proposed 2014 quotas
1-Phenylcyclohexylamine	3 g
1-Piperidinocyclohexanecarbonitrile (PCC)	3 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500 g
Alfentanil	17,625 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	18,375,000 g
Amphetamine (for sale)	49,000,000 g
Carfentanil	6 g
Cocaine	240,000 g
Codeine (for conversion)	68,750,000 g
Codeine (for sale)	46,125,000 g
Dextropropoxyphene	19 g
Dihydrocodeine	100,750 g
Diphenoxylate	750,000 g
Ecgonine	127,500 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	5,968,750 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	6 g
Levorphanol	2,000 g
Lisdexamfetamine	23,750,000 g
Meperidine	6,250,000 g
Meperidine Intermediate-A	6 g

Basic class—schedule II	Proposed 2014 quotas
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	6 g
Methadone (for sale)	31,875,000 g
Methadone Intermediate	38,875,000 g
Methamphetamine	3,911,375 g
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,600,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)].	
Methylphenidate	96,750,000 g
Morphine (for conversion)	91,250,000 g
Morphine (for sale)	62,500,000 g
Nabilone	30,375 g
Noroxymorphone (for conversion)	12,250,000 g
Noroxymorphone (for sale)	1,262,500 g
Opium (powder)	112,500 g
Opium (tincture)	625,000 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	9,250,000 g
Oxycodone (for sale)	149,375,000 g
Oxymorphone (for conversion)	17,250,000 g
Oxymorphone (for sale)	7,750,000 g
Pentobarbital	35,000,000 g
Phenazocine	6 g
Phencyclidine	6 g
Phenmetrazine	3 g
Phenylacetone	29,980,050 g
Racemethorphan	3 g
Remifentanil	3,750 g
Secobarbital	215,003 g
Sufentanil	6,255 g
Tapentadol	17,500,000 g
Thebaine	145,000,000 g

Basic class—list I chemicals	Proposed 2014 quotas
Ephedrine (for conversion)	15,100,000 g
Ephedrine (for sale)	2,900,000 g
Phenylpropanolamine (for conversion)	25,700,000 g
Phenylpropanolamine (for sale)	5,300,000 g
Pseudoephedrine (for conversion)	5,000 g
Pseudoephedrine (for sale)	156,000,000 g

The Deputy Administrator further proposes that aggregate production quotas for all other Schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 be established at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2014 aggregate production quotas and assessment of annual needs as needed.

Comments

Pursuant to 21 CFR 1303.11 and 21 CFR 1315.11, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Deputy Administrator may hold a public hearing on one or more issues raised. In the event the Deputy Administrator decides in his sole discretion to hold such a hearing, the Deputy Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments and after a hearing, if one is held, the Deputy Administrator will publish in the **Federal Register** a Final Order establishing the 2014 aggregate production quota for each basic class of controlled substance and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Dated: June 27, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013-16052 Filed 7-2-13; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Office of Juvenile Justice and Delinquency Prevention

[OMB Number 1121-0219]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Juvenile Residential Facility Census (Extension, Without Change, of a Currently Approved Collection)

ACTION: 60 Day Notice.

The Department of Justice (DOJ), Office of Justice Programs, Office of Juvenile Justice and Delinquency Prevention, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until September 3, 2013. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Brecht Donoghue, (202) 305-1270, Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, U.S. Department of Justice, 810 Seventh Street NW., Washington, DC 20531.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection Back to Top

(1) *Type of information collection:* Extension, without change, of a currently approved collection.

(2) *The title of the form/collection:* Juvenile Residential Facility Census.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is CJ-15, Office of Juvenile Justice and Delinquency Prevention, United States Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Federal Government, State, Local or Tribal. Other: Not-for-profit institutions; Business or other for-profit.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that 2,545 respondents will complete a 2-hour questionnaire.

(6) *An estimate of the total public burden (in hours) associated with the collection:* Approximately 5,090 hours.

If additional information is required, contact: Jerri Murray, Department Clearance Officer, U.S. Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Suite 3W-1407B, Washington, DC 20530.

Chemical	Proposed AAN	Establish AAN
ephedrine (for conversion)	15,100,000	1,000,000
ephedrine (for sale)	2,900,000	3,000,000
phenylpropanolamine (for conversion)	25,700,000	44,800,000
pseudoephedrine (for sale)	156,000,000	192,000,000
Drug	**Proposed APQ w/ 25% buffer**	**Establish APQ w/ 25% buffer**
1-[1-(2-Thienyl)cyclohexyl]piperidine	5	15
carfentanil	6	19
cathinone	26	70
dihydromorphine	3,300,000	3,990,000
dimethyltryptamine	25	35
d-methamphetamine (for conversion)	2,600,000	1,500,000
ecgonine	127,500	144,000
hydromorphone	5,968,750	6,750,000
levomethorphan	6	195
lysergic acid diethylamide	30	35
metazocine	6	19
methamphetamine	3,911,375	2,811,375
methyldesorphine	-	2
noroxymorphone (for conversion)	12,250,000	17,500,000
oxymorphone (for conversion)	17,250,000	25,000,000
phencyclidine	6	19
phenylacetone	29,980,050	67,000,000

Drug	Company	Comment	Amount	Response	Proposed APQ	Establish APQ	Change
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	(b)(4)	increase APQ	10	APQ sufficient	15	15	-
(1-(5-fluoro-pentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone		increase APQ	10	APQ sufficient	15	15	-
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)		increase APQ	10	APQ sufficient	15	15	-
cathinone		increase APQ	40	justified, increase APQ	26	70	44
d-amphetamine (for sale)		increase APQ	1,800,000	APQ sufficient	49,000,000	49,000,000	-
		increase APQ	1,300,000				
d,l-amphetamine (for sale)		increase APQ	950,000				
		increase APQ	830,000				
codeine (for conversion)		increase APQ	790,000	APQ sufficient	68,750,000	68,750,000	-
		increase APQ	1,500,000				
codeine (for sale)		increase APQ	7,060,000	APQ sufficient	46,125,000	46,125,000	-
fentanyl		increase APQ	124,000	APQ sufficient	2,108,750	2,108,750	-
hydrocodone (for sale)		increase APQ	7,400,000	APQ sufficient	99,625,000	99,625,000	-
hydromorphone		increase APQ	160,000	justified, increase APQ	5,968,750	6,750,000	781,250
levomethorphan		increase APQ	150	justified, increase APQ	6	195	189
methylphenidate		increase APQ	1,740,000	APQ sufficient	96,750,000	96,750,000	-
morphine (for conversion)		increase APQ	3,230,000	APQ sufficient	91,250,000	91,250,000	-
		increase APQ	9,000,000				
		increase APQ	150,000				
morphine (for sale)		increase APQ	1,400,000	APQ sufficient	62,500,000	62,500,000	-
noroxymorphone (for conversion)		increase APQ	10,800,000	justified, increase APQ	12,250,000	17,500,000	5,250,000
		increase APQ	970,000				
opiravine		increase APQ	15,000,000	APQ sufficient	22,750,000	22,750,000	-
oxycodone (for sale)		increase APQ	4,250,000	APQ sufficient	149,375,000	149,375,000	-
		increase APQ	470,000				
oxymorphone (for conversion)		increase APQ	13,000,000	justified, increase APQ	17,250,000	25,000,000	7,750,000
		increase APQ	6,211,000				
oxymorphone (for sale)		increase APQ	300,000	APQ sufficient	7,750,000	7,750,000	-
		increase APQ	90,000				
phenylacetone		increase APQ	30,000,000	justified, increase APQ	29,980,050	67,000,000	37,019,950
tapentadol		increase APQ	500,000	APQ sufficient	17,500,000	17,500,000	-
tetrahydrocannabinol		increase APQ	10,000	APQ sufficient	491,000	491,000	-
thebaine		increase APQ	2,225,000	APQ sufficient	145,000,000	145,000,000	-
		increase APQ	500,000				

Number of registrants/entities commenting: 6
Number of drugs commented on: 24

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CMEA Chemical	Company	Comment	Amount	Response	Proposed AAN	Establish AAN	Change
PPA (for conversion)	(b)(4)	increase AAN	11,000,000		25,700,000	44,800,000	19,100,000

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

Additional Drug Considerations:

Drug	Response	Proposed	Revised	Change
1-[1-(2-Thienyl)cyclohexyl]piperidine	increase APQ, based on additional ref std manufacturer request	5	15	10
carfentanil	increase APQ, based on additional ref std manufacturer request	6	19	13
ecgonine	adjust to 2013 Final APQ value, represents 2014 pending requests	127,500	144,000	16,500
dihydromorphine	increase APQ, based on new requests - set to 2013 Final Revised value	3,300,000	3,990,000	690,000
dimethyltryptamine	increase APQ, based on change in quantity requested from ref std manufacturer - (b)(4)	25	35	10
lysergic acid diethylamide	increase APQ, based on change in quantity requested from ref std manufacturer -	30	35	5
metazocine	increase APQ, based on change in quantity requested from ref std manufacturer -	6	19	13
methamphetamine	decrease APQ, based on adjustment of d-methamphetamine (for conversion)	3,911,375	2,811,375	(1,100,000)
d-methamphetamine (for conversion)	decrease APQ, based on decreasing requests for last 3 years	2,600,000	1,500,000	(1,100,000)
methyldesorphine	increase APQ, based on new request from ref std manufacturer - (b)(4)	-	2	2
phencyclidine	increase APQ, based on additional ref std manufacturer request requests	6	19	13

Additional Chemical Considerations:

Drug	Response	Proposed	Revised	Change
ephedrine (for conversion)	decrease AAN, based on historic lack of utilization	15,100,000	1,000,000	(14,100,000)
ephedrine (for sale)	increase AAN, based on new requests	2,900,000	3,000,000	100,000
pseudoephedrine (for sale)	increase AAN, based on new requests	156,000,000	192,000,000	36,000,000

CONFIDENTIAL

(b)(4)

30 July 2013

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

Subject: Comment on Proposed 2014 Aggregate Production Quotas
Docket No. DEA-378

Dear Sir/Madam:

(b)(4) is submitting this comment in reference to the Proposed 2014 Aggregate Production Quotas (APQs) published in the Federal Register under citation Vol. 78, No. 128, pages 40186-40189, dated 03 July 2013. This is Docket No. DEA-378. This comment is CONFIDENTIAL BUSINESS INFORMATION and relates to five controlled substances. We request that portions of this comment highlighted below be redacted.

For the first three controlled substances, which are synthetic cannabinoids, the substances became scheduled on May 16, 2013. Because of that, no applications for initial manufacturing quotas were submitted during the annual application period in early 2013. Therefore, (b)(4) is submitting this comment to request that the APQ for those three substances (listed below) be revised as required to allow for issuance of 10 gram initial quotas to (b)(4) for these drug classes.

Additionally, (b)(4) is currently in negotiations with one of its customers to provide a bulk synthesis of Levomethorphan. (b)(4) has a Letter of Intent from the customer indicating their intent to enter into a Purchase Order agreement with (b)(4) for the manufacture of this substance. A copy of that Letter of Intent can be provided upon request. The Purchase Order agreement will be executed at a later date. The Letter of Intent is for (b)(4) to deliver a minimum of 80 grams of Levomethorphan. However, more could be delivered if enough material is produced that meets the customer's specification. As part of public comment for the proposed adjustments to the 2013 APQ's, (b)(4) submitted a comment requesting the APQ for Levomethorphan be revised to cover this project.

However, as mentioned in that comment, it is unknown when the APQ will be revised, how long it will take obtain our revised manufacturing quota and a revised procurement quota necessary to purchase the required quantity of the starting material needed for the synthesis, and how long the actual production time to complete the synthesis will take. Therefore, it is unclear as to whether there ultimately will be sufficient time to produce the final substance in 2013. Because of that, (b)(4) is submitting this comment in response to the proposed initial

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2014 APQ for this drug class to cover the eventuality that the final product cannot be obtained in 2013.

Therefore, (b)(4) is requesting that the APQ for Levomethorphan be revised to allow for a 150 gram increase to (b)(4) Levomethorphan manufacturing quota for 2014. That quantity will cover both the deliverable quantity for the customer and any non-specification material produced during the synthetic process. The quantity of non-specification material to be produced during this project is unknown at this point due to uncertainty in the production yield for synthesis at this scale.

Finally, (b)(4) is currently in negotiations with one of its customers to provide a bulk synthesis of Cathinone HCl. (b)(4) has a Letter of Intent from the customer indicating their intent to enter into a Purchase Order agreement with (b)(4) for the manufacture of this substance. A copy of that Letter of Intent can be provided upon request. The Purchase Order agreement will be executed at a later date. The Letter of Intent is for (b)(4) to deliver a minimum of 25 grams of Cathinone HCl. The customer is wishing to obtain the material in 2013. However, if a procurement source cannot be found in 2013, the plan is for (b)(4) to manufacture the material in 2014. Therefore, (b)(4) is requesting that the APQ for Cathinone be revised to allow for a 40 gram increase to (b)(4) Levomethorphan manufacturing quota for 2014. That quantity will cover both the deliverable quantity for the customer and any non-specification material produced during the synthetic process. The quantity of non-specification material to be produced during this project is unknown at this point due to uncertainty in the production yield for synthesis at this scale.

Based on this information, (b)(4) requests that the 2014 aggregate production quotas for the following five substances be adjusted as needed to ensure that (b)(4) anticipated requirement in the amounts listed below are covered:

XLR11	10 g
UR-144	10 g
AKB48	10 g
Levomethorphan	150 g
Cathinone	40 g

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

Sincerely,

(b)(6)

Vice President
Regulatory Affairs

(b)(4)

(b)(4)

(b)(4) location

CONFIDENTIAL

~~RECEIVED~~
~~ODE~~

~~2013 JUL 26 AM 7:10~~

July 31, 2013

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

2013 AUG -7 AM 7:11

RECEIVED
ODE

Subject: Docket No. DEA-378

Dear Sirs:

I, (b)(4);(b)(6) manufacturing registration (b)(4);(b)(7)(E) am submitting this comment on the 2014 Proposed Aggregate Production Quota for various products as published in the July 3, 2013 Federal Register. We consider the information in this first paragraph to be "PERSONAL IDENTIFYING INFORMATION" and this information should not be released under the Freedom of Information Act per 5 USC Sec. 552(b)(4). In addition, the following information is "CONFIDENTIAL BUSINESS INFORMATION". The following items' manufacturing quota should be increased by the identified quantity: (i) Amphetamine (for sale) by 2,750,000 grams as base [950,000 grams for D,L-Amphetamine and 1,800,000 grams for D-Amphetamine]; (ii) Codeine (for conversion) by 1,500,000 grams as base; (iii) Morphine (for conversion) by 3,230,000 grams as base; and (iv) Morphine (for sale) by 1,400,000 grams as base. The following items' procurement quota should be increased by the identified quantity: (i) Phenylpropanolamine (for conversion) by 11,000,000 grams as base. These numbers are over and above the volumes identified in our late April 2013 requests for 2014. As noted herein, this first paragraph of this letter contains personal identifying and confidential business information and should be redacted in its entirety from any public docket.

We feel the proposed quantities for the material mentioned above are not sufficient to provide for adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements, and that the quotas should be increased to cover our needs. For these items an appropriate Electronic DEA Quota Application Form 189 or Form 250 will be submitted shortly pertaining to the items for which we are submitting comments.

Very truly yours

(b)(4) location

RECEIVED
ODE

CONFIDENTIAL

2013 AUG -7 AM 7:11

July 31, 2013

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

Subject: Docket No. DEA-378

Dear Sirs:

I, (b)(4);(b)(6) manufacturing registration (b)(4);(b)(7)(E) am submitting this comment on the 2014 Proposed Aggregate Production Quota for various products as published in the July 3, 2013 Federal Register. We consider the information in this first paragraph to be "PERSONAL IDENTIFYING INFORMATION" and this information should not be released under the Freedom of Information Act per 5 USC Sec. 552(b)(4). In addition, the following information is "CONFIDENTIAL BUSINESS INFORMATION". The following items' manufacturing quota should be increased by the identified quantity: (i) Codeine (for conversion) by 790,000 grams as base; (ii) Fentanyl by 124,000 grams as base; (iii) Hydrocodone by 7,400,000 grams as base; (iv) Methylphenidate by 1,740,000 grams as base; (v) Morphine (for conversion) by 150,000 grams as base, (vi) Noroxymorphone by 970,000 grams as base; (vii) Oxymorphone by 90,000 grams as base; (viii) Oxycodone by 470,000 grams as base; (ix) Thebaine by 500,000 grams as base; and (x) Tetrahydrocannabinol by 10,000 grams as base. These numbers are over and above the volumes identified in our late April 2013 requests for 2014. 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.

(conv) ←

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

(b)(4)

July 31, 2013

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

Attn: DEA Federal Register Representative [Docket No. DEA-378]

This letter constitutes (b)(4) comments on the Proposed Initial Aggregate Production Quotas for 2014, as published in Federal Register on Wednesday July 3, 2013, FR Volume 78, No. 128, pages 40186-40189.

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

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

1100 (A) d,l-Amphetamine (for Sale)
(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 830,000 g AA of d,l-amphetamine (for sale) manufacturing quota for 2014 (reference DEA online submission #116053). Total requested amphetamine quota is 2,130,000 g AA.

1100 (B2) d-Amphetamine (for Sale)
(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 1,300,000 g AA of d-amphetamine (for sale) manufacturing quota for 2014 (reference DEA online submission number #116718).

9668 Noroxymorphone (for Conversion)
(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 10,000,000 g AA of noroxymorphone (for conversion) manufacturing quota for 2014 (reference DEA online submission #116699).

9330 Oripavine
(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 15,000,000 g AA of oripavine manufacturing quota for 2014 (reference DEA online submission #116697).

(b)(4)

Attn: DEA Federal Register Representative [Docket No. DEA-378]

9652 (A) Oxymorphone (for Conversion)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 13,000,000 g AA of oxymorphone (for conversion) manufacturing quota for 2014 (reference DEA online submission #116698).

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

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

(b)(6)

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

July 26, 2013 *Confidential*

REFERENCE: **Docket No. DEA-378**

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

RE: Comment to Federal Register FR Doc 2013-16052, Controlled Substances: Proposed Aggregate Production Quotas for 2014

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

DEA Drug Code Numbers: **9780, Tapentadol**

This correspondence serves as a written comment to the Federal Register Volume 78, Number 128, Docket No. DEA-378 published on July 3, 2013.

(b)(4) requests that the Proposed Aggregate Production Quota for 2014 be adjusted to factor in the following estimated product needs of (b)(4) in 2014.

	Controlled Substance	DEA Drug Code/ Schedule	2014 Proposed Aggregate Production Quota	2014 (b)(4) Estimated Bulk Manufacturing Requirements
1.	Tapentadol	9780 / C-II	17,500,000 grams	500,000 grams

(cont.)

Summary and Background:

1. Tapentadol (DEA Drug Code 9780) – 500,000 grams

   The proposed 2014 Aggregate Production Quota for Tapentadol of 17,500,000 grams may not be adequate to cover (b)(4) projected product needs for 2014.

   CONFIDENTIAL BUSINESS INFORMATION

   (b)(4)

Sincerely,

(b)(6)

Director, Quality Assurance and Regulatory Affairs

(b)(4)

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

(b)(4)

(b)(4)

August 1, 2013

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

RE: Docket No. DEA–378 (b)(4) **Comment**

Dear Sirs:

(b)(4);(b)(7)(E) have submitted quota correspondence as set forth in the table below for the following manufacturing categories. (b)(4) requests that the correspondence provided to the Quota Unit, which constitutes "CONFIDENTIAL BUSINESS INFORMATION", be considered during the 2014 Aggregate Production Quota review.

Quota Category	Quota Application Ref. #	Material Name	Action Needed
Manufacturing	116716	Codeine - 9050 (fs)	An aggregate increase on (b)(4) customer demand
Manufacturing	116738	Morphine for Conversion- 9300	An aggregate increase based on (b)(4) customer demand and development initiative
Manufacturing	116743	Oxycodone for Sale – 9143	An aggregate increase based on (b)(4) customer demand
Manufacturing	116742	Thebaine - 9333	An aggregate increase based on (b)(4) customer demand
Manufacturing	116739 116740	Oxymorphone for Conversion -9652 Oxymorphone for Sale -9652	An aggregate increase based on (b)(4) customer demand and development initiative
Manufacturing	116713	Hydromorphone - 9150	An aggregate increase based on (b)(4) customer demand

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

Best regards.

(b)(6)

Director, Controlled Substance Compliance

(b)(4) Data 20[illegible]-2013 (est)

Substance	2010	% Change	2011	% Change	2012	% Change	2013*	% Change
Amphetamine	**8,875.83**	**13.24%**	**9,704.48**	**9.34%**	**10,985.94**	**13.20%**	**11,090.23**	**0.95%**
Cocaine	53.89	-0.87%	48.53	-9.95%	44.13	-9.06%	41.57	-5.80%
Codeine	25,351.25	-7.36%	26,169.83	3.23%	23,636.32	-9.68%	23,415.00	-0.94%
Dihydrocodeine	112.37	-14.28%	107.21	-4.59%	75.49	-29.59%	51.46	-31.83%
Diphenoxylate	480.24	-1.70%	462.59	-3.67%	419.28	-9.36%	410.18	-2.17%
Ephedrine	1,478.40	5.29%	1,535.42	3.86%	1,977.02	28.76%	1,949.50	-1.39%
Fentanyl	510.25	1.17%	539.84	5.80%	588.43	9.00%	568.65	-3.36%
Hydrocodone	**61,719.78**	**3.68%**	**65,108.61**	**5.49%**	**65,080.42**	**-0.04%**	**63,431.75**	**-2.53%**
Hydromorphone	1,460.16	8.85%	1,675.24	14.73%	1,928.50	15.12%	1,959.41	1.60%
Levorphanol	0.14	-96.92%	0.32	136.46%	1.61	399.07%	2.27	40.84%
Lisdexamfetamine	**10,311.46**	**25.22%**	**12,337.73**	**19.65%**	**14,036.47**	**13.77%**	**13,899.53**	**-0.98%**
Meperidine	2,579.09	-12.75%	2,302.98	-10.71%	1,893.12	-17.80%	1,639.66	-13.39%
Methadone	7,859.04	0.11%	7,639.33	-2.80%	7,191.03	-5.87%	6,426.51	-10.63%
Methamphetamine	14.86	-2.06%	13.86	-6.74%	14.61	5.37%	13.79	-5.57%
Methylphenidate	**18,704.32**	**3.39%**	**19,217.53**	**2.74%**	**19,752.34**	**2.78%**	**18,739.29**	**-5.13%**
Morphine	28,997.24	4.40%	30,435.64	4.96%	31,015.39	1.90%	29,021.13	-6.43%
Opium	84.35	-9.23%	84.96	0.72%	81.37	-4.22%	78.79	-3.18%
Oxycodone	**68,320.72**	**17.17%**	**70,878.97**	**3.74%**	**67,940.06**	**-4.15%**	**63,061.44**	**-7.18%**
Oxymorphone	**1,653.43**	**31.45%**	**2,655.72**	**60.62%**	**1,960.18**	**-26.19%**	**1,867.25**	**-4.74%**
Pentazocine	694.40	-3.08%	839.71	20.93%	712.52	-15.15%	628.19	-11.84%
Pentobarbital	85.41	-10.11%	79.12	-7.37%	46.59	-41.11%	26.98	-42.09%
Pseudoephedrine	127,452.77	-9.11%	104,473.28	-18.03%	94,447.67	-9.60%	99,264.27	5.10%
Remifentanil	0.89	0.73%	1.05	18.00%	1.12	7.58%	1.16	3.53%
Secobarbital	23.20	-2.85%	20.78	-10.43%	15.67	-24.59%	12.56	-19.85%
Sufentanil	0.07	-14.98%	0.05	-22.81%	0.05	1.44%	0.05	-7.94%

*Estimates based on Jan-Jun 2013 Data

Basic Class: 1100

Total PQ Requested: 34,153,834.125

2014 Initial APQ Worksheets

FDA Est: -.097

IMS Est: .01

Company	DEA Num	Drug Code	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		1100-B2	5.000	5.000	0.000	32,704,729.054	0.000	0.000	0.092	0.000	4.000	3.812	5.000
		1100-B2	3,000,000.000	1,248,437.000	403,393.000	32,704,729.054	0.012	421,266.532	157,532.000	0.000	2,850,000.000	1,052,979.750	2,284,223.790
		1100-B2	2,725,500.000	2,487,000.000	2,048,177.000	32,704,729.054	0.063	2,135,929.126	1,259,737.000	0.000	2,473,000.000	2,510,052.750	2,021,674.407
		1100-B2	19,000,000.000	7,831,156.000	5,744,758.000	32,704,729.054	0.176	5,999,300.942	1,295,297.000	300,000.000	18,800,000.000	6,644,839.750	19,000,000.000
		1100-B2	10.000	10.000	0.000	32,704,729.054	0.000	0.000	0.000	0.000	1.000	7.500	10.000
		1100-B2	194,000.000	150,000.000	0.000	32,704,729.054	0.000	0.000	0.000	0.000	184,000.000	112,500.000	75,500.000
		1100-B2	98,590.000	24,500.000	0.000	32,704,729.054	0.000	0.000	0.000	0.000	98,590.000	18,375.000	80,215.000
		1100-B2	3,000,000.000	4,232,069.000	3,884,476.000	32,704,729.054	0.119	4,056,592.206	2,701.000	0.000	3,000,000.000	3,176,092.500	3,000,000.000
		1100-B2	2,300,000.000	1,200,000.000	4,144,466.000	32,704,729.054	0.127	4,328,102.033	1,244,299.000	0.000	2,300,000.000	1,833,224.250	2,300,000.000
		1100-B2	1,300,000.000	402,238.000	174,287.000	32,704,729.054	0.005	182,009.436	144,757.000	4,380.000	1,044,562.000	410,246.250	830,018.295
		1100-B2	1,000.000	5,000.000	1,267.200	32,704,729.054	0.000	1,323.348	1,759.900	0.000	1,000.000	5,069.925	1,000.000
		1100-A	5.000	0.000	0.000	32,704,729.054	0.000	0.000	0.000	0.000	4.000	0.000	5.000
		1100-A	3,000,000.000	1,133,437.000	393,665.000	32,704,729.054	0.012	411.186	320,077.000	0.000	2,850,000.000	75,003,881.000	1,707,985.482
		1100-A	2,573,800.000	2,487,000.000	1,833,584.000	32,704,729.054	0.056	5,830.599	1,361,632.000	0.000	2,300,400.000	2,865,474.000	1,554,062.089
		1100-A	20.000	10.000	0.000	32,704,729.054	0.000	0.000	0.000	10.000	20.000	7.500	20.000
		1100-A	30.000	20.000	20.854	32,704,729.054	0.000	0.063	9.265	0.000	21.000	21.054	30.000
		1100-A	194,000.000	150,000.000	0.000	32,704,729.054	0.000	0.000	0.000	0.000	184,000.000	112,500.000	75,500.000
		1100-A	84,850.000	24,500.000	0.000	32,704,729.054	0.000	0.000	0.000	0.000	84,850.000	18,375.000	80,475.000
		1100-A	2,200,000.000	600,000.000	3,196,303.000	32,704,729.054	0.098	3,641.440	535,285.000	0.000	2,200,000.000	1,228,448.250	1,776,786.600
		1100-A	2,500,000.000	1,848,516.000	3,857,512.000	32,704,729.054	0.118	11,023.659	261,851.000	0.000	2,500,000.000	3,158,275.250	2,710,005.959
		1100-A	1,500,000.000	847,232.000	307,727.000	32,704,729.054	0.009	827.556	276,013.000	0.000	1,496,172.000	394,756.750	1,032,519.810
		1100-C	5.000	0.000	0.000	32,704,729.054	0.000	0.000	0.000	0.000	4.000	0.000	5.000
		1100-C	20.000	0.000	0.000	32,704,729.054	0.000	0.000	0.000	10.000	20.000	0.000	20.000
		1100-C	10.000	10.000	0.000	32,704,729.054	0.000	0.000	1.307	0.000	1.300	8.460	10.000
MQ Totals:			43,671,645.000	26,388,260.000									36,525,961.433

2013 Final Initial APQ:	34,100,000.000
2013 Final Revised APQ:	37,748,800.000
FDA Est: (2013 Initial APQ * 1 + FDA Est):	30,792,300.000
IMS Est: (2013 Initial APQ * 1 + IMS Est):	34,441,000.000
2014 Final Initial APQ:	39,200,000.000

Year	DEA Name	DEA Num	Requested	Granted	Commercial Man	APQ
2014	(b)(4);(b)(7)(E)		5		5	
2014			289,000		289,000	
	Total Pending		289,005		289,005	2,080,000
2013	(b)(4);(b)(7)(E)		361,000	361,000	361,000	
2013			250,000	238,500	238,500	
	Total Approved		611,000	599,500	599,500	2,291,000
2012	(b)(4);(b)(7)(E)		1,729,000	1,135,000	1,135,000	
2012			380,000	318,000	318,000	
	Total Approved		2,109,000	1,453,000	1,453,000	2,331,000
2011	(b)(4);(b)(7)(E)		1,475,000	1,475,000	1,475,000	
2011			320,000	320,000	320,000	
	Total Approved		1,795,000	1,795,000	1,795,000	2,331,000

BASIC CLASS:	2014 Initial Quota Worksheets			Oripavine			9330											
Company:	(b)(4)			(b)(4)			(b)(4)			(b)(4)			(b)(4)			(b)(4)		
Request:	1674.0			1000.0			480.0			15000.0			5800.0			700.0		
Current Year MQ:	1467.0			1000.0	(buprenorphine pd)		462.7			10400.0			2312.0			700.0		
Year end inventory	277.5			0.0			0.0	(b)(4)		570.6			484.2			2976.5	(PQ inventory)	
Calculations	amt needed	substance MQ	yield	amt needed	substance MQ	yield	amt needed	substance MQ	yield	amt needed	substance MQ	yield	amt needed	substance MQ	yield	amt needed	substance MQ	yield
hydromorphone	346.667	156.000	0.450				166.875	133.500	0.800	0.000	0.000	0.540	2131.855	1827.000	0.857			
oripavine	1000.000	(b)(4)																
oripavine/buprenorphine derivative				1000.000	700.000	0.700												
oxymorphone (sale)	317.778	143.000	0.450				148.256	127.500	0.860									
oxymorphone (conv)										11604.938	10444.444	0.900				0.000		0.800
total needed	1664.444			1000.000			315.131			11604.938			2131.855			0.000		
INITIAL MQs																		
est need	2169.768			1500.000			509.593			16535.551			2758.603			-2801.500		
MQ:																		
Total Initial MQs:	1665.000			1000.000			480.000			11605.000			2132.000			700.000		
Total MQs:	17582.000	+ others	0.005			=	17582.005											
FURTHER CALCULATIONS																		
Proposed Initial APQ	18200																	

Basic Class: 9339-0

Total PO Requested: 5,977,005.000

2014 Initial APQ Worksheets

FDA Est:

IMS Est:

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2013 Sales	2012 DEA MQ Sales	Sales	Share of 2014 Total PO	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2013 Projected Inventory	2013 DEA Projected Inventory	Adj Avail Calc	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	7,456,837.370	0.000	0.000	0.000	0.000	4.000	1.000	8.000	3.750	0.250	0.250
		1,000,000.000	1,000,000.000	0.000	7,456,837.370	0.000	0.000	0.000	0.000	1,000,000.000	0.000	0.000	750,000.000	250,000.000	750,000.000
		1,674,000.000	1,467,099.000	645,573.000	7,456,837.370	0.113	677,766.431	277,542.000	0.000	1,674,000.000	105,000.000	70,566.000	1,308,439.500	1,143,351.795	1,308,439.500
		15,000,000.000	10,460,001.000	4,532,217.000	7,456,837.370	0.608	3,632,784.561	970,821.000	0.000	14,444,444.000	1,061,733.000	-5,473,823.000	5,227,966.750	10,614,803.701	10,614,803.701
		4,225,000.000	3,128,000.000	1,467,204.370	7,456,837.370	0.197	1,176,033.136	1,252,200.000	0.000	2,857,000.000	1,415,000.000	1,521,200.000	3,263,650.000	735,341.428	3,263,650.000
		469,000.000	462,716.000	911,849.000	7,456,837.370	0.062	496,420.870	0.000	0.000	476,000.000	4,000.000	-13,284.000	347,037.000	741,989.087	460,000.000
		700,000.000	700,000.000	0.000	7,456,837.370	0.000	0.000	0.000	0.000	700,000.000	0.000	0.000	525,000.000	175,000.000	525,000.000
MQ Totals:		23,089,005.000	17,156,780.000												16,951,683.451

2013 Final Initial APQ:	16,200,000.000
2013 Final Revised APQ:	16,200,000.000
FDA Est: (2013 Initial APQ * 1 + FDA Est):	16,200,000.000
IMS Est: (2013 Initial APQ * 1 + IMS Est):	16,200,000.000

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 115535		Date Submitted	15-APR-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
ORIPAVINE		Schedule/List Number	2
Name and Address of Registrant		Drug Code	9330-0
(b)(4)		Quota Year	2014
		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)		Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

	Quotas Previously Issued by DEA			
Quota History	2012	2013	2014	Quota Requested
	3,684,000.0	3,126,000.0	0.0	4,235,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	0.0	0.0	1,415,000.0	1,415,000.0
b.In-Process Material.....	1,252,200.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	1,252,200.0	0.0	1,415,000.0	1,415,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	2,504.92	0.0	2,857,000.0	2,857,000.0
b Exports.....	0.85	0.0	0.0	0.0
	2,505.77	0.0	2,857,000.0	2,857,000.0
Acquisition/Production				
a.Domestic Sources.....	3,184,006.7	0.0	4,235,000.0	4,235,000.0
	3,184,006.7	0.0	4,235,000.0	4,235,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2011	2012	2014	
HYDROMORPHONE	9150-0	874,020	1,140,220	1,827,000	85.70

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID: 116697		Date Submitted	31-JUL-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
ORIPAVINE		Schedule/List Number	2
Name and Address of Registrant		Drug Code	9330-0
(b)(4);(b)(7)(E)		Quota Year	2014
		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)		Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

Quota History	Quotas Previously Issued by DEA			
	2012	2013	2014	Quota Requested
	6,300,000.0	8,444,444.0	0.0	15,000,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	570,621.0	0.0	1,081,733.0	1,081,733.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	570,621.0	0.0	1,081,733.0	1,081,733.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	14,444,444.0	14,444,444.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	14,444,444.0	14,444,444.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	15,000,000.0	15,000,000.0
	0.0	0.0	15,000,000.0	15,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2011	2012	2014	
OXYMORPHONE (FOR CONVERSION)	9652-A	5,826,234	3,530,345	10,444,444	90.00

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

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

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 115756		Date Submitted	25-APR-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
ORIPAVINE		Schedule/List Number	2
Name and Address of Registrant		Drug Code	9330-0
(b)(4)		Quota Year	2014
		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)		Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

Quota History	Quotas Previously Issued by DEA			
	2012	2013	2014	Quota Requested
	1,630,000.0	1,467,039.0	0.0	1,674,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31	277,547.0	0.0	105,000.0	105,000.0
a.Bulk Controlled Substance/List 1 Chemical...	0.0	0.0	0.0	0.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	277,547.0	0.0	105,000.0	105,000.0
Disposition(Sale)/Utilization	798,775.0	0.0	1,674,000.0	1,674,000.0
a.Domestic.....	0.0	0.0	0.0	0.0
b Exports.....	798,775.0	0.0	1,674,000.0	1,674,000.0
Acquisition/Production	797,922.0	0.0	1,674,000.0	1,674,000.0
a.Domestic Sources.....	797,922.0	0.0	1,674,000.0	1,674,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2011	2012	2014	
HYDROMORPHONE	9150-0	0	0	156,000	45.00
OXYMORPHONE (FOR SALE)	9652-8	0	35,053	143,000	45.00

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

Quota is for supply of 1,000Kg to (b)(4);(b)(7)(F) (b)(4) will also use Oripavine for internal conversion to Oxymorphone and Hydromorphone for sale to (b)(4);(b)(7)(E) and (b)(4)

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 116698		Date Submitted	31-JUL-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
OXYMORPHONE (FOR CONVERSION)		Schedule/List Number	0
Name and Address of Registrant		Drug Code	9652-A
(b)(4)		Quota Year	2014
		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)		Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

Quota History	Quotas Previously Issued by DEA			
	2012	2013	2014	Quota Requested
	7,766,000.0	7,600,000.0	0.0	13,000,000.0
Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	28,600.0	0.0	893,096.0	893,096.0
b.In-Process Material.....	0.0	0.0	1,000,000.0	1,000,000.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	0.0	0.0
	28,600.0	0.0	1,893,096.0	1,893,096.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	13,192,729.0	13,192,729.0
b Exports.....	0.0	0.0	0.0	0.0
	0.0	0.0	13,192,729.0	13,192,729.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	13,000,000.0	13,000,000.0
	0.0	0.0	13,000,000.0	13,000,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose			% Yield
		2011	2012	2014	
NOROXYMORPHONE (FOR SALE)	9668-B	0	0	6,707	63.00
NOROXYMORPHONE (FOR CONVERSION)	9668-A	4,319,604	3,328,952	13,186,022	63.00

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

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

APPLICATION FOR INDIVIDUAL MANUFACTURING QUOTA

Request ID. 116060		Date Submitted	01-MAY-13
Name of Basic Class or List 1 Chemical (only 1 per DEA-189)			
OXYMORPHONE (FOR CONVERSION)		Schedule/List Number	0
Name and Address of Registrant		Drug Code	9652-A
(b)(4)		Quota Year	2014
		DEA Registration Number	(b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)		Fax. No	(b)(4);(b)(6)
Email Address		Phone No.	

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

Quota History	Quotas Previously Issued by DEA 2012	2013	2014	Quota Requested
	1,000,000.0	1,782,600.0	0.0	2,500,000.0

Production Data	2nd Preceding Year	1st Preceding Year	Estimate for Current Year	Estimate for Year Requested
Inventory as of Dec 31				
a.Bulk Controlled Substance/List 1 Chemical...	0.0	0.0	2,500,000.0	2,500,000.0
b.In-Process Material.....	0.0	0.0	0.0	0.0
c. Contained in FINISHED Dosage Forms.....	0.0	0.0	2,500,000.0	2,500,000.0
Disposition(Sale)/Utilization				
a.Domestic.....	0.0	0.0	0.0	0.0
b Exports.....	0.0	0.0	0.0	0.0
Acquisition/Production				
a.Domestic Sources.....	0.0	0.0	2,500,000.0	2,500,000.0
	0.0	0.0	2,500,000.0	2,500,000.0

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

Name of New Substance	Drug	Amount Used for this Purpose 2011	2012	2014	% Yield

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

Transfer Registrant	Explanation of Transfer

Date of Destruction	Explanation

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

Remarks

Three batches @ 833 kg each for validation. This oxymorphone will be converted to noroxymorphone (conversion) in early 2015 and then converted into naloxone. The oxymorphone quota granted for 2013 will be returned and not used.

Basic Class: 9652-B

2014 Initial APQ Worksheets

Total PQ Requested: 3,441,787.250

FDA Est: N/A

IMS Est: .047

Company	DEA Num	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MQ Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	Adj Avail Calc	MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	3,570,963.674	0.000	0.000	0.007	0.000	4.000	3.755	5.000
		60.000	60.000	4.774	3,570,963.674	0.000	4.601	222.199	0.000	5.000	211.649	60.000
		143,000.000	37,500.000	10,762.000	3,570,963.674	0.003	10,372.534	13,845.000	0.000	143,000.000	39,506.750	113,995.792
		950,000.000	617,660.000	286,960.000	3,570,963.674	0.080	276,577.671	197,838.000	0.000	920,000.000	611,638.500	604,624.339
		4,000,000.000	2,775,400,000.000	2,663,842.000	3,570,963.674	0.802	2,760,229.032	885,842.000	0.000	3,277,692.000	3,214,381.500	3,292,136.290
		3,000.000	5,000.000	657.900	3,570,963.674	0.000	634.097	8,900.000	0.000	3,000.000	10,425.000	3,000.000
		3,150,000.000	955,000.000	406,349.000	3,570,963.674	0.114	391,647.412	219,085.000	0.000	1,430,000.000	880,563.750	1,430,000.000
		210,000.000	402,000.000	2,388.000	3,570,963.674	0.001	2,301.603	411,016.000	0.000	191,250.000	609,762.000	210,000.000
MQ Totals:		8,466,065.000	5,417,245.000									5,653,821.421

2013 Final Initial APQ:	5,500,000.000
2013 Final Revised APQ:	5,600,000.000
FDA Est: (2013 Initial APQ * 1 + FDA Est):	5,500,000.000
IMS Est: (2013 Initial APQ * 1 + IMS Est):	5,239,300.000
2014 Final Initial APQ:	6,200,000.000
with 25% buffer	7,750,000.000

2014 Establish Aggregate Production Quotas and Assessment of Annual Needs

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

- The attached Federal Register notice, prepared for your signature, proposes to establish calendar year 2014 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.

- Expeditious publication of this notice is necessary to ensure that quota is available at the beginning of 2014 for manufacturing.

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

Controlled Substances

- The APQ for **1-[1-(2-Thienyl)cyclohexyl]piperidine, carfentanil, cathinone, dimethyltryptamine, levomethorphan, lysergic acid diethylamide, metazocine, methyldesorphine,** and **phencyclidine** were increased due to additional applications received to support the manufacturing of diagnostic kits and / or reference standards.

- The APQ increase for **hydromorphone** is based on domestic sales and export requirements as evidenced by registrant and IMS data. The APQ for dihydromorphine was increased since it is used to manufacture hydromorphone.

- The APQ for **ecgonine** was increased based on changes in the manufacturing process for the final substance (cocaine) by registrants who received reduced manufacturing quotas in 2013 before the APQ was revised to accommodate their manufacturing activities.

- The APQ for **noroxymorphone (for conversion), noroxymorphone (for sale)** and **oxymorphone (for conversion)** were raised based on the increased manufacturing of non-controlled opiate antagonists ("nal—drugs" such as naloxone or naltrexone) for both the domestic and export markets.

- The APQ for **methamphetamine and d-methamphetamine (for conversion) were** reduced based on decreased demand. Historical data shows decreasing quota requests for these substances.

- The APQ for **phenylacetone** was increased due to comments received which noted that a large domestic amphetamine manufacturer will switch suppliers to a domestic manufacturer of phenylacetone used in the manufacture of amphetamine salts. That amphetamine manufacturer had previously used phenylacetone imported from an overseas supplier.

List I chemicals

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

- The AAN for **ephedrine (for conversion)** was reduced based on decreased demand. Historical calculation based the AAN on APQ of methamphetamine and AAN of pseudoephedrine. ODQ notes manufacturers of methamphetamine utilize phenylacetone as the precursor chemical of choice and that there is no bulk domestic manufacturing of pseudoephedrine. ODQ recommends 1000 kg to provide for product development efforts for manufacturers who have proposed new synthetic routes to manufacture methamphetamine via ephedrine (for conversion).

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-378]

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 2014

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

ACTION: Notice.

SUMMARY: This notice establishes the initial 2014 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

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

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Background

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II and for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The 2014 aggregate production quotas and assessment of annual needs represent those quantities of Schedules I and II controlled substances and the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in the United States in 2014 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 3, 2013, 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 2014," was published in the Federal Register (78 FR 40186). That notice proposed the 2014 aggregate production quotas for each basic class of controlled substance listed in Schedules I and II and the 2014 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 2, 2013.

Comments Received

DEA received seven comments from DEA-registered manufacturers within the published comment period on a total of 23 Schedule I and II controlled substances and one List I chemical. Commenters stated that the proposed aggregate production quotas 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), N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48), cathinone, amphetamine (for sale), codeine (for conversion), codeine (for sale), fentanyl, hydrocodone (for sale), hydromorphone, levomethorphan, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), phenylacetone, tapentadol, tetrahydrocannabinol, and thebaine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. One commenter stated that the proposed assessment of annual needs quota for phenylpropanolamine (for conversion) was insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

Determination of 2014 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2014 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 2013 manufacturing quotas, current 2013 sales and inventories, 2014 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 1-[1-(2-Thienyl)cyclohexyl]piperidine, carfentanil, cathinone, dihydromorphine, dimethyltryptamine, ecgonine, hydromorphone, levomethorphan, lysergic acid diethylamide, metazocine, methamphetamine, d-methamphetamine (for conversion), methyldesorphine, noroxymorphone (for conversion), oxymorphone (for conversion), phencyclidine, phenylacetone, ephedrine (for conversion), ephedrine (for sale), phenylpropanolamine (for conversion), and pseudoephedrine (for sale) are warranted. This notice reflects those adjustments.

Regarding (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11), N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48), amphetamine (for sale), codeine (for conversion), codeine (for sale), fentanyl, hydrocodone (for sale), methylphenidate, morphine (for conversion), morphine (for sale), oripavine, oxycodone (for sale), oxymorphone (for sale), tapentadol, tetrahydrocannabinol, thebaine, and phenylpropanolamine (for sale), the DEA has determined that the proposed initial 2014 aggregate production quotas and assessment of annual needs are sufficient to meet the current 2014 estimated medical, scientific,

research, and industrial needs of the United States. This notice finalizes these aggregate production quotas at the same amounts as proposed.

DEA also specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. See 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, 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 established aggregate production quotas reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. 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.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Deputy Administrator hereby establishes the 2014 aggregate production quotas for the following Schedule I and II controlled substances and the 2014 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class – Schedule I	Established 2014 Quotas
(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15 g
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15 g
1-(1-Phenylcyclohexyl)pyrrolidine	10 g
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
1-[1-(2-Thienyl)cyclohexyl]piperidine	15 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45 g
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45 g
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45 g
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45 g
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45 g
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45 g
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45 g
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45 g
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P)	30 g
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30 g
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30 g
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30 g
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	30 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30 g
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	25 g
2,5-Dimethoxyamphetamine	25 g
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30 g
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30 g
3,4,5-Trimethoxyamphetamine	25 g
3,4-Methylenedioxyamphetamine (MDA)	55 g
3,4-Methylenedioxymethamphetamine (MDMA)	50 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	50 g
3,4-Methylenedioxypyrovalerone (MDPV)	35 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g

4-Bromo-2,5-dimethoxyamphetamine (DOB)	25 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25 g
4-Methoxyamphetamine	100 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25 g
4-Methylaminorex	25 g
4-Methyl-N-methylcathinone (mephedrone)	45 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homiolog)	53 g
5-Methoxy-3,4-methylenedioxyamphetamine	25 g
5-Methoxy-N,N-diisopropyltryptamine	25 g
5-Methoxy-N,N-dimethyltryptamine	25 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	25 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	25 g
Aminorex	25 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	70 g
Codeine Methylbromide	5 g
Codeine-N-oxide	200 g
Desomorphine	5 g
Diethyltryptamine	25 g
Difenoxin	50 g
Dihydromorphine	3,990,000 g
Dimethyltryptamine	35 g
Dipipanone	5 g
Fenethylline	5 g

Gamma-hydroxybutyric acid	70,250,000 g
Heroin	25 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	35 g
Marihuana	21,000 g
Mescaline	25 g
Methaqualone	10 g
Methcathinone	25 g
Methyldesorphine	2 g
Methyldihydromorphine	2 g
Morphine Methylbromide	5 g
Morphine Methylsulfonate	5 g
Morphine-N-oxide	175 g
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15 g
N-Benzylpiperazine	25 g
N,N-Dimethylamphetamine	25 g
N-Ethyl-1-phenylcyclohexylamine	5 g
N-Ethylamphetamine	24 g
N-Hydroxy-3,4-methylenedioxyamphetamine	24 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Parahexyl	5 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	30 g
Psilocyn	30 g
Tetrahydrocannabinols	491,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Established 2014 Quotas
1-Phenylcyclohexylamine	3 g
1-Piperdinocyclohexanecarbonitrile (PCC)	3 g

4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500 g
Alfentanil	17,625 g
Alphaprodine	3 g
Amobarbital	9 g
Amphetamine (for conversion)	18,375,000 g
Amphetamine (for sale)	49,000,000 g
Carfentanil	19 g
Cocaine	240,000 g
Codeine (for conversion)	68,750,000 g
Codeine (for sale)	46,125,000 g
Dextropropoxyphene	19 g
Dihydrocodeine	100,750 g
Diphenoxylate	750,000 g
Ecgonine	144,000 g
Ethylmorphine	3 g
Fentanyl	2,108,750 g
Glutethimide	3 g
Hydrocodone (for sale)	99,625,000 g
Hydromorphone	6,750,000 g
Isomethadone	5 g
Levo-alphacetylmethadol (LAAM)	4 g
Levomethorphan	195 g
Levorphanol	2,000 g
Lisdexamfetamine	23,750,000 g
Meperidine	6,250,000 g
Meperidine Intermediate-A	6 g
Meperidine Intermediate-B	11 g
Meperidine Intermediate-C	6 g
Metazocine	19 g
Methadone (for sale)	31,875,000 g
Methadone Intermediate	38,875,000 g
Methamphetamine	2,811,375 g
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000 g
Morphine (for conversion)	91,250,000 g
Morphine (for sale)	62,500,000 g
Nabilone	30,375 g
Noroxymorphone (for conversion)	17,500,000 g
Noroxymorphone (for sale)	1,462,500 g

Opium (powder)	112,500 g
Opium (tincture)	625,000 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	9,250,000 g
Oxycodone (for sale)	149,375,000 g
Oxymorphone (for conversion)	25,000,000 g
Oxymorphone (for sale)	7,750,000 g
Pentobarbital	35,000,000 g
Phenazocine	6 g
Phencyclidine	19 g
Phenmetrazine	3 g
Phenylacetone	67,000,000 g
Racemethorphan	3 g
Remifentanil	3,750 g
Secobarbital	215,003 g
Sufentanil	6,255 g
Tapentadol	17,500,000 g
Thebaine	145,000,000 g

Basic Class – List I Chemicals	Established 2014 Quotas
Ephedrine (for conversion)	1,000,000 g
Ephedrine (for sale)	3,000,000 g
Phenylpropanolamine (for conversion)	44,800,000 g
Phenylpropanolamine (for sale)	5,300,000 g
Pseudoephedrine (for conversion)	5,000 g
Pseudoephedrine (for sale)	192,000,000 g

The Deputy Administrator also establishes aggregate production quotas for all other Schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2014 aggregate production quotas and assessment of annual needs as needed.

8/20/13
Dated:

Thomas M. Harrigan,
Deputy Administrator

OC:_____

OD:_____

OD/D:_(b)(6)_ 8-30-13

ODX:_____

ODXS:_____

ODW (b)(6) 8.30.13

ODQ

ODQ:SHA for (b)(6) 08-29-13

Webcims # ODEQ-13-587

(DFN#: 680-03 Drug Control Files - Manufacturing and Procurement Quotas)

To submit comments:	Send them to:
By mail	Assistant Attorney General, U.S. DOJ--ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Under Section 7003(d) of the Resource Conservation and Recovery Act ("RCRA"), a commenter may request an opportunity for a public meeting in the affected area.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html*. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for $22.25 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the appendices and signature pages, the cost is $16.00.

Maureen M. Katz,

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

[FR Doc. 2013-21850 Filed 9-6-13; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-378]

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 2014

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

ACTION: Notice.

SUMMARY: This notice establishes the initial 2014 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA) and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: *Effective:* September 9, 2013.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Background

Section 306 of the CSA (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II and for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR 0.104.

The 2014 aggregate production quotas and assessment of annual needs represent those quantities of Schedules I and II controlled substances and the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in the United States in 2014 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 3, 2013, 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 2014," was published in the **Federal Register** (78 FR 40186). That notice proposed the 2014 aggregate production quotas for each basic class of controlled substance listed in Schedules I and II and the 2014 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 2, 2013.

Comments Received

DEA received seven comments from DEA-registered manufacturers within the published comment period on a total of 23 Schedule I and II controlled substances and one List I chemical. Commenters stated that the proposed aggregate production quotas 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), N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48), cathinone, amphetamine (for sale), codeine (for conversion), codeine (for sale), fentanyl, hydrocodone (for sale), hydromorphone, levomethorphan, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), phenylacetone, tapentadol, tetrahydrocannabinol, and thebaine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. One commenter stated that the proposed assessment of annual needs quota for phenylpropanolamine (for conversion) was insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

Determination of 2014 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2014 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 2013 manufacturing quotas, current 2013 sales and inventories, 2014 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 1-[1-(2-Thienyl)cyclohexyl]piperidine, carfentanil, cathinone, dihydromorphine, dimethyltryptamine, ecgonine, hydromorphone, levomethorphan, lysergic acid diethylamide, metazocine, methamphetamine, d-methamphetamine (for conversion), methyldesorphine, noroxymorphone (for conversion), oxymorphone (for conversion), phencyclidine, phenylacetone, ephedrine (for conversion), ephedrine (for sale),

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

Regarding (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), (1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11), N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48), amphetamine (for sale), codeine (for conversion), codeine (for sale), fentanyl, hydrocodone (for sale), methylphenidate, morphine (for conversion), morphine (for sale), oripavine, oxycodone (for sale), oxymorphone (for sale), tapentadol, tetrahydrocannabinol, thebaine, and phenylpropanolamine (for sale), the DEA has determined that the proposed initial 2014 aggregate production quotas and assessment of annual needs are sufficient to meet the current 2014 estimated medical, scientific, research, and industrial needs of the United States. This notice finalizes these aggregate production quotas at the same amounts as proposed.

DEA also specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. See 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, 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 established aggregate production quotas reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. 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.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Deputy Administrator hereby establishes the 2014 aggregate production quotas for the following Schedule I and II controlled substances and the 2014 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class—Schedule I	Established 2014 Quotas (grams)
(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-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-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
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-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25

Basic Class—Schedule I	Established 2014 Quotas (grams)
4-Methyl-N-methylcathinone (mephedrone)	45
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
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
Beta-hydroxy-3-methylfentanyl	2
Beta-hydroxyfentanyl	2
Betameprodine	2
Betaprodine	2
Butotenine	3
Cathinone	70
Codeine Methylbromide	5
Codeine-N-oxide	200
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
Gamma-hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	21,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	2
Methyldihydromorphine	2
Morphine Methylbromide	5
Morphine Methylsulfonate	5
Morphine-N-oxide	175
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15
N-Benzylpiperazine	25
N,N-Dimethylamphetamine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	18
Para-fluorofentanyl	2
Parahexyl	5
Phenomorphan	2
Pholcodine	2
Properidine	2
Psilocybin	30
Psilocyn	30
Tetrahydrocannabinols	491,000
Thiofentanyl	2
Tilidine	10
Trimeperidine	2

Basic Class—Schedule II	Established 2014 Quotas (grams)
1-Phenylcyclohexylamine	3
1-Piperidinocyclohexanecarbonitrile (PCC)	3
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,625
Alphaprodine	3
Amobarbital	9
Amphetamine (for conversion)	18,375,000
Amphetamine (for sale)	49,000,000
Carfentanil	19
Cocaine	240,000
Codeine (for conversion)	68,750,000
Codeine (for sale)	46,125,000
Dextropropoxyphene	19
Dihydrocodeine	100,750
Diphenoxylate	750,000
Ecgonine	144,000
Ethylmorphine	3
Fentanyl	2,108,750
Glutethimide	3
Hydrocodone (for sale)	99,625,000
Hydromorphone	6,750,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	195
Levorphanol	2,000
Lisdexamfetamine	23,750,000
Meperidine	6,250,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	38,875,000
Methamphetamine	2,811,375

[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]

Methylphenidate	96,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	30,375
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,462,500
Opium (powder)	112,500
Opium (tincture)	625,000
Oripavine	22,750,000
Oxycodone (for conversion)	9,250,000
Oxycodone (for sale)	149,375,000
Oxymorphone (for conversion)	25,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	67,000,000
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	17,500,000
Thebaine	145,000,000

Basic Class—List I Chemicals	Proposed 2014 Quotas
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	3,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	5,300,000
Pseudoephedrine (for conversion)	5,000
Pseudoephedrine (for sale)	192,000,000

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 2014 aggregate production quotas and assessment of annual needs as needed.

Dated: August 30, 2013.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2013–21797 Filed 9–6–13; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Application No. D–11758]

Notice of Proposed Exemption Involving AT&T Inc. (Together With AT&T Inc.'s Affiliates, AT&T or the Applicant) Located in Dallas, TX

AGENCY: Employee Benefits Security Administration, U.S. Department of Labor.

ACTION: Notice of Proposed Exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (the Department) of a proposed individual exemption from certain prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974, as amended (ERISA or the Act), and the Internal Revenue Code of 1986, as amended (the Code). The proposed transactions involve AT&T, the AT&T Pension Benefit Plan (the Plan), and the SBC Master Pension Trust (the Trust). The proposed exemption, if granted, would affect the Plan and its participants and beneficiaries.

Effective Date: If granted, this proposed exemption will be effective as of September 1, 2013.

DATES: Written comments and requests for a public hearing on the proposed exemption should be submitted to the Department within 55 days from the date of publication of this **Federal Register** Notice.

ADDRESSES: Comments and requests for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the proposed exemption and the manner in which the person would be adversely affected by the exemption, if granted. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing. All written comments and requests for a public hearing concerning the proposed exemption should be sent to the Office of Exemption Determinations, Employee Benefits Security Administration, Room N–5700, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210, Attention: Application No. D–11758. Interested persons are also invited to submit comments and/or hearing requests to EBSA via email or FAX. Any such comments or requests should be sent either by email to: *moffitt.betty@dol.gov*, or by FAX to (202) 219–0204 by the end of the scheduled comment period. The application for exemption and the comments received will be available for public inspection in the Public Documents Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N–1513, 200 Constitution Avenue NW., Washington, DC 20210. Comments and hearing requests will also be available online at *www.regulations.gov* and *www.dol.gov/ebsa*, at no charge.

Warning: If you submit written comments or hearing requests, do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments and hearing requests may be posted on the Internet and can be retrieved by most Internet search engines.

FOR FURTHER INFORMATION CONTACT: Anna Mpras Vaughan, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor, telephone (202) 693–8565. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: This document contains a notice of proposed exemption that, if granted, would provide exemptive relief from sections 406(a)(1)(A), 406(a)(1)(B), 406(a)(1)(D), 406(a)(1)(E), 406(a)(2), 406(b)(1), 406(b)(2), and 407(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A), 4975(c)(1)(B), 4975(c)(1)(D) and 4975(c)(1)(E) of the Code. The proposed exemption has been requested by AT&T pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (76 FR 66637, 66644, October 27, 2011). Effective December 31, 1978, section 102 of the Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue administrative exemptions under section 4975(c)(2) of the Code to the Secretary of Labor. Accordingly, this notice of proposed exemption is being issued solely by the Department.

Summary of Facts and Representations[1]

Background

1. AT&T Inc. (together with its affiliates, AT&T), formerly known as SBC Communications Inc., is a holding company incorporated in 1983 under the laws of the State of Delaware that has its principal executive offices in Dallas, Texas. AT&T, a provider of telecommunications services, offers its services and products to consumers in the U.S. and to businesses and other providers of telecommunications services worldwide. The services and products that AT&T offers vary by market, and include: wireless communications, local exchange services, long-distance services, data/broadband and Internet services, video services, telecommunications equipment, managed networking and wholesale services.

2. AT&T is the sponsor of the AT&T Pension Benefit Plan (the Plan). Effective December 14, 2010, the Plan was amended (the 2010 Amendment) to name the Plan's named fiduciary, AT&T Services, as the plan administrator. AT&T Services, pursuant to delegation (the Delegation) from its Board of Directors (the Board) dated July 1, 2011, delegated to the AT&T Inc. Benefit Plan Investment Committee (the Committee) all powers and authority that may be necessary or appropriate to the establishment, qualification, administration, maintenance, and operation of the SBC Master Pension Trust (the Trust) established as part of the Plan. Notwithstanding its power to delegate authority, the Committee retains, and may not delegate, the authority to authorize "company-directed" investments (i.e., investments that have not been delegated to a third party investment manager) in amounts greater than $200,000,000.

3. In addition to AT&T Services and the Committee, other Plan fiduciaries include Brock Fiduciary Services LLC (the Independent Fiduciary), an investment manager that is independent of AT&T Inc.

[1] The Summary of Facts and Representations is based on the Applicant's representations and does not reflect the views of the Department.

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

*Estimates based on Jan-Mar 2014 Data

(b)(4) Data 2011 - 2014 (est)

2014 Revised APQ
Worksheets

Basic Class: 9170-B
PQ Total(CM+PD): 2,331.000

FDA Est:
IMS Est: -.059

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	702,222.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,030,000.000	580,000.000	701,757.000	702,222.000	0.999	2,329.456	285,969.000	0.000	-282,940.707	-107,617.929	0.000
MQ Totals:		1,030,002.000	580,002.000	701,757.000				285,969.000	0.000	-282,940.707		0.000

Final Initial APQ:	600,000.000		
Proposed Revised:	1,031,000.000	Adjusted for (b)(4) denial	
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-862,474.500	CFR 50%:	-687,618.000
2013 Initial APQ:	600,000.000		
FDA Est = 2013 APQ * (1 + FDA Est):	600,000.000		
IMS Est = 2013 APQ * (1 + IMS Est):	564,360.000		
	1,288,750.000	with 25% buffer	

2014 Revised APQ
Worksheets

Basic Class: 9801-0
PQ Total(CM+PD): 1,104,315.000

FDA Est: .072
IMS Est: -.007

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	998,926.931	0.000	0.000	0.101	0.000	-0.101	-0.101	0.000
		200,000.000	151,000.000	36,960.000	998,926.931	0.037	40,859.327	53,892.000	0.000	-774.875	6,422.159	0.000
		97,526.000	94,776.000	58,343.393	998,926.931	0.058	64,498.698	6,032.341	72,080.000	149,695.993	161,256.877	0.000
		2.000	2.000	0.538	998,926.931	0.000	0.595	1.010	0.000	-0.237	-0.132	0.000
		14,151.000	14,151.000	9,082.000	998,926.931	0.009	10,040.163	103.000	0.000	12,949.211	14,717.703	0.000
		20,490.000	0.000	0.000	998,926.931	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		474,000.000	461,271.000	245,042.000	998,926.931	0.245	270,894.244	230,549.000	0.000	121,613.516	169,328.306	0.000
		810,000.000	810,000.000	645,039.000	998,926.931	0.646	713,091.440	298,686.000	95,600.000	723,932.871	845,538.050	0.000
		1,640.000	1,640.000	0.000	998,926.931	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		16,000.000	16,000.000	4,460.000	998,926.931	0.004	4,930.536	17,597.000	0.000	-11,187.304	-10,318.830	0.000
		613.000	613.000	0.000	998,926.931	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		6,500.000	6,500.000	0.000	998,926.931	0.000	0.000	0.000	500.000	500.000	500.000	0.000
MQ Totals:		1,641,017.000	1,556,058.000	998,926.931				606,660.452	188,180.000	996,929.048		0.000

Final Initial APQ:	1,687,000.000	
Proposed Revised:	1,687,000.000	OK with pending requests
Final Revised APQ:	0.000	
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-506,445.952	CFR 50%: -532,792.969
2013 Initial APQ:	1,687,000.000	
FDA Est = 2013 APQ * (1 + FDA Est):	1,808,464.000	
IMS Est = 2013 APQ * (1 + IMS Est):	1,675,191.000	

pending requests
(b)(4) 82,400.00

2014 Revised APQ
Worksheets

Basic Class: 9193-A
PQ Total(CM+PD): 0.000

FDA Est:
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		101,000,000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		101,000,000	0.000	0.000				0.000	0.000	0.000		0.000

Final Initial APQ:	0.000		
Proposed Revised:	110,000,000	Adjusted for (b)(4)	denial
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	0.000	CFR 50%:	0.000
2013 Initial APQ:	0.000		
FDA Est = 2013 APQ * (1 + FDA Est):	0.000		
IMS Est = 2013 APQ * (1 + IMS Est):	0.000		
	137,500,000	with 25% buffer	

2014 Revised APQ
Worksheets

Basic Class: 9193-B
PQ Total(CM+PO): 65,322,425.000

FDA Est: .015
IMS Est: -.034

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	45,068,169.355	0.000	0.000	0.051	0.000	-0.051	-0.051	0.000
		141,100.000	99,400.000	0.000	45,068,169.355	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		20.000	20.000	3.575	45,068,169.355	0.000	5.182	74.093	0.000	-87.357	-66.722	0.000
		231,000.000	175,079.000	39,742.000	45,068,169.355	0.001	57,602.602	12,258.000	0.000	62,625.382	69,680.752	0.000
		7,320.000	7,320.000	10,994.030	45,068,169.355	0.000	15,934.898	0.000	0.000	20,715.368	22,667.131	0.000
		7,400,000.000	3,200,000.000	3,230,559.000	45,068,169.355	0.072	4,682,416.681	5,043,303.000	0.000	1,043,838.686	1,617,357.602	0.000
		30,000,000.000	19,274,159.000	22,852,826.000	45,068,169.355	0.507	33,123,200.560	7,741,178.000	12,200.000	35,331,162.728	39,388,229.200	0.000
		3,600,000.000	1,885,910.000	148,721.000	45,068,169.355	0.003	215,558.264	2,031,970.000	0.000	-1,751,744.256	-1,725,341.919	0.000
		24,000,000.000	22,958,367.000	18,075,426.630	45,068,169.355	0.401	26,198,775.054	3,655,635.900	0.000	30,402,771.670	33,611,690.075	0.000
		5,310,000.000	2,184,719.000	605,442.000	45,068,169.355	0.013	877,535.968	2,209,940.000	0.000	-1,069,143.241	-961,659.540	0.000
		9,000,000.000	6,981,532.000	103,852.000	45,068,169.355	0.002	150,524.516	3,645,502.000	0.000	-3,649,620.126	-3,631,383.352	0.000
MQ Totals:		79,689,445.000	56,768,511.000	45,057,568.235				24,539,851.044	12,200.000	60,390,356.803		0.000

Final Initial APQ:	79,700,000.000		
Proposed Revised:	79,700,000.000	OK with pending requests	
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	16,677,265.456	CFR 50%:	11,613,551.265
2013 Initial APQ:	79,700,000.000		
FDA Est = 2013 APQ * (1 + FDA Est):	80,895,500.000		
IMS Est = 2013 APQ * (1 + IMS Est):	76,990,200.000		

pending request
(b)(4) 41,700.000 but really should be (for conversion)

2014 Revised APQ
Worksheets

Basic Class: 9150-0
PQ Total(CM+PD): 3,313,103.000

FDA Est: .106
IMS Est: -.036

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		100,000.000	78,700.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		30.000	30.000	2.921	3,574,775.079	0.000	2.707	49.447	0.000	-45.928	-45.333	0.000
		78,000.000	78,000.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		233,891.000	191,628.000	128,462.930	3,574,775.079	0.036	119,058.496	35,920.696	0.000	116,856.849	145,019.406	0.000
		535,998.000	535,998.000	679,936.334	3,574,775.079	0.190	630,187.125	209,218.035	0.000	609,999.228	748,475.455	0.000
		445,000.000	445,000.000	334,715.000	3,574,775.079	0.094	310,213.998	251,602.000	0.000	151,676.198	219,844.248	0.000
		1,390,000.000	1,179,810.000	997,252.000	3,574,775.079	0.279	924,253.560	392,859.000	0.000	808,670.628	1,011,770.950	0.000
		1,725,000.000	1,674,818.000	1,389,895.400	3,574,775.079	0.389	1,288,072.211	855,997.550	0.000	818,496.324	1,101,544.084	0.000
		220,000.000	97,711.000	44,542.000	3,574,775.079	0.012	41,281.544	31,189.000	0.000	22,477.007	31,548.430	0.000
MQ Totals:		4,727,724.000	4,279,698.000	3,574,718.585				1,776,835.728	0.000	2,530,130.106		0.000

Final Initial APQ:	5,400,000.000		
Proposed Revised:	5,400,000.000	OK with pending requests	
Final Revised APQ:	0.000		
MQ Needed PQ * 1.5 - Revised MQ - Inventory:	-1,086,879.228	CFR 50%:	-1,021,475.332
2013 Initial APQ:	4,775,000.000		
FDA Est = 2013 APQ * (1 + FDA Est):	5,281,150.000		
IMS Est = 2013 APQ * (1 + IMS Est):	4,604,055.000		

pending request			
	(b)(4)	42,065.000	2-May-14

2014 Revised APQ
Worksheets

Basic Class: 9220-0
PQ Total(CM+PQ): 4,448.000

FDA Est:
IMS Est: .084

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	1,907.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		3,600.000	1,598.000	1,907.000	1,907.000	1.000	4,448.000	42.000	41.000	5,781.400	6,035.750	0.000
MQ Totals:		3,602.000	1,600.000	1,907.000				42.000	41.000	5,781.400		0.000

Final Initial APQ:	1,600.000		
Proposed Revised:	3,700.000	Adjusted for (b)(4) denial	
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	5,030.000	CFR 50%:	4,394.750
2013 Initial APQ:	3,600.000		
FDA Est = 2013 APQ * (1 + FDA Est):	3,600.000		
IMS Est = 2013 APQ * (1 + IMS Est):	3,902.760		
	4,625.000	with 25% buffer	

2014 Revised APQ
Worksheets

Basic Class: 9230-0
PQ Total(CM+PD): 2,459,351,000

FDA Est: -.28
IMS Est: -.113

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5,000	5,000	0.000	2,500,073.540	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		4,000,000.000	3,339,899.000	2,170,921.000	2,500,073.540	0.868	2,135,559.873	668,753.000	500,000.000	2,607,474.835	3,043,427.092	0.000
		5.000	5.000	1.540	2,500,073.540	0.000	1.515	4.791	0.000	-2.822	-2.512	0.000
		26,100.000	0.000	0.000	2,500,073.540	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		710,000.000	710,000.000	329,151.000	2,500,073.540	0.132	323,789.612	93,082.000	95,700.000	423,544.495	489,642.785	0.000
MQ Totals:		4,736,110.000	4,049,909.000	2,500,073.540				761,839.791	595,700.000	3,031,016.509		0.000

Final Initial APQ:	5,000,000.000		
Proposed Revised:	5,000,000.000	OK with pending requests	
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-1,122,722.291	CFR 50%:	-1,112,541.856
2013 Initial APQ:	5,500,000.000		
FDA Est = 2013 APQ * (1 + FDA Est):	4,070,000.000		
IMS Est = 2013 APQ * (1 + IMS Est):	4,860,150.000		

pending requests

(b)(4)	26,100.000	23-Apr-14

2014 Revised APQ
Worksheets

Basic Class: 9300-A
PQ Total(CM+PD): 4,917,510.000

FDA Est:
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		131,000.000	131,000.000	0.000	47,803,753.801	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		43,480.000	43,480.000	25,980.801	47,803,753.801	0.001	2,672.811	101,581.852	0.000	-98,107.457	-91,745.868	0.000
		6,730,000.000	5,350,000.000	3,335,263.000	47,803,753.801	0.070	343,094.166	24,303.000	3,840,950.000	4,262,669.419	5,079,333.400	0.000
		150,000.000	0.000	0.000	47,803,753.801	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		44,000,000.000	44,000,000.000	36,564,556.000	47,803,753.801	0.765	3,761,348.335	12,904,910.000	0.000	-8,015,157.154	937,814.419	0.000
		5,000.000	2,875.000	160.000	47,803,753.801	0.000	16.459	69.210	0.000	-47.813	-8.636	0.000
		18,000,000.000	10,430,762.000	7,877,794.000	47,803,753.801	0.165	810,378.426	2,451,207.000	0.000	-1,397,715.045	531,214.533	0.000
		2,371,901.000	1,201,901.000	0.000	47,803,753.801	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,960,000.000	0.000	0.000	47,803,753.801	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		72,391,381.000	61,160,018.000	47,803,753.801				15,482,071.062	3,840,950.000	-5,248,356.062		0.000

Final Initial APQ:	73,000,000.000		
Proposed Revised:	73,000,000.000	OK with pending requests	
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-69,265,824.062	CFR 50%:	-58,544,263.112
2013 Initial APQ:	63,000,000.000		
FDA Est = 2013 APQ * (1 + FDA Est):	83,000,000.000		
IMS Est = 2013 APQ * (1 + IMS Est):	63,000,000.000		

pending requests

(b)(4)	1,960,000.000	27-MAR-14
	1,170,000.000	09-APR-14

2014 Revised APQ
Worksheets

Basic Class: 9300-B
PQ Total(CM+PD): 40,730,343.000

FDA Est: 019
IMS Est: -.031

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	35,757,656.635	0.000	0.000	0.026	0.000	-0.026	-0.026	0.000
		100.000	100.000	2.195	35,757,656.635	0.000	2.500	130.578	0.000	-127.328	-126.904	0.000
		162,630.000	0.000	0.000	35,757,656.635	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		700,000.000	248,820.000	52,500.080	35,757,656.635	0.001	59,801.074	157,184.176	0.000	-79,442.768	-69,307.814	0.000
		6,000,000.000	4,779,867.000	3,271,287.000	35,757,656.635	0.091	3,726,292.904	71,327.000	0.000	4,772,749.775	5,404,260.880	0.000
		14,600,000.000	14,244,006.000	12,910,984.000	35,757,656.635	0.361	14,706,467.265	5,199,456.000	225,000.000	14,143,951.445	16,636,374.082	0.000
		1,000.000	1,000.000	0.360	35,757,656.635	0.000	0.410	0.000	0.000	0.533	0.603	0.000
		25,550,000.000	19,333,578.000	16,047,146.000	35,757,656.635	0.449	18,278,763.830	6,729,629.000	0.000	17,032,563.979	20,130,412.258	0.000
		1,500,000.000	703,454.000	163,724.000	35,757,656.635	0.004	175,101.834	0.000	0.000	227,632.384	257,308.292	0.000
		5,400,000.000	4,200,000.000	0.000	35,757,656.635	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		57,013,735.000	43,510,828.000	32,435,643.635				12,157,926.780	225,000.000	36,097,327.982		0.000

Final Initial APQ:	50,000,000.000		
Proposed Revised:	50,000,000.000	OK with pending request	
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	5,426,759.720	CFR 50%:	3,353,084.879
2013 Initial APQ:	48,200,000.000		
FDA Est = 2013 APQ * (1 + FDA Est):	49,115,800.000		
IMS Est = 2013 APQ * (1 + IMS Est):	46,691,340.000		

pending request
(b)(4) 451,180.000 2-May-14

2014 Revised APQ
Worksheets

Basic Class: 9330-0
PQ Total(CM+PD): 5,977,005.000

FDA Est:
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	13,621,761.480	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,100,000.000	1,100,000.000	639,490.000	13,621,761.480	0.047	280,597.699	3,167.000	0.000	361,610.009	507,452.624	0.000
		2,437,143.000	1,674,318.000	178,502.000	13,621,761.480	0.013	78,323.743	253,484.000	0.000	-151,663.134	-110,953.621	0.000
		14,700,000.000	10,732,298.000	10,146,533.000	13,621,761.480	0.745	4,452,131.875	69,282.000	0.000	5,718,489.437	8,032,516.093	0.000
		4,235,000.000	3,283,650.000	2,565,244.480	13,621,761.480	0.188	1,125,587.106	151,100.000	0.000	1,312,183.238	1,897,195.003	0.000
		480,000.000	347,037.000	91,992.000	13,621,761.480	0.007	40,364.577	0.000	0.000	52,473.950	73,453.722	0.000
		700,000.000	612,500.000	0.000	13,621,761.480	0.000	0.000	324,264.000	0.000	-324,264.000	-324,264.000	0.000
		430,000.000	0.000	0.000	13,621,761.480	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		24,082,148.000	17,749,808.000	13,621,761.480				801,297.000	0.000	6,968,809.500		0.000

Final Initial APQ: 18,200,000.000
Proposed Revised: 22,100,000.000 Adjusted for (b)(4) denial
Final Revised APQ: 0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory: -9,585,597.500 CFR 50%: -7,674,408.380
2013 Initial APQ: 18,200,000.000
FDA Est = 2013 APQ * (1 + FDA Est): 18,200,000.000
IMS Est = 2013 APQ * (1 + IMS Est): 18,200,000.000

27,625,000.000 with 25% buffer

requests considered
(b)(4) 8,600,000 (granted only 3,971kg after APQ adjustment should receive 3,868kg more)
430,000

2014 Revised APQ
Worksheets

Basic Class: 9143-B
PQ Total(CM+PD): 82,511,169.000

FDA Est:
IMS Est: -.009

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	1.520	78,591,255.584	0.000	1.596	2.000	0.000	0.075	0.375	0.000
		200,000.000	180,000.000	0.000	78,591,255.584	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		60.000	60.000	9.824	78,591,255.584	0.000	10.314	810.806	0.000	-797.398	-795.458	0.000
		1,335,520.000	1,335,520.000	46,062.000	78,591,255.584	0.001	48,399.445	23,138.000	0.000	39,728.278	46,826.806	0.000
		20,966.000	6,000.000	0.000	78,591,255.584	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		3,350,000.000	1,365,000.000	292,405.000	78,591,255.584	0.004	308,989.349	789,049.000	0.000	-389,962.847	-332,211.064	0.000
		24,000,000.000	24,000,000.000	14,839,041.000	78,591,255.584	0.189	15,579,171.126	14,301,862.000	88,954.000	6,040,014.464	8,976,816.157	0.000
		68,750,000.000	64,131,406.000	45,700,030.000	78,591,255.584	0.581	47,979,420.492	23,181,550.000	495,000.000	39,706,696.639	48,732,733.115	0.000
		1,000.000	1,000.000	866,355.240	78,591,255.584	0.011	909,566.632	92,406.000	0.000	1,090,030.621	1,261,141.100	0.000
		24,000,000.000	24,000,000.000	16,658,868.000	78,591,255.584	0.212	17,487,666.285	11,182,045.000	6,000,000.000	17,551,921.170	20,841,754.856	0.000
		875,000.000	784,635.000	190,483.000	78,591,255.584	0.002	199,983.763	537,901.000	0.000	-277,922.109	-240,300.547	0.000
MQ Totals:		122,532,551.000	115,803,630.000	78,591,255.584				50,088,763.806	6,583,954.000	63,759,709.894		0.000

Final Initial APQ:	119,500,000.000		
Proposed Revised:	119,500,000.000	Ok with pending requests	
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-42,125,640.306	CFR 50%:	-43,105,818.600
2013 Initial APQ:	105,200,000.000		
FDA Est = 2013 APQ * (1 + FDA Est):	105,200,000.000		
IMS Est = 2013 APQ * (1 + IMS Est):	104,305,800.000		

pending request

(b)(4)	14,966.000	2-May-14

2014 Revised APQ
Worksheets

Basic Class: 9739-0
PQ Total(CM+PD): 3,050.000

FDA Est:
IMS Est: .035

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	0.683	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,232.000	0.000	0.000	0.683	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		5.000	5.000	0.000	0.683	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,820.000	1,820.000	0.000	0.683	0.000	0.000	2,723.000	0.000	-2,723.000	-2,723.000	0.000
		1,540.000	1,165.000	0.000	0.683	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		5.000	5.000	0.683	0.683	1.000	3,050.000	0.813	0.000	3,964.187	3,811.858	0.000
MQ Totals:		4,607.000	3,000.000	0.683				2,723.813	0.000	1,241.187		0.000

Final Initial APQ:	3,000.000		
Preposed Revised:	4,700.000	Adjusted for (b)(4)	
Final Revised APQ:	0.000		
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-1,148.813	CFR 50%:	-1,911.142
2013 Initial APQ:	3,000.000		
FDA Est = 2013 APQ * (1 + FDA Est):	3,000.000		
IMS Est = 2013 APQ * (1 + IMS Est):	3,105.900		

5,875.000 with 25% buffer

2014 Revised APQ
Worksheets

Basic Class: 9050-B
PQ Total(CM+PD): 25,306,205.000

FDA Est:
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	26,011,178.528	0.000	0.000	1.800	0.000	-1.800	-1.800	0.000
		100.000	100.000	1.035	26,011,178.528	0.000	1.011	43.693	0.000	-42.578	-42.370	0.000
		148,000.000	148,000.000	106,667.000	26,011,178.528	0.004	103,778.035	458,397.000	0.000	-321,488.155	-300,010.206	0.000
		13,500,000.000	13,145,613.000	12,022,448.000	26,011,178.528	0.462	11,696,808.005	5,171,283.000	8,140.000	10,042,447.407	12,463,229.257	0.000
		21,270,000.000	17,231,585.000	13,170,419.000	26,011,178.528	0.506	12,813,484.903	5,127,800.000	0.000	11,529,704.374	14,181,635.879	0.000
		1,000.000	1,000.000	1.330	26,011,178.528	0.000	1.294	0.000	0.000	1.682	1.950	0.000
		5,280,000.000	2,554,914.000	711,841.000	26,011,178.528	0.027	692,353.698	0.000	0.000	990,059.677	1,043,352.247	0.000
MQ Totals:		40,199,105.000	33,081,197.000	26,011,178.369				10,755,525.693	8,140.000	22,150,680.606		0.000

Final Initial APQ:	36,900,000.000
Proposed Revised:	36,900,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-5,877,415.193
2013 Initial APQ:	39,605,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	39,605,000.000
IMS Est = 2013 APQ * (1 + IMS Est):	39,605,000.000

CFR 50%: -5,701,171.851

Although comment received from (b)(4) there are no pending requests to consider

current APQ sufficient

2014 Revised Aug
Worksheets

Basic Class: 9801-0
PQ Total(CM+PD): 1,047,139.000

FDA Est: .072
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5,000	5,000	0.000	998,926.931	0.000	0.000	0.101	0.000	-0.101	-0.101	0.000
		200,000.000	151,000.000	36,960.000	998,926.931	0.037	36,743.832	53,892.000	0.000	-3,525.018	3,777.790	0.000
		177,178.000	175,426.000	58,343.393	998,926.931	0.058	61,159.270	6,032.341	112,080.000	185,554.710	197,082.595	0.000
		2.000	2.000	0.536	998,926.931	0.000	0.564	1.010	0.000	-0.277	-0.171	0.000
		14,151.000	14,151.000	9,082.000	998,926.931	0.009	9,520.332	103.000	0.000	12,273.432	14,067.915	0.000
		20,480.000	0.000	0.000	998,926.931	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		474,000.000	461,271.000	245,042.000	998,926.931	0.245	256,868.673	230,549.000	0.000	103,380.274	151,797.341	0.000
		810,000.000	810,000.000	645,039.000	998,926.931	0.646	676,171.072	259,686.000	95,600.000	675,936.393	803,387.593	0.000
		1,640.000	1,640.000	0.000	998,926.931	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		16,000.000	16,000.000	4,460.000	998,926.931	0.004	4,675.257	17,597.000	0.000	-11,519.166	-10,637.929	0.000
		613.000	613.000	0.000	998,926.931	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		0.001	6,600.000	0.000	998,926.931	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		1,714,067.001	1,636,708.000	998,926.931				606,860.452	207,680.000	962,100.248		0.000

Final Initial APQ:	1,687,000.000
Proposed Revised:	1,687,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-672,659.952
2013 Initial APQ:	1,687,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	1,808,464.000
IMS Est = 2013 APQ * (1 + IMS Est):	1,687,000.000

CFR 50%: -684,912.969

pending requests: request grant
(b)(4) (6,600) (6,600)

new + current MQ 1,630,108

current APQ sufficient

2014 Revised APQ
Worksheets

Basic Class: 9193-B
PQ Total(CM+PD): 64,310,220.000

FDA Est: -.014
IMS Est: -.034

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	45,068,169.355	0.000	0.000	0.051	0.000	-0.051	-0.051	0.000
		141,100.000	99,400.000	0.000	45,068,169.355	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		20.000	20.000	3.575	45,068,169.355	0.000	5.101	74.393	0.000	-67.461	-66.823	0.000
		231,000.000	175,079.000	39,742.000	45,068,169.355	0.001	56,710.020	12,258.000	0.000	61,466.025	68,565.024	0.000
		7,320.000	7,320.000	10,994.030	45,068,169.355	0.000	15,687.979	0.000	0.000	20,394.373	22,356.481	0.000
		7,400,000.000	3,200,000.000	3,230,559.000	45,068,169.355	0.072	4,609,860.196	5,043,303.000	0.000	949,515.255	1,526,661.995	0.000
		30,000,000.000	19,274,159.000	22,852,826.000	45,068,169.355	0.507	32,609,939.314	7,741,178.000	12,200.000	34,663,943.109	38,745,652.643	0.000
		3,600,000.000	1,885,910.000	148,721.000	45,068,169.355	0.003	212,218.077	2,031,970.000	0.000	-1,756,086.500	-1,729,517.154	0.000
		41,500,000.000	22,958,367.000	18,075,428.630	45,068,169.355	0.401	25,792,811.388	3,655,635.900	0.000	29,875,018.906	33,104,235.493	0.000
		5,310,000.000	2,184,719.000	605,442.000	45,068,169.355	0.013	863,938.091	2,209,940.000	0.000	-1,086,820.481	-978,656.686	0.000
		9,000,000.000	6,951,532.000	103,852.000	45,068,169.355	0.002	148,192.062	3,845,502.000	0.000	-3,652,852.319	-3,634,288.922	0.000
MQ Totals:		97,169,445.000	58,766,511.000	45,067,568.235				24,539,861.044	12,200.000	59,074,509.854		0.000

Final Initial APQ:	79,700,000.000
Proposed Revised:	79,700,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	15,158,957.958
2013 Initial APQ:	79,700,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	78,584,200.000
IMS Est = 2013 APQ * (1 + IMS Est):	76,990,200.000

CFR 50%: 10,348,295.016

pending requests: request grant
(b)(4) 18,541,633 18,541,633

new + current MQ 75,308,144

current APQ sufficient

2014 Revised APQ
Worksheets

Basic Class: 9150-0
PQ Total(CM+PD): 3,386,794.000

FDA Est: .072
IMS Est: -.036

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		100,000.000	76,700.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		30.000	30.000	2.921	3,574,775.079	0.000	2.767	49.447	0.000	-45.849	-45.258	0.000
		78,000.000	78,000.000	0.000	3,574,775.079	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		233,691.000	191,626.000	128,462.930	3,574,775.079	0.036	121,707.652	35,920.698	0.000	122,299.251	148,328.601	0.000
		556,297.120	556,298.000	679,938.334	3,574,775.079	0.190	644,183.465	-209,218.035	0.000	628,220.496	765,995.905	0.000
		445,000.000	445,000.000	334,715.000	3,574,775.079	0.094	317,113.868	251,602.000	0.000	160,646.029	228,469.085	0.000
		1,390,000.000	1,179,810.000	997,252.000	3,574,775.079	0.279	944,811.076	392,859.000	0.000	835,395.399	1,037,467.845	0.000
		2,110,000.000	1,674,818.000	1,389,805.400	3,574,775.079	0.389	1,316,721.888	855,997.550	0.000	855,740.904	1,137,356.160	0.000
		130,000.000	97,711.000	44,542.000	3,574,775.079	0.012	42,199.743	31,189.000	0.000	23,670.662	32,696.175	0.000
MQ Totals:		5,043,023.120	4,299,998.000	3,574,718.585				1,776,835.728	0.000	2,625,926.892		0.000

Final Initial APQ:	5,400,000.000
Proposed Revised:	5,400,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-996,642.728
2013 Initial APQ:	4,775,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	5,118,600.000
IMS Est = 2013 APQ * (1 + IMS Est):	4,604,055.000

CFR 50%: -949,661.582

pending requests:	request	grant
(b)(4)	42,065	34,438
	435,182	435,182
	32,289	23,351
total new		492,971

new + current MQ granted 4,792,969

current APQ sufficient

[redacted]

2014 Revised APQ
Worksheets

Basic Class: 9220-0
PQ Total(CM+PD): 4,448.000

FDA Est:
IMS Est: .064

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		2.000	2.000	0.000	1,907.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		3,600.000	1,598.000	1,907.000	1,907.000	1.000	4,448.000	42.000	0.000	5,740.400	5,994.750	0.000
MQ Totals:		3,602.000	1,600.000	1,907.000				42.000	0.000	5,740.400		0.000

Final Initial APQ:	1,600.000
Proposed Revised:	3,700.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.6 - Revised MQ - Inventory:	5,030.000
2013 Initial APQ:	3,600.000
FDA Est = 2013 APQ * (1 + FDA Est):	3,600.000
IMS Est = 2013 APQ * (1 + IMS Est):	3,802.760

CFR 50%: 4,394.750

pending requests:	request	grant
(b)(4)	2,002	2,002
new + current MQ granted	3,602	

revised APQ sufficient

2014 Revised APQ
Worksheets

Basic Class: 9250-0
PQ Total(CM+PQ): 18,897,110.000

FDA Est: -.121
IMS Est: -.047

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		2,000,000.000	6,376,000.000	5,266,603.000	19,975,758.454	0.265	5,001,326.687	3,491,767.000	0.000	3,009,957.953	4,081,592.358	0.000
		10.000	10.000	1.454	19,975,758.454	0.000	1.375	6.841	0.000	-5.053	-4.758	0.000
		1,052,000.000	339,395.000	65,916.000	19,975,758.454	0.003	62,356.676	10,087.000	0.000	78,976.670	84,337.645	0.000
		13,000,000.000	10,155,194.000	11,396,639.000	19,975,758.454	0.571	10,781,216.383	3,456,715.000	41,830.000	10,600,696.271	12,910,767.703	0.000
		5,402,000.000	4,532,275.000	3,226,429.000	19,975,758.454	0.162	3,052,208.899	546,478.000	0.000	3,421,393.309	4,075,390.124	0.000
MQ Totals:		21,454,010.000	21,402,874.000	19,975,758.454				7,505,053.841	41,830.000	17,103,019.159		0.000

Final Initial APQ:	25,500,000.000
Proposed Revised:	25,500,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-562,262.841
2013 Initial APQ:	20,000,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	17,580,000.000
IMS Est = 2013 APQ * (1 + IMS Est):	19,058,000.000

CFR 50%: -292,600,727

pending requests	request	grant
(b)(4)	869,725	301,736
new + current MQ	21,704,610	

current APQ sufficient

2014 Revised APQ
Worksheets

Basic Class: 9254-0
PQ Total(CM+PD): 55.000

FDA Est:
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		10.000	10.000	0.000	22,287,908.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		2,295,000.000	822,975.000	194,755.000	22,287,908.000	0.009	0.481	66,287.000	0.000	-66,286.375	-17,597.649	0.000
		14,000,000.000	11,928,645.000	10,780,285.000	22,287,908.000	0.484	26.602	2,170,972.000	0.000	-2,170,937.417	924,132.503	0.000
		6,810,000.000	5,070,739.000	4,002,598.000	22,287,908.000	0.180	9.877	1,258,126.000	0.000	-1,258,113.160	-257,464.153	0.000
MQ Totals:		23,105,010.000	17,822,369.000	14,977,638.000				3,495,385.000	0.000	-3,495,336.951		0.000

Final Initial APQ:	31,100,000.000
Proposed Revised:	31,100,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-21,317,671.500
2013 Initial APQ:	26,000,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	26,000,000.000
IMS Est = 2013 APQ * (1 + IMS Est):	26,000,000.000

CFR 50%: -17,573,275.750

pending requests	request	grant
(b)(4)	1,739,261	1,224,277
new + current MQ	19,046,646	

current APQ sufficient

2014 Revised APQ
Worksheets

Basic Class: 9300-A
PQ Total:(CM+PD): 4,917,510.000

FDA Est:
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		131,000.000	131,000.000	0.000	47,803,753.601	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		43,480.000	43,480.000	25,960.601	47,803,753.601	0.001	2,672.611	101,581.652	0.000	-98,107.457	-81,745.888	0.000
		6,700,000.000	5,350,000.000	3,335,263.000	47,803,753.601	0.070	343,094.168	24,303.000	3,840,950.000	4,262,669.419	5,079,330.460	0.000
		150,000.000	0.000	0.000	47,803,753.601	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		44,000,000.000	44,000,000.000	36,564,556.000	47,803,753.601	0.765	3,761,348.335	12,904,910.000	0.000	-8,015,157.164	937,914.419	0.000
		5,000.000	2,875.000	160.000	47,803,753.601	0.000	16.459	69.210	0.000	-47.813	-8.636	0.000
		15,500,000.000	15,500,000.000	7,677,794.000	47,803,753.601	0.165	810,378.426	2,451,207.000	0.000	-1,397,715.046	531,214.533	0.000
		2,371,901.000	2,371,901.000	0.000	47,803,753.601	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,960,000.000	1,960,000.000	0.000	47,803,753.601	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		70,891,381.000	69,359,256.000	47,803,753.601				15,482,071.062	3,840,950.000	-5,248,358.062		0.000

Final Initial APQ:	73,000,000.000
Proposed Revised:	73,000,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-77,485,062.062
2013 Initial APQ:	83,000,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	83,000,000.000
IMS Est = 2013 APQ * (1 + IMS Est):	83,000,000.000

CFR 50%: -66,743,531.112

no pending requests to consider
(b)(4) equest granted on 7-16-14

2014 Revised APQ Worksheets

Basic Class: 9300-B
PQ Total(CM+PD): 42,569,500.000

FDA Est: -.083
IMS Est: -.031

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 35% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4),(b)(7)(E)		5.000	5.000	0.000	35,757,656.635	0.000	0.000	0.026	0.000	-0.026	-0.026	0.000
		100.000	100.000	2.195	35,757,656.635	0.000	2.613	130.576	0.000	-127.181	-126.763	0.000
		152,630.000	0.000	0.000	35,757,656.635	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		700,000.000	248,620.000	52,500.080	35,757,656.635	0.001	62,591.360	157,184.176	0.000	-76,932.409	-65,932.457	0.000
		1,892,000.000	0.000	3,322,313.000	35,757,656.635	0.093	3,554,857.385	1,260,218.000	0.000	3,891,096.600	4,493,858.981	0.000
		3,067,867.000	4,779,867.000	3,271,287.000	35,757,656.635	0.091	3,894,468.068	71,327.000	0.000	4,991,481.488	5,814,579.835	0.000
		14,600,000.000	14,244,006.000	12,910,984.000	35,757,656.635	0.361	15,370,529.982	5,199,456.000	225,000.000	15,007,232.976	17,466,452.477	0.000
		26,550,000.000	19,333,576.000	16,047,146.000	35,757,656.635	0.449	19,104,131.700	6,729,829.000	0.000	16,105,542.210	21,162,122.125	0.000
		1,000.000	1,000.000	0.360	35,757,656.635	0.000	0.429	0.000	0.000	0.557	0.626	0.000
		1,600,000.000	703,454.000	153,724.000	35,757,656.635	0.004	183,008.464	0.000	0.000	237,911.003	267,191.560	0.000
		5,400,000.000	4,200,000.000	0.000	35,757,656.635	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		53,793,602.000	43,510,828.000	35,757,656.635				13,438,142.780	225,000.000	42,127,207.220		0.000

Final Initial APQ:	50,000,000.000
Proposed Revised:	50,000,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	6,905,279.220
2013 Initial APQ:	48,200,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	44,199,400.000
IMS Est = 2013 APQ * (1 + IMS Est):	46,691,340.000

CFR 50%: 5,202,318.379

pending requests:	request	grant
(b)(4)	451,180	96,471
	1,692,000	1,692,000
	(1,692,000)	(1,692,000)
total new granted	96,471	
new grant + current MQ	43,607,299	
current APQ sufficient		

2014 Revised APQ
Worksheets

Basic Class: 9630-0
PQ Total(CM+PD): 1,247,154.000

FDA Est:
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		54,350.000	35,000.000	21,054.000	386,654.000	0.054	67,909.760	14,352.000	0.000	73,930.688	75,798.700	0.000
		430,000.000	430,000.000	365,600.000	386,654.000	0.946	1,179,244.240	173,187.000	0.000	1,359,930.512	1,392,268.300	0.000
		40,000.000	35,000.000	0.000	386,654.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		524,350.000	500,000.000	386,654.000				187,539.000	0.000	1,433,761.200		0.000

Final Initial APQ:	500,000.000
Proposed Revised:	500,000.000
Final Revised APQ:	624,000.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	1,183,192.000
2013 Initial APQ:	1,030,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	1,030,000.000
IMS Est = 2013 APQ * (1 + IMS Est):	1,030,000.000

CFR 50%: 968,067.000

previously denied:	requested	granted
(b)(4)	54,350	35,000
	40,000	35,000
Total new grant	94,350	70,000
total new + current MQ granted	594,350	
5% buffer for possible other request	29,718	
Estimated total MQ need	624,068	(round down for APQ)
Adjusted APQ with 25% buffer	780,000	

2014 Revised
APQ Worksheets

Basic Class: 9330-0
PQ Total(CM+PD): 5,977,005.000

FDA Est:
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	13,621,761.480	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,100,000.000	1,100,000.000	839,490.000	13,621,761.480	0.047	280,597.699	3,167.000	0.000	361,610.009	507,452.624	0.000
		2,437,143.000	1,674,318.000	176,502.000	13,621,761.480	0.013	78,323.743	253,484.000	0.000	-151,663.134	-110,953.821	0.000
		13,900,000.000	10,732,298.000	10,146,533.000	13,621,761.480	0.745	4,452,131.875	69,282.000	0.000	5,718,489.437	8,032,518.093	0.000
		5,250,000.000	3,283,650.000	2,565,244.480	13,621,761.480	0.188	1,125,587.106	151,100.000	0.000	1,312,163.238	1,897,195.003	0.000
		480,000.000	347,037.000	91,992.000	13,621,761.480	0.007	40,364.577	0.000	0.000	52,473.950	73,453.722	0.000
		700,000.000	612,500.000	0.000	13,621,761.480	0.000	0.000	324,264.000	0.000	-324,264.000	-324,264.000	0.000
		430,000.000	430,000.000	0.000	13,621,761.480	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		24,297,148.000	18,179,808.000	13,621,761.480				801,297.000	0.000	6,968,809.500		0.000

Final Initial APQ:	18,200,000.000
Proposed Revised:	22,100,000.000
Final Revised APQ:	24,500,000.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-10,015,697.500
2013 Initial APQ:	18,200,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	18,200,000.000
IMS Est = 2013 APQ * (1 + IMS Est):	18,200,000.000

CFR 50%: -8,104,408.380

pending requests:	requesting	granting
(b)(4)	3,167,702	3,167,702
	1,966,350	1,966,350
Total new grant	5,134,052	5,134,052
total new + current MQ granted	23,313,860	
5% buffer for possible other request	1,165,693	
Estimated total MQ need	24,479,553	(round up for APQ)
Adjusted APQ with 25% buffer	30,625,000	

2014 Revised APQ
Worksheets

Basic Class: 9143-B
PQ Total(CM+PD): 93,930,326.000

FDA Est: -.09
IMS Est: -.009

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	1.520	78,591,255.584	0.000	1.817	2.000	0.000	0.362	0.651	0.000
		200,000.000	160,000.000	0.000	78,591,255.584	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		60.000	60.000	9.824	78,591,255.564	0.000	11.741	810.806	0.000	-795.542	-793.673	0.000
		1,335,520.000	1,335,520.000	46,062.000	78,591,255.584	0.001	55,052.164	23,138.000	0.000	48,429.813	57,192.705	0.000
		20,966.000	6,000.000	0.000	78,591,255.584	0.000	0.000	0.000	0.000	0.000	0.000	0.000
		2,894,665.000	1,365,000.000	292,405.000	78,591,255.584	0.004	349,475.228	789,049.000	0.000	-334,731.203	-279,103.715	0.000
		24,000,000.000	24,000,000.000	14,839,041.000	78,591,255.584	0.189	17,735,255.001	14,301,862.000	68,954.000	8,842,923.502	11,565,921.002	0.000
		68,750,000.000	64,131,408.000	45,700,030.000	78,591,255.584	0.581	54,619,548.218	23,161,550.000	495,030.000	48,338,860.074	57,032,890.263	0.000
		1,000.000	1,000.000	866,355.240	78,591,255.584	0.011	1,035,445.368	92,406.000	0.000	1,253,674.278	1,416,490.770	0.000
		24,000,000.000	24,000,000.000	16,656,858.000	78,591,255.584	0.212	19,907,876.897	11,162,045.000	6,000,000.000	20,698,194.967	23,867,018.122	0.000
		820,000.000	784,539.000	190,483.000	78,591,255.584	0.002	227,660.573	537,901.000	0.000	-241,942.255	-205,704.534	0.000
MQ Totals:		122,022,215.000	115,803,630.000	78,591,255.584				50,088,783.806	6,563,954.000	78,604,613.994		0.000

Final Initial APQ:	119,500,000.000
Proposed Revised:	119,500,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 + Revised MQ - Inventory:	-24,996,904.606
2013 Initial APQ:	105,200,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	95,732,000.000
IMS Est = 2013 APQ * (1 + IMS Est):	104,305,800.000

CFR 50%: -28,831,672.410

pending requests	request	grant
(b)(4)	14,966	14,966
	1,529,665	1,126,780
	35,361	-
new grant		1,141,746
new + current MQ granted	116,945,376	

current APQ sufficient

2014 Revised APQ
Worksheets

Basic Class: 9652-A
PQ Total(CM+PD): 2,059,663.000

FDA Est:
IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		11,300,000.000	11,300,000.000	6,300,568.000	7,793,786.000	0.808	1,665,050.437	1,579,762.000	0.000	584,803.569	2,076,683.047	0.000
		2,751,000.000	2,751,000.000	1,493,218.000	7,793,786.000	0.192	394,612.563	269,680.000	0.000	243,316.331	596,690.203	0.000
		-2,500,000.000	2,499,000.000	0.000	7,793,786.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		16,551,000.000	16,550,000.000	7,793,786.000				1,849,442.000	0.000	828,119.900		0.000

Final Initial APQ:	20,000,000.000
Proposed Revised:	20,000,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-15,309,947.500
2013 Initial APQ:	14,700,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	14,700,000.000
IMS Est = 2013 APQ * (1 + IMS Est):	14,700,000.000

CFR 50%: -13,676,416.750

no pending requests to consider

current APQ sufficient

2014 Revised APQ Worksheets

Basic Class: 9652-B
PQ Total(CM+PDI): 3,153,648.000

FDA Est: -.185
IMS Est: .046

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5.000	0.000	3,604,592.071	0.000	0.000	0.007	0.000	-0.007	-0.007	0.000
		60.000	60.000	4.211	3,604,592.071	0.000	3.684	215.858	0.000	-211.079	-210.210	0.000
		143,000.000	143,000.000	8,820.000	3,604,592.071	0.002	7,716.595	23,682.000	0.000	-13,650.427	-11,831.257	0.000
		980,000.000	611,638.000	413,833.000	3,604,592.071	0.115	361,986.410	211,218.000	0.000	259,234.333	344,548.262	0.000
		4,000,000.000	2,810,598.000	2,802,150.000	3,604,592.071	0.777	2,451,593.570	1,132,591.000	0.000	2,054,480.641	2,632,438.462	0.000
		3,000.000	3,000.000	41,930.660	3,604,592.071	0.012	36,685.198	34,990.290	0.000	12,700.467	21,348.922	0.000
		1,255,000.000	1,183,734.000	330,495.000	3,604,592.071	0.092	289,149.195	310,739.000	0.000	65,154.954	133,321.244	0.000
		210,000.000	210,000.000	7,559.000	3,604,592.071	0.002	6,613.349	295,828.000	0.000	-287,230.646	-285,671.564	0.000
MQ Totals:		6,591,065.000	4,962,035.000	3,604,592.071				2,009,264.165	0.000	2,090,478.235		0.000

Final Initial APQ:	8,200,000.000
Proposed Revised:	8,200,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-2,240,827.165
2013 Initial APQ:	5,500,000.000
FDA Est = 2013 APQ * (1 + FDA Est):	4,482,500.000
IMS Est = 2013 APQ * (1 + IMS Est):	5,754,100.000

CFR 50%: -2,128,091.147

no pending requests to consider

(b)(4) request granted on 7-16-14

Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised 2011	Final Revised 2012	Final Revised 2013	Initial 2014	Proposed Revised 2014
Schedule I:					
Psilocybin	2	2	10	30	30
Psilocyn	2	2	12	30	30
Schedule II:					
Diphenoxylate	730,000	900,000	867,500	750,000	1,288,750
Ecgonine	83,000	83,000	144,000	144,000	174,375
Hydrocodone (for conversion)	0	0	0	0	137,500
Levorphanol	3,600	3,600	4,500	2,000	4,625
Oripavine	8,000,000	15,300,000	22,750,000	22,750,000	27,625,000
Phenylacetone	8,000,000	16,000,000	42,393,750	67,000,000	45,750,000
Remifentanil	2,500	2,500	3,750	3,750	5,875

NOTES:
As of 2013 CII values have a 25% buffer added to the calculated US requirements.

2014 Proposed Adjusted Aggregate Production Quotas and Assessment of Annual Needs

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

- The attached Federal Register notice, prepared for your signature, proposes to adjust the calendar year 2014 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.

- 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 1 chemicals

- The AAN for **pseudoephedrine (for sale)** was increased due to changes in registrant requirements. Several DEA registrants were denied legitimate supplies of these controlled substances because their requirements exceeded the established AAN. The AAN was established based on the timely submission of registrant applications which had requested to import lower quantities of API and / or finished dosage forms than in previous years'.

Schedule I substances

- The APQ for **psilocybin** and **psilocin** were increased. The manufacturing of these substances will be used for analytical standards, reference, and research material. New DEA registrant(s) entering the reference standard market at the bulk manufacturing level.

Schedule II substances

- The APQ for **diphenoxylate (for sale), ecgonine,** and **levorphanol** were increased due to increased registrant requirements. Several DEA registrants were denied legitimate supplies of these controlled substances because their requirements exceeded the established APQ.

- The APQ for **hydrocodone (for conversion)** is proposed to be increased from zero. A DEA

registered bulk manufacturer is requesting the material for product development efforts in the development of a different synthesis route to manufacture hydromorphone.

- The APQ for **oripavine** was increased due to the increased domestic sales and exports of the non-controlled substances naltrexone, naloxone, and nalbuphine which utilize oripavine as the starting material. The synthesis route includes the controlled substances oxymorphone (for conversion) and noroxymorphone (for conversion).

- 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.

- The APQ for **phenylacetone** was decreased based on a registrant's decision to import the bulk API instead of manufacturing it domestically and the subsequent withdrawal of their manufacturing quota.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-378]

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 2014

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

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2014 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-378" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov*. Paper comments that duplicate electronic submissions are

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

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

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

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

Legal Authority

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

The DEA published the established aggregate production quotas for schedule I and II controlled substances and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine for 2014 in the *Federal Register* (78 FR 55099) on September 9, 2013. 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 2014 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2014 aggregate production quotas for certain schedule I and II controlled substances to be manufactured in the United States in 2014 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 2014 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported to the United States in 2014 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 2013 year-end inventories, 2013 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 2014 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 2014 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 2014 aggregate production quotas for certain schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Previously Established 2014 Quotas (g)	Proposed Adjusted 2014 Quotas (g)
Schedule I		
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15	No change
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15	No change
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15	No change
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15	No change
1-(1-Phenylcyclohexyl)pyrrolidine	10	No change
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	No change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	No change
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	No change
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45	No change
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45	No change
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45	No change
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45	No change
1-Methyl-4-phenyl-4-propionoxypiperidine	2	No change
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45	No change
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45	No change
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45	No change
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45	No change
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45	No change
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45	No change
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45	No change
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C-P)	30	No change
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30	No change
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30	No change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30	No change
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30	No change
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	15	No change

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	No change
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15	No change
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30	No change
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15	No change
2-(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	No change
3-Methylfentanyl	2	No change
3-Methylthiofentanyl	2	No change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	No change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	No change
4-Fluoro-*N*-methylcathinone (4-FMC)	15	No change
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	No change
4-Methyl-*N*-methylcathinone (mephedrone)	45	No change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15	No change
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68	No change
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53	No change
5-Methoxy-3,4-methylenedioxyamphetamine	25	No change
5-Methoxy-*N*,*N*-diisopropyltryptamine	25	No change
5-Methoxy-*N*,*N*-dimethyltryptamine	25	No change

Acetyl-*alpha*-methylfentanyl	2	No change
Acetyldihydrocodeine	2	No change
Acetylmethadol	2	No change
Allylprodine	2	No change
Alphacetylmethadol	2	No change
alpha-Ethyltryptamine	25	No change
Alphameprodine	2	No change
Alphamethadol	2	No change
alpha-Methylfentanyl	2	No change
alpha-Methylthiofentanyl	2	No change
alpha-Methyltryptamine (AMT)	25	No change
alpha-Pyrrolidinobutiophenone (α-PBP)	15	No change
alpha-Pyrrolidinopentiophenone (α-PVP)	15	No change
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
Betaprodine	2	No change
Bufotenine	3	No change
Cathinone	70	No change
Codeine methylbromide	5	No change
Codeine-*N*-oxide	200	No change
Desomorphine	5	No change
Diethyltryptamine	25	No change
Difenoxin	50	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	No change
Hydromorphinol	2	No change
Hydroxypethidine	2	No change
Ibogaine	5	No change

Lysergic acid diethylamide (LSD)	35	No change
Marihuana	650,000	No change
Mescaline	25	No change
Methaqualone	10	No change
Methcathinone	25	No change
Methyldesorphine	2	No change
Methyldihydromorphine	2	No change
Morphine methylbromide	5	No change
Morphine methylsulfonate	5	No change
Morphine-*N*-oxide	175	No change
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	15	No change
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	15	No change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	15	No change
N,*N*-Dimethylamphetamine	25	No change
Naphthylpyrovalerone (naphyrone)	15	No change
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	No change
para-Fluorofentanyl	2	No change
Parahexyl	5	No change
Phenomorphan	2	No change
Pholcodine	2	No change
Properidine	2	No change
Psilocybin	30	40
Psilocyn	30	50
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15	No change
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	15	No change
Tetrahydrocannabinols	491,000	No change

Thiofentanyl	2	No change
Tilidine	10	No change
Trimeperidine	2	No change
Schedule II		
1-Phenylcyclohexylamine	3	No change
1-Piperidinocyclohexanecarbonitrile	3	No change
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500	No change
Alfentanil	17,625	No change
Alphaprodine	3	No change
Amobarbital	9	No change
Amphetamine (for conversion)	18,375,000	No change
Amphetamine (for sale)	49,000,000	No change
Carfentanil	19	No change
Cocaine	240,000	No change
Codeine (for conversion)	68,750,000	No change
Codeine (for sale)	46,125,000	No change
Dextropropoxyphene	19	No change
Dihydrocodeine	100,750	No change
Diphenoxylate	750,000	1,288,750
Ecgonine	144,000	174,375
Ethylmorphine	3	No change
Fentanyl	2,108,750	No change
Glutethimide	3	No change
Hydrocodone (for conversion)	0	137,500
Hydrocodone (for sale)	99,625,000	No change
Hydromorphone	6,750,000	No change
Isomethadone	5	No change
Levo-alphacetylmethadol (LAAM)	4	No change
Levomethorphan	195	No change
Levorphanol	2,000	4,625
Lisdexamfetamine	23,750,000	No change
Meperidine	6,250,000	No change
Meperidine Intermediate-A	6	No change
Meperidine Intermediate-B	11	No change
Meperidine Intermediate-C	6	No change
Metazocine	19	No change
Methadone (for sale)	31,875,000	No change
Methadone Intermediate	38,875,000	No change
Methamphetamine	2,811,375	No change

[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]		
Methylphenidate	96,750,000	No change
Morphine (for conversion)	91,250,000	No change
Morphine (for sale)	62,500,000	No change
Nabilone	30,375	No change
Noroxymorphone (for conversion)	17,500,000	No change
Noroxymorphone (for sale)	1,262,500	No change
Opium (powder)	112,500	No change
Opium (tincture)	625,000	No change
Oripavine	22,750,000	27,625,000
Oxycodone (for conversion)	9,250,000	No change
Oxycodone (for sale)	149,375,000	No change
Oxymorphone (for conversion)	25,000,000	No change
Oxymorphone (for sale)	7,750,000	No change
Pentobarbital	35,000,000	No change
Phenazocine	6	No change
Phencyclidine	19	No change
Phenmetrazine	3	No change
Phenylacetone	67,000,000	45,750,000
Racemethorphan	3	No change
Remifentanil	3,750	5,875
Secobarbital	215,003	No change
Sufentanil	6,255	No change
Tapentadol	17,500,000	No change
Thebaine	145,000,000	No change
List I Chemicals		
Ephedrine (for conversion)	1,000,000	No change
Ephedrine (for sale)	3,000,000	No change
Phenylpropanolamine (for conversion)	44,800,000	No change
Phenylpropanolamine (for sale)	5,300,000	No change
Pseudoephedrine (for conversion)	5,000	No change
Pseudoephedrine (for sale)	192,000,000	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 2014 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 2014 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:

Thomas M. Harrigan,
Deputy Administrator.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–378]

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 2014

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

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2014 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 July 14, 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–378" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov*. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments via regular or express mail, they should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

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

Legal Authority

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

The DEA published the established aggregate production quotas for schedule I and II controlled substances and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine for 2014 in the **Federal Register** (78 FR 55099) on September 9, 2013. 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 2014 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2014 aggregate production quotas for certain schedule I and II controlled substances to be manufactured in the United States in 2014 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 2014 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported to the United States in 2014 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 2013 year-end inventories, 2013 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 2014 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 2014 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 2014 aggregate production quotas for certain schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Previously established 2014 quotas (g)	Proposed adjusted 2014 quotas (g)
Schedule I		
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15	No change. ✓
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15	No change. ✓
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15	No change. ✓
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15	No change. ✓
1-(1-Phenylcyclohexyl)pyrrolidine	10	No change. ✓
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	No change. ✓
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	No change. ✓
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	No change. ✓
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45	No change. ✓
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45	No change. ✓
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45	No change. ✓
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45	No change. ✓
1-Methyl-4-phenyl-4-propionoxypiperidine	2	No change. ✓
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45	No change. ✓
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45	No change. ✓
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45	No change. ✓
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45	No change. ✓
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45	No change. ✓
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45	No change. ✓
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45	No change. ✓
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C-P)	30	No change. ✓
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30	No change. ✓
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30	No change. ✓
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30	No change. ✓
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30	No change. ✓
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36).	15	No change. ✓
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	No change. ✓
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82).	15	No change. ✓
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30	No change. ✓
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15	No change. ✓
2-(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. ✓

Basic class	Previously established 2014 quotas (g)	Proposed adjusted 2014 quotas (g)
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-Methylonedioxy-*N*-methylcathinone (methylone)	50	No change.
3,4-Methylenedioxypyrovalerone (MDPV)	35	No change.
3-Fluoro-*N*-methylcathinone (3-FMC)	15	No change.
3-Methylfentanyl	2	No change.
3-Methylthiofentanyl	2	No change.
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	No change.
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	No change.
4-Fluoro-*N*-methylcathinone (4-FMC)	15	No change.
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	No change.
4-Methyl-*N*-methylcathinone (mephedrone)	45	No change.
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15	No change.
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68	No change.
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog).	53	No change.
5-Methoxy-3,4-methylenedioxyamphetamine	25	No change.
5-Methoxy-*N*,*N*-diisopropyltryptamine	25	No change.
5-Methoxy-*N*,*N*-dimethyltryptamine	25	No change.
Acetyl-*alpha*-methylfentanyl	2	No change.
Acetyldihydrocodeine	2	No change.
Acetylmethadol	2	No change.
Allylprodine	2	No change.
Alphacetylmethadol	2	No change.
alpha-Ethyltryptamine	25	No change.
Alphameprodine	2	No change.
Alphamethadol	2	No change.
alpha-Methylfentanyl	2	No change.
alpha-Methylthiofentanyl	2	No change.
alpha-Methyltryptamine (AMT)	25	No change.
alpha-Pyrrolidinobutiophenone (α-PBP)	15	No change.
alpha-Pyrrolidinopentiophenone (α-PVP)	15	No change.
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.
Betaprodine	2	No change.
Bufotenine	3	No change.
Cathinone	70	No change.
Codeine methylbromide	5	No change.
Codeine-*N*-oxide	200	No change.
Desomorphine	5	No change.
Diethyltryptamine	25	No change.
Difenoxin	50	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	No change.
Hydromorphinol	2	No change.
Hydroxypethidine	2	No change.
Ibogaine	5	No change.
Lysergic acid diethylamide (LSD)	35	No change.
Marihuana	650,000	No change.
Mescaline	25	No change.
Methaqualone	10	No change.
Methcathinone	25	No change.
Methyldesorphine	2	No change.
Methyldihydromorphine	2	No change.
Morphine methylbromide	5	No change.

Basic class	Previously established 2014 quotas (g)	Proposed adjusted 2014 quotas (g)
Morphine methylsulfonate	5	No change.
Morphine-*N*-oxide	175	No change.
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	15	No change.
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	15	No change.
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	15	No change.
N,N-Dimethylamphetamine	25	No change.
Naphthylpyrovalerone (naphyrone)	15	No change.
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	No change.
para-Fluorofentanyl	2	No change.
Parahexyl	5	No change.
Phenomorphan	2	No change.
Pholcodine	2	No change.
Properidine	2	No change.
Psilocybin	30	40
Psilocyn	30	50
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15	No change.
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	15	No change.
Tetrahydrocannabinols	491,000	No change.
Thiofentanyl	2	No change.
Tilidine	10	No change.
Trimeperidine	2	No change.
Schedule II		
1-Phenylcyclohexylamine	3	No change.
1-Piperidinocyclohexanecarbonitrile	3	No change.
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500	No change.
Alfentanil	17,625	No change.
Alphaprodine	3	No change.
Amobarbital	9	No change.
Amphetamine (for conversion)	18,375,000	No change.
Amphetamine (for sale)	49,000,000	No change.
Carfentanil	19	No change.
Cocaine	240,000	No change.
Codeine (for conversion)	68,750,000	No change.
Codeine (for sale)	46,125,000	No change.
Dextropropoxyphene	19	No change.
Dihydrocodeine	100,750	No change.
Diphenoxylate	750,000	1,288,750
Ecgonine	144,000	174,375
Ethylmorphine	3	No change.
Fentanyl	2,108,750	No change.
Glutethimide	3	No change.
Hydrocodone (for conversion)	0	137,500
Hydrocodone (for sale)	99,625,000	No change.
Hydromorphone	6,750,000	No change.
Isomethadone	5	No change.
Levo-alphacetylmethadol (LAAM)	4	No change.
Levomethorphan	195	No change.
Levorphanol	2,000	4,625
Lisdexamfetamine	23,750,000	No change.
Meperidine	6,250,000	No change.
Meperidine Intermediate-A	6	No change.
Meperidine Intermediate-B	11	No change.
Meperidine Intermediate-C	6	No change.
Metazocine	19	No change.
Methadone (for sale)	31,875,000	No change.
Methadone Intermediate	38,875,000	No change.
Methamphetamine	2,811,375	No change.
[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]		
Methylphenidate	96,750,000	No change.
Morphine (for conversion)	91,250,000	No change.

Basic class	Previously established 2014 quotas (g)	Proposed adjusted 2014 quotas (g)
Morphine (for sale)	62,500,000	No change.
Nabilone	30,375	No change.
Noroxymorphone (for conversion)	17,500,000	No change.
Noroxymorphone (for sale)	1,262,500	No change.
Opium (powder)	112,500	No change.
Opium (tincture)	625,000	No change.
Oripavine	22,750,000	27,625,000
Oxycodone (for conversion)	9,250,000	No change.
Oxycodone (for sale)	149,375,000	No change.
Oxymorphone (for conversion)	25,000,000	No change.
Oxymorphone (for sale)	7,750,000	No change.
Pentobarbital	35,000,000	No change.
Phenazocine	6	No change.
Phencyclidine	19	No change.
Phenmetrazine	3	No change.
Phenylacetone	67,000,000	45,750,000
Racemethorphan	3	No change.
Remifentanil	3,750	5,875
Secobarbital	215,003	No change.
Sufentanil	6,255	No change.
Tapentadol	17,500,000	No change.
Thebaine	145,000,000	No change.
List I Chemicals		
Ephedrine (for conversion)	1,000,000	No change.
Ephedrine (for sale)	3,000,000	No change.
Phenylpropanolamine (for conversion)	44,800,000	No change.
Phenylpropanolamine (for sale)	5,300,000	No change.
Pseudoephedrine (for conversion)	5,000	No change.
Pseudoephedrine (for sale)	192,000,000	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 2014 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 2014 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: June 4, 2014.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2014-13804 Filed 6-11-14; 8:45 am]

BILLING CODE 4410-09-P

OFFICE OF MANAGEMENT AND BUDGET

Fiscal Year 2014 Cost of Hospital and Medical Care Treatment Furnished by the Department of Defense Medical Treatment Facilities; Certain Rates Regarding Recovery From Tortiously Liable Third Persons

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

ACTION: Notice.

SUMMARY: By virtue of the authority vested in the President by Section 2(a) of Pub. B. 87-603 (76 Stat. 593; 42 U.S.C. 2652), and delegated to the Director of the Office of Management and Budget by the President through Executive Order No. 11541 of July 1, 1970, the rates referenced below are hereby established. These rates are for use in connection with the recovery from tortiously liable third persons for the cost of inpatient medical services furnished by military treatment facilities through the Department of Defense (DoD). The rates have been established in accordance with the requirements of OMB Circular A-25, requiring reimbursement of the full cost of all services provided. The *FY14 inpatient medical rates* referenced are effective upon publication of this notice in the Federal Register and will remain in effect until further notice. Previously published outpatient medical and dental, and cosmetic surgery rates remain in effect until further notice. Pharmacy rates are updated periodically. A full disclosure of the rates is posted on DoD's Uniform Business Office Web site: *http://www.tricare.mil/ocfo/mcfs/ubo/mhs_rates.cfm.*

Brian C. Deese,

Deputy Director.

[FR Doc. 2014-13687 Filed 6-11-14; 8:45 am]

BILLING CODE P

Drug	Company	Comment	Amount	Response	Proposed APQ	Revised APQ	Change
4-Anilino-phenethyl-4-piperidine (ANPP)	(b)(4)	increase APQ	120,474	APQ sufficient	2,150,000	2,150,000	-
codeine (for sale)		increase APQ	unknown	APQ sufficient	36,900,000	36,900,000	-
diphenoxylate		increase APQ	890,000	APQ sufficient	1,031,000	1,031,000	-
hydromorphone		increase APQ	435,182	APQ sufficient	5,400,000	5,400,000	-
levorphanol		increase APQ	2,002	APQ sufficient	3,700	3,700	-
morphine (for conversion)		increase APQ	5,069,238	APQ sufficient	73,000,000	73,000,000	-
oripavine		increase APQ	3,167,702	justified, increase APQ	22,100,000	24,500,000	2,400,000
oxycodone (for sale)		increase APQ	1,529,665	APQ sufficient	119,500,000	119,500,000	-
oxymorphone (for conversion)		increase APQ	143,491	APQ sufficient	20,000,000	20,000,000	-
oxymorphone (for sale)		increase APQ	374,000	APQ sufficient	6,200,000	6,200,000	-
tetrahydrocannabinol 5		increase APQ	65,668	APQ sufficient	393,000	393,000	-

Number of registrants/entities commenting: 5
Number of drugs commented on: 11 11

CMEA Chemical	Company	Comment	Amount	Response	Proposed AAN	Establish AAN	Change

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

Additional Drug Considerations:

Drug	Response	Proposed	Revised	Change
4-Anilino-phenethyl-4-piperidine (ANPP)	APQ sufficient	see above		see above
cocaine	APQ sufficient	192,000	192,000	-
ecgonine	proposed revised APQ increased in anticipation of grant	139,500	139,500	-
dihydromorphine	APQ sufficient	3,990,000	3,990,000	-
fentanyl	request to relinquish quota, APQ sufficient	1,687,000	1,687,000	-
gamma hydroxybutric acid	APQ sufficeint	56,200,000	56,200,000	-
hydrocodone (for sale)	APQ sufficient	79,700,000	79,700,000	-
hydromorphone	2 registrant requests for increases of 32,289 + 42,065 g, respectively	see above		see above
methadone	APQ sufficeint	25,500,000	25,500,000	-
methadone intermediate	APQ sufficeint	31,100,000	31,100,000	-
methylphenidate	APQ sufficient	77,400,000	77,400,000	-
morphine (for sale)	APQ sufficient	50,000,000	50,000,000	-
opium tincture	increase aPQ, based on previous customer denials - 50,000	500,000	624,000	124,000
oripavine	increase APQ, based on additional customer need - 1,966,350g	see above		see above
oxycodone (for sale)	APQ sufficeint	see above		see above
pentobarbital	APQ sufficient	28,000,000	28,000,000	-
tetrahydrocannabinols	registrant is changing sub-drug codes, APQ sufficient	see above		see above

Additional Chemical Considerations:

Drug	Response	Proposed	Revised	Change
ephedrine (for sale)	increase AAN in response to customer demands - 1,123,500	3,000,000	4,200,000	1,200,000
pseudoephedrine (for sale)	APQ sufficient	224,500,000	224,500,000	-

CONFIDENTIAL

July 9, 2014

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

Subject: Docket No. DEA-378

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

Dear Sirs:

I, (b)(4);(b)(6) manufacturing registration [redacted] am submitting this comment on the Proposed Adjustments to the Aggregate Production Quota for 2014 for various products as published in the June 12, 2014 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 manufacturing quota for the following item should be increased by the identified quantity: (i) Oxycodone by 1,994,665 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 quantity for the material mentioned above is not sufficient to provide for adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements, and that the quota should be increased to cover our needs. For this item, quota request was submitted and we are awaiting a response from the Agency.

Very truly yours

(b)(4)

(b)(4)

June 30, 2014

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

RE: Docket No. DEA-378 (b)(4) **Comment**

Dear Sirs:

(b)(4) requests the following actions be considered on the drug codes listed below during the 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 2014.

Quota Category	Drug Code	Action Needed
Manufacturing	Codeine - 9050	An aggregate increase on (b)(4) customer demand
Manufacturing	Morphine for Conversion- 9300	An aggregate increase based on (b)(4) customer demand and development initiative
Manufacturing	Oxymorphone for Conversion -9652 Oxymorphone for Sale -9652	An aggregate increase based on (b)(4) customer demand and development initiative
Manufacturing	Hydromorphone - 9150	An aggregate increase based on (b)(4) customer demand

Thank you in advance for considering th hydrocodone stions regarding this request, please do not hesitate to contact

Best regards,

(b)(6)

Director, Controlled Substance Compliance

(b)(4)

(b)(4)

June 30, 2014

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

RE: Docket No. DEA-378 (b)(4) **Comment**

Dear Sirs:

(b)(4);(b)(7)(E) requests the following actions be considered on the drug codes listed below during the 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 2014.

Quota Category	Drug Code	Action Needed
Manufacturing	Codeine - 9050	An aggregate increase on (b)(4) customer demand
Manufacturing	Morphine for Conversion- 9300	An aggregate increase based on (b)(4) customer demand and development initiative
Manufacturing	Oxymorphone for Conversion -9652 Oxymorphone for Sale -9652	An aggregate increase based on (b)(4) customer demand and development initiative
Manufacturing	Hydromorphone - 9150	An aggregate increase based on (b)(4) customer demand

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

Best regards,

(b)(6)

Director, Controlled Substance Compliance

(b)(4) Hydroco ota Summary

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

	Quota Category	Material Name	2014 Initial Quota Grant (kg base)	Requested Quota (kg base)	Increase (kg base)	Distribution/Sales (kg base)
June 26, 2014 Submission	Procurement	Hydrocodone – 9193	14,830	21,450	6,620	22,435
July 2, 2014 Revision	Procurement	Hydrocodone – 9193	14,830	29,450	14,620	23,372

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

	Quota Category	Material Name	2014 Initial Quota Grant (kg base)	Requested Quota (kg base)	Increase (kg base)	Distribution/Sales (kg base)
June 26, 2014 Submission	Procurement	CPS-Thebaine – 9670	28,579	34,000	5,421	26,422
	Manufacturing	Hydrocodone for Sale – 9193	22,958	32,500	9,542	
July 2, 2014 Revision	Procurement	CPS-Thebaine – 9670	28,579	45,600	17,021	34,419
	Manufacturing	Hydrocodone for Sale – 9193	22,958	41,500	18,542	

* Confidential
* received w/ applications for adjustment

		(b)(4);(b)(7)(E)						(b)(4);(b)(7)(E)				Combined	
		1/1/14-6/13/14		2014 Remaining		Total 2014		1/1/14-6/13/14		Total 2014		Total 2014	
Customer	Reg #	kgs, as salt	kgs, as base	kgs, as salt	kgs, as base	kgs, as salt	kgs, as base	kgs, as salt	kgs, as base	kgs, as salt	kgs, as base	kgs, as salt	kgs, as base
(b)(4);(b)(7)(E)		28.6	17.4	280.0	170.8	308.6	188.2	1.3	0.8	1.3	0.8	309.9	189.0
		5.0	3.1	-	-	5.0	3.1		-	-	-	5.0	3.1
		5.0	3.1	35.0	21.4	40.0	24.4		-	-	-	40.0	24.4
		192.4	117.3	200.0	122.0	392.4	239.3		-			392.4	239.3
		557.6	340.1	-	-	557.6	340.1		-	-	-	557.6	340.1
			-	-	-	-	-		-	-	-	-	-
		2,304.2	1,405.6	1,081.0	659.4	3,385.2	2,065.0		-	-	-	3,385.2	2,065.0
		85.5	52.2	-	-	85.5	52.2		-			85.5	52.2
		191.5	116.8	1,000.0	610.0	1,191.5	726.8		-	-	-	1,191.5	726.8
		165.0	100.7	825.0	503.3	990.0	603.9		-	-	-	990.0	603.9
		0.1	0.1	-	-	0.1	0.1		-			0.1	0.1
		10.0	6.1	-	-	10.0	6.1		-	-	-	10.0	6.1
		0.1	0.0	-	-	0.1	0.0		-			0.1	0.0
			-	-	-	-	-	0.00003	0.00002			-	-
		0.3	0.2	-	-	0.3	0.2		-			0.3	0.2
		12.0	7.3	5.0	3.1	17.0	10.4		-	-	-	17.0	10.4
		1.0	0.6	2.0	1.2	3.0	1.8		-	-	-	3.0	1.8
			-	106.0	64.7	106.0	64.7		-	-	-	106.0	64.7
			-	125.0	76.3	125.0	76.3		-	-	-	125.0	76.3
		0.0	0.0	-	-	0.0	0.0		-			0.0	0.0
		0.1	0.1	-	-	0.1	0.1		-			0.1	0.1
		0.8	0.5	-	-	0.8	0.5	0.00005	0.00003			0.8	0.5
		6.0	3.7	-	-	6.0	3.7		-			6.0	3.7
			-	-	-	-	-		-	-	-	-	-
		1,194.6	728.7	4,300.0	2,623 0	5,494.6	3,351.7	2,319.2	1,414.7	2,319.2	1,414.7	7,813.8	4,766.4
		75.0	45.8	130.0	79.3	205.0	125.1		-	-	-	205.0	125.1
		0.0	0.0	-	-	0.0	0.0		-			0.0	0.0
		5.0	3.1	-	-	5.0	3.1		-	-	-	5.0	3.1
		0.2	0.1	-	-	0.2	0.1		-			0.2	0.1
		0.0	0.0	-	-	0.0	0.0		-			0.0	0.0
		60.0	36.6	30.0	18.3	90.0	54.9		-	-	-	90.0	54.9
		147.8	90.1	160.0	97.6	307.8	187.7		-	-	-	307.8	187.7
		0.0	0.0	435.0	265.4	435.0	265.4		-			435.0	265.4
		54.8	33.4		-	54.8	33.4		-	-	-	54.8	33.4
				400.0	244.0	400.0	244.0					400.0	244.0
		8.3	5.0		-	8.3	5.0		-	-	-	8.3	5.0
		0.1	0.1		-	0.1	0.1		-			0.1	0.1
			-	5.0	3.1	5.0	3.1		-	-	-	5.0	3.1
		565.8	345.1	1,600.0	976.0	2,165.8	1,321.1		-	-	-	2,165.8	1,321.1

(b)(4);(b)(7)(E)	0.5	0.3		-	0.5	0.3		-			0.5	0.3
	6,986.3	4,261.6	7,461.0	4,551.2	14,447.3	8,812.8	5,825.9	3,553.8	5,825.9	3,553.8	20,273.1	12,366.6
	1,084.8	661.7	3,015.0	1,839.2	4,099.8	2,500.9		-	-	-	4,099.8	2,500.9
	3.9	2.4		-	3.9	2.4		-			3.9	2.4
		-		-	-	-	0.00050	0.00031			-	-
	168.0	102.5	3,200.0	1,952.0	3,368.0	2,054.5		-	-	-	3,368.0	2,054.5
		-		-	-	-		-	-	-	-	-
	13,920.1	8,491.3	24,395.0	14,881.0	38,315.1	23,372.2	8,146.4	4,969.3	8,146.4	4,969.3	46,461.5	28,341.5

(b)(4)

2014 Quota	Current	Requested Quota	Change
CPS-ATA - Procure WT	0	0	0
hydrocodone - Make WT	1,886	1,886	0
hydrocodone - procure WT	14,830	29,450	14,620

2014 Inventory Calculations	With Current Quota	With Additional Quota
2013 Ending Inventory	8,639	8,639
Non saleable material	110	110
2012 Validation Material	1,914	1,914
2013 Available End. Inv.	**6,615**	**6,615**
2014 API Quota (Procure)	14,830	29,450
2014 API Quota (Manufacture)	0	0
2014 Dispositions:		
Sales	23,372	23,372
Processing Losses	(1,303)	(2,439)
2014 Ending Inventory	**-3,230**	**10,254**
Converted to % Yearend	**-15.7%**	**50.0%**

	kgs, base
2013 Dispositions	17,665
2014 Estimated Dispositions	23,372
Average	20,519
50% Inventory Allowance	10,259

	ACTUAL YEAR TO DATE (5/31/14)				ESTIMATE WITH REMAINING QUOTA			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	Input to Step	Output of Step	Loss by step
Hydrocodone for Sale - MQ										
CPS Thebaine to Crude hydrocodone (CHB)	0	87.5%	0		0	0		0	0	
CHB to purified hydrocodone base (PHB)	0	94.0%	0	0	0	0	0	0	0	0
PHB to hydrocodone bitartrate (HBT)	0	94.2%	0	0	0	0	0	0	0	0
HBT to HBT Finished Good API	0	99.4%	0	0	0	0	0	0	0	0
Total MQ				0			0			0
Hydrocodone for Sale - PQ										
PHB to hydrocodone bitartrate (HBT)	5,302	93.1%	4,936	(366)	9,567	8,907	(660)	14,620	13,611	(1,009)
HBT to HBT Finished Good API	5,500	99.1%	5,449	(51)	9,359	9,272	(87)	13,611	13,485	(127)
Reprocessing of OOS HBT	0	91.1%	0	0	1,566	1,427	(139)			
Total PQ				(417)			(886)			(1,135)

(b)(4) Hydroc nventory Calculations

2014 Quota	Current	Requested Quota	Change
CPS-ATA - Procure AT	28,579	45,600	17,021
hydrocodone - Make AT	22,958	41,500	18,542
hydrocodone - procure AT	5,000	5,000	0
hydrocodone - procure WT	14,830	29,450	14,620

2014 Inventory Calculations	With Current Quota	With Additional Quota
2013 Ending Inventory	3,714	3,714
Non saleable material	60	60
2013 Available End. Inv.	**3,654**	**3,654**
2014 API Quota (Manufacture)	22,958	41,500
2014 Dispositions:		
Sales	34,419	34,419
Processing Losses	(1,665)	(2,644)
2014 Ending Inventory	**-9,472**	**8,090**
Converted to % Yearend	**-36.1%**	**30.8%**

	kgs, base
2013 Dispositions to (b)(4)	18,047
2013 Dispositions	1
2014 Estimated Dispositions to (b)(4)	29,450
2014 Estimated Dispositions	4,969
Average	26,234
50% Inventory Allowance	7,916

	ACTUAL YEAR TO DATE (5/31/14)				ESTIMATE ON			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	Input to Step	Output of Step	Loss by step
Hydrocodone for Sale										
CPS Thebaine to Crude hydrocodone (CHB)	18,357	86.1%	15,801		8,314	7,157		21,540	18,542	
CHB to purified hydrocodone base (PHB)	15,039	94.7%	14,245	(794)	7,157	6,779	(378)	18,542	17,562	(979)
PHB to hydrocodone bitartrate (HBT)	3,483	89.8%	3,126	(357)	0	0	0	0	0	0
HBT to HBT Finished Good API	4,081	99.1%	4,045	(36)	0	0	0	0	0	0
Reprocessing of OOS HBT	1,288	92.2%	1,187	(101)						
Total				(1,287)			(378)			(979)

2014 CPS-Thebaine Inventory Calculations	With Current Quota	With Additional Quota
2013 Ending Inventory	12,972	12,972
Non saleable material	1	1
2013 Available End. Inv.	**12,971**	**12,971**
2014 CPS ATA Quota	28,579	45,600
2014 Import Requirement for External Manuf. (AFC)	920	920
Total 2014 CPS Requirement	29,499	46,520
2014 Dispositions:		
Converted to Hydrocodone for Sale	48,211	48,211
Disposition from Import to External Manuf (AFC)	920	920
Total Dispositions	49,131	49,131
2014 Ending Inventory	**-6,661**	**10,360**
Converted to % Yearend	**-19.4%**	**30.1%**

	kgs, base
2013 Dispositions	19,683
2014 Estimated Dispositions	49,131
Average	34,407
30% Inventory Allowance	10,322

As of: 7/16/14 8:45 AM
Received: July 14, 2014
Status: Posted
Posted: July 16, 2014
Tracking No. 1jy-8d7w-ol7d
Comments Due: July 22, 2014
Submission Type: Web

PUBLIC SUBMISSION

Docket: DEA-2014-0009
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 2014

Comment On: DEA-2014-0009-0001
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 2014

Document: DEA-2014-0009-0004
Comment on FR Doc # N/A

Submitter Information

Name: (b)(6)
Address:
(b)(4)
Email: (b)(4);(b)(6)
Phone:

General Comment

This attached letter constitutes (b)(4);(b)(7)(E) comments on the Proposed Revised Aggregate Production Quotas for 2014.

Attachments

(b)(4) 2014 Comment to Docket No. DEA-378

The attachment is restricted to restrict all because it contains confidential business information data

(b)(4)

July 14, 2014

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

Attn: DEA Federal Register Representative [Docket No. DEA-378]

This letter constitutes (b)(4) comments on the Proposed Revised Aggregate Production Quotas for 2014, as published in Federal Register on June 12, 2014, FR Volume 79, No. 113, pages 33780-33784. 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").

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

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 1,040,000 grams AA of 4-Anilino-N-phenethyl-4-piperidine (ANPP) manufacturing quota for 2014, reference DEA online submission number 120142.

9170 Diphenoxylate

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 890,000 grams AA of Diphenoxylate manufacturing quota for 2014, reference DEA online submission number 120107.

9220 Levorphanol

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 3,600 grams AA of Levorphanol manufacturing quota for 2014, reference DEA online submission 120083.

9330 Oripavine

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 13,900,000 grams AA of Oripavine manufacturing quota for 2013, reference DEA online submission 120144.

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

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

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

Request ID	Date Submitted	DEA Num	Company	Drug Name	Drug Code	Quota Year	Requested Quota	Current Quota	Increase/Decrease	Remarks
120142	10-Jul-14			4-ANILINO-N-PHENETHYL-4-PIPERIDINE (ANPP)	8333-0	2014	1,040,000.00	919,526.00	120,474.00	Supplemental documentation in support of this request will be emailed separately to ODE.Quota@usdoj.gov.
120157	15-Jul-14			4-ANILINO-N-PHENETHYL-4-PIPERIDINE (ANPP)	8333-0	2014	0.001 1,040,000.00	6,560.00 926,086.00	-6,560.00 113,914.00	Customer has canceled the ANPP manufacture for 2014. THis request has been moved out to 2015.
120162	16-Jul-14			ALL OTHER TETRAHYDROCANNABINOLS	7370-A	2014	11	0	11	
118031	5-Feb-14			ALL OTHER TETRAHYDROCANNABINOLS	7370-A	2014	15,000.00 15,011.00	0 0.00	15,000.00 15,011.00	Active Ingredient material to support Process Development and cGMP/clinical material to support parent company's (b)(4) product development and clinical studies.
119752	2-May-14			COCAINE	9041-0	2014	70,261.00	53,240.00	17,021.00	Please reference the attached supporting documentation for justification purposes. Regarding additional information or questions, please contact (b)(6) information is located on justification. Thank you.
119753	2-May-14			DIHYDROMORPHINE	9145-0	2014	332,105.00	260,650.00	71,455.00	Please reference the attached supporting documentation for justification purposes. Regarding additional information or questions, please contact (b)(6) information is located on justification. Thank you.
120107	2-Jul-14			DIPHENOXYLATE (FOR SALE)	9170-B	2014	890,000.00	0	890,000.00	Supplemental documentation in support of this request will be emailed separately to ODE.Quota@usdoj.gov.
119754	2-May-14			ECGONINE	9180-0	2014	79,235.12	50,220.00	29,015.12	Please reference the attached supporting documentation for justification purposes. Regarding additional information or questions, please contact (b)(6) information is located on justification. Thank you.
120158	15-Jul-14			FENTANYL	9801-0	2014	0.001	6,500.00	-6,500.00	Customer has canceled 2014 Manufacture. This production will be moved to 2015.
120087	1-Jul-14			GAMMA HYDROXYBUTYRIC ACID	2010-0	2014	42,502,000.00	38,402,023.00	4,099,977.00	(b)(4) is requesting an additional 6 batches worth of quota to meet 2014 sales for its customer.
120124	7-Jul-14			HYDROCODONE (FOR SALE)	9193-B	2014	41,500,000.00	22,958,367.00	18,541,633.00	Process losses estimated at 2,844,000 grams. Replaces submission refernce # 120065
120022	20-Jun-14		(b)(4);(b)(7)(E)	HYDROMORPHONE	9150-0	2014	130,000.00	97,711.00	32,289.00	[An addl 33,000 grams of quota is needed to run a validation campaign at an increased batch size. (b)(4) now has 5 potential customers and 2014 sales are forecasted to be 109kg (97 kg as base). Due to this demand, (b)(4) needs to inc..]
119755	2-May-14			HYDROMORPHONE	9150-0	2014	233,691.00	191,626.00	42,065.00	Please reference the attached supporting documentation for justification purposes. Regarding additional information or questions, please contact (b)(6) information is located on justification. Thank you.
120114	3-Jul-14			HYDROMORPHONE	9150-0	2014	2,110,000.00 2,473,691.00	1,674,818.00 1,964,155.00	435,182.00 509,536.00	Process losses are estimated to be 167,200 grams.
120083	1-Jul-14			LEVORPHANOL	9220-0	2014	3,600.00	1,598.00	2,002.00	Supplemental documentation in support of this request will be emailed separately to ODE.Quota@usdoj.gov.
120089	1-Jul-14			METHADONE	9250-0	2014	5,402,000.00	4,532,275.00	869,725.00	[Quota is requested to make 3 additional batches of Methadone Base. Methadone HCl year-end inventory will be 1075 kg or 956,750 grams as base. Q1 2015 sales will be 1225 kg or 1,050,250 grams as base. New 2015 production will not be availa..]
120088	1-Jul-14			METHADONE-INTERMEDIATE	9254-0	2014	6,810,000.00	5,070,739.00	1,739,261.00	[Methadone Intermediate is used in the manufacture of Methadone (for sale). Year-end inventory of 2296 kg is being requested in order to manufacture Methadone (for sale) in January 2015. Missing from above is the 2013 actual dispositions o..]
120011	19-Jun-14			METHYLPHENIDATE	1724-0	2014	70,000.00	0	70,000.00	
119758	2-May-14			MORPHINE (FOR SALE)	9300-B	2014	700,000.00	248,820.00	451,180.00	Please reference the attached supporting documentation for justification purposes. Regarding additional information or questions, please contact (b)(6) information is located on justification. Thank you.
120010	19-Jun-14			MORPHINE (FOR SALE)	9300-B	2014	1,692,000.00	0	1,692,000.00	[We would like to reduce the Morphine (for sale) manufacturing quota at (b)(4) registration by the amount of this request. Do to temporary short term constraints, we need to move production of the Morphine (for sale) base..]
120146	11-Jul-14			MORPHINE (FOR SALE)	9300-B	2014	3,067,867.00 5,479,867.00	4,779,867.00 5,026,687.00	-1,692,000.00 451,180.00	We are requesting a reduction in our quota of 1,692 kg, which (b)(4);(b)(7)(E) is requesting an increase in their quota of 1,692 kg.

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

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

proposed revised comments received as of 7-21-14
MO pending requests

120144	10-Jul-14	(b)(4);(b)(7)(E)	ORIPAVINE	9330-0	2014	13,900,000.00	10,732,298.00	3,167,702.00	Supplemental documentation in support of this request will be emailed separately to ODE.Quota@usdoj.gov. Process losses are estimated at 1,380,000 grams. 2,705,000 Oripavine converted to Hydromorphone (9150). Hydromorphone (9150) does not appear on Converted Substances list but does appear on registration.
120113	3-Jul-14		ORIPAVINE	9330-0	2014	5,250,000.00	3,283,650.00	1,966,350.00	
						19,150,000.00	14,015,948.00	5,134,052.00	
120089	1-Jul-14		OXYCODONE (FOR SALE)	9143-B	2014	820,000.00	784,639.00	35,361.00	[Our current quota is short 36 kg from what is needed to make an additional 3 full scale batches, most of which will be sold during 2014. Q1 2015 sales are projected to be 440 kg or 396,000 grams as base. Oxycodone will be produced at ~4X.]
119757	2-May-14		OXYCODONE (FOR SALE)	9143-B	2014	20,966.00	6,000.00	14,966.00	Please reference the attached supporting documentation for justification purposes. Regarding additional information or questions, please contact (b)(6) Information is located on justification. Thank you.
120030	23-Jun-14		OXYCODONE (FOR SALE)	9143-B	2014	2,894,665.00	1,365,000.00	1,529,665.00	[We are requesting this increase to support (b)(4) plans to launch Oxycodone HCl later this year. Please note the DEA set our 2014 quota at 1,365 kg, with 900 to support commercial activities and 465 kg to support development activit..]
						3,735,531.00	2,155,639.00	1,579,892.00	
120086	1-Jul-14		PENTOBARBITAL	2270-0	2014	26,525,000.00	23,400,000.00	3,125,000.00	(b)(4) projected 2014 sales have increased and Q1 2015 sales are now at 5M I or 4,550,000 grams as base. Sufficient inventory is needed until a new campaign can be run in 2015.

2014 Final Adjusted Aggregate Production Quotas and Annual Assessment of Needs

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

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

- The attached Federal Register notice, prepared for your signature, reflects the calendar year 2014 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:

<u>List I Chemicals:</u>

- 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.

<u>Controlled Substances:</u>

- OD is recommending an increase in the APQ for **opium tincture.** The increase is based on domestic sales and import requirements from registrant applications and projected demand.

- 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. The synthesis route for these non-controlled substances includes the controlled substances oxymorphone (for conversion) and noroxymorphone (for conversion).

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA-378]

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 2014

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

ACTION: Notice.

SUMMARY: This notice establishes the final adjusted 2014 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, as well as the 2014 aggregate production quotas for three recently temporarily controlled substances.

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:

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. 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.

The DEA published the 2014 established aggregate production quotas for controlled substances in schedules I and II and for the assessment of annual needs for the List I chemicals

ephedrine, pseudoephedrine, and phenylpropanolamine in the Federal Register (78 FR 55099) on September 9, 2013. That notice stated that the Deputy Administrator would adjust, as needed, the established aggregate production quotas in 2014 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The 2014 proposed adjusted aggregate production quotas for controlled substances in schedules I and II and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the Federal Register on June 12, 2014 (79 FR 33780) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before July 14, 2014.

Analysis for Final Adjusted 2014 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the June 12, 2014, notice of proposed adjusted aggregate production quotas and assessment of annual needs, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Five companies submitted timely comments regarding a total of 11 schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 4-anilino-phenethyl-4-piperidine (ANPP), codeine (for sale), diphenoxylate, hydromorphone, levorphanol, morphine (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), and tetrahydrocannabinols 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 for the proposed adjustments to the 2014 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

The DEA has taken into consideration the above comments along with the relevant 2013 year-end inventories, initial 2014 manufacturing and import quotas, 2014 export requirements,

actual and projected 2014 sales, research and product development requirements, and the additional applications received. Based on all of the above, the Deputy Administrator has determined that the proposed adjusted 2014 aggregate production quotas and assessment of annual needs for opium tincture, oripavine, and ephedrine (for sale) required additional consideration and hereby further adjusts the 2014 aggregate production quota and assessment of annual needs for these substances. Regarding 4-anilino-phenethyl-4-piperidine (ANPP), codeine (for sale), diphenoxylate, hydromorphone, levorphanol, morphine (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), and tetrahydrocannabinols the Deputy Administrator hereby determines that the proposed adjusted 2014 aggregate production quotas and assessment of annual needs for these substances and List I chemicals as published on June 12, 2014 (79 FR 33780) are sufficient to meet the current 2014 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 2014 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all proposed revised schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting revised established aggregate production quota will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as

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

Pursuant to the above, the Deputy Administrator hereby finalizes the 2014 aggregate production quotas for the following schedule I and II controlled substances and the 2014 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 2014 quotas (g)
Schedule I	
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	15
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-*n*-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-*N*-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-*N*-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-*N*-methylcathinone (3-FMC)	15
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-*N*-methylcathinone (4-FMC)	15
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-*N*-ethylcathinone (4-MEC)	15
4-Methyl-*N*-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-*N*,*N*-diisopropyltryptamine	25
5-Methoxy-*N*,*N*-dimethyltryptamine	25
Acetyl-*alpha*-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25

Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	15
alpha-Pyrrolidinopentiophenone (α-PVP)	15
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-N-oxide	200
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	650,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	2
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	175
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
para-Fluorofentanyl	2
Parahexyl	5
Phenomorphan	2
Pholcodine	2
Properidine	2
Psilocybin	40
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	15
Tetrahydrocannabinols	491,000
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	3
1-Piperidinocyclohexanecarbonitrile	3
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,625
Alphaprodine	3
Amobarbital	9
Amphetamine (for conversion)	18,375,000
Amphetamine (for sale)	49,000,000
Carfentanil	19
Cocaine	240,000
Codeine (for conversion)	68,750,000
Codeine (for sale)	46,125,000
Dextropropoxyphene	19
Dihydrocodeine	100,750
Diphenoxylate	1,288,750
Ecgonine	174,375
Ethylmorphine	3
Fentanyl	2,108,750
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	6,750,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4

Levomethorphan	195
Levorphanol	4,625
Lisdexamfetamine	23,750,000
Meperidine	6,250,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	38,875,000
Methamphetamine	2,811,375
[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	30,375
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,262,500
Opium (powder)	112,500
Opium (tincture)	780,000
Oripavine	30,625,000
Oxycodone (for conversion)	9,250,000
Oxycodone (for sale)	149,375,000
Oxymorphone (for conversion)	25,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	45,750,000
Racemethorphan	3
Remifentanil	5,875
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	17,500,000
Thebaine	145,000,000
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,200,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	5,300,000
Pseudoephedrine (for conversion)	5,000
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:

Thomas M. Harrigan,
Deputy Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
ODW:_____
ODQ:_____
ODQ:(b)(6) _____:(b)(6) 08-12-14
SBF-CM # ODEQ 14 - 819
(DFN#: 680-03 Drug control files - Manufacturing and Procurement quotas)

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–378]

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 2014

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

ACTION: Notice.

SUMMARY: This notice establishes the final adjusted 2014 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, as well as the 2014 aggregate production quotas for three recently temporarily controlled substances.

DATES: Effective August 25, 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:

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. 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.

The DEA published the 2014 established aggregate production quotas for controlled substances in schedules I and II and for the assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the Federal Register (78 FR 55099) on September 9, 2013. That notice stated that the Deputy Administrator would adjust, as needed, the established aggregate production quotas in 2014 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The 2014 proposed adjusted aggregate production quotas for controlled substances in schedules I and II and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the Federal Register on June 12, 2014 (79 FR 33780) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before July 14, 2014.

Analysis for Final Adjusted 2014 Aggregate Production Quotas and Assessment of Annual Needs

Consideration has been given to the criteria outlined in the June 12, 2014, notice of proposed adjusted aggregate production quotas and assessment of annual needs, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Five companies submitted timely comments regarding a total of 11 schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 4-anilino-phenethyl-4-piperidine (ANPP), codeine (for sale), diphenoxylate, hydromorphone, levorphanol, morphine (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), and tetrahydrocannabinols 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 for the proposed adjustments to the 2014 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

The DEA has taken into consideration the above comments along with the relevant 2013 year-end inventories, initial 2014 manufacturing and import quotas, 2014 export requirements, actual and projected 2014 sales, research and product development requirements, and the additional applications received. Based on all of the above, the Deputy Administrator has determined that the proposed adjusted 2014 aggregate production quotas and assessment of annual needs for opium tincture, oripavine, and ephedrine (for sale) required additional consideration and hereby further adjusts the 2014 aggregate production quota and assessment of annual needs for these substances. Regarding 4-anilino-phenethyl-4-piperidine (ANPP), codeine (for sale), diphenoxylate, hydromorphone, levorphanol, morphine (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), and tetrahydrocannabinols the Deputy Administrator hereby determines that the proposed adjusted 2014 aggregate production quotas and assessment of annual needs for these substances and List I chemicals as published on June 12, 2014 (79 FR 33780) are sufficient to meet the current 2014 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 2014 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. *See* 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all proposed revised schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting revised established aggregate production quota will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

Pursuant to the above, the Deputy Administrator hereby finalizes the 2014 aggregate production quotas for the following schedule I and II controlled substances and the 2014 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 2014 quotas (g)
Schedule I	
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl]methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	15
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-*n*-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-*N*-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-*N*-methylcathinone (methylone)	50
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-Fluoro-*N*-methylcathinone (3-FMC)	15
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-*N*-methylcathinone (4-FMC)	15
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-*N*-ethylcathinone (4-MEC)	15
4-Methyl-*N*-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-*N*,*N*-diisopropyltryptamine	25
5-Methoxy-*N*,*N*-dimethyltryptamine	25
Acetyl-*alpha*-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2

Basic class	Final adjusted 2014 quotas (g)
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
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-N-oxide	200
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	650,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	2
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	175
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
para-Fluorofentanyl	2
Parahexyl	5
Phenomorphan	2
Pholcodine	2
Properidine	2
Psilocybin	40
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB–22; 5F–PB–22)	15
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB–22; QUPIC)	15
Tetrahydrocannabinols	491,000
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	3
1-Piperidinocyclohexanecarbonitrile	3
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,525
Alphaprodine	3

Basic class	Final adjusted 2014 quotas (g)
Amobarbital	9
Amphetamine (for conversion)	18,375,000
Amphetamine (for sale)	49,000,000
Carfentanil	19
Cocaine	240,000
Codeine (for conversion)	68,750,000
Codeine (for sale)	46,125,000
Dextropropoxyphene	19
Dihydrocodeine	100,750
Diphenoxylate	1,288,750
Ecgonine	174,375
Ethylmorphine	3
Fentanyl	2,108,750
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	6,750,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	195
Levorphanol	4,625
Lisdexamfetamine	23,750,000
Meperidine	6,250,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	38,875,000
Methamphetamine	2,811,375
[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	30,375
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,262,500
Opium (powder)	112,500
Opium (tincture)	780,000
Oripavine	30,625,000
Oxycodone (for conversion)	9,250,000
Oxycodone (for sale)	149,375,000
Oxymorphone (for conversion)	25,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	45,750,000
Racemethorphan	3
Remifentanil	5,875
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	17,500,000
Thebaine	145,000,000
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,200,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	5,300,000
Pseudoephedrine (for conversion)	5,000
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: August 15, 2014.

Thomas M. Harrigan,

Deputy Administrator.

[FR Doc. 2014-20137 Filed 8-22-14; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Application: CATALENT CTS, LLC; Correction

ACTION: Notice of correction.

In the Tuesday, June 17, 2014, **Federal Register** document number 2014-14123, Vol. 79, No. 116, page 34551, third column, the second paragraph, remove the first sentence from the paragraph: "In reference to drug code 7360, the company plans to import a synthetic cannabidiol."

Dated: August 19, 2014.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2014-20119 Filed 8-22-14; 8:45 am]

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MILLENNIUM CHALLENGE CORPORATION

[MCC FR 14-05]

Report on Countries That Are Candidates for Millennium Challenge Account Eligibility in Fiscal Year 2015 and Countries That Would Be Candidates But for Legal Prohibitions

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: Section 608(d) of the Millennium Challenge Act of 2003 requires the Millennium Challenge Corporation to publish a report that identifies countries that are "candidate countries" for Millennium Challenge Account assistance during FY 2015. The report is set forth in full below.

Dated: August 19, 2014.

Thomas G. Hohenthaner,

Acting VP/General Counsel and Corporate Secretary, Millennium Challenge Corporation.

Report on Countries That Are Candidates for Millennium Challenge Account Eligibility for Fiscal Year 2015 and Countries That Would Be Candidates but for Legal Prohibitions

Summary

This report to Congress is provided in accordance with section 608(a) of the Millennium Challenge Act of 2003, as amended, 22 U.S.C. 7701, 7707(a) (the Act).

The Act authorizes the provision of Millennium Challenge Account (MCA) assistance for countries that enter into a Millennium Challenge Compact with the United States to support policies and programs that advance the progress of such countries to achieve lasting economic growth and poverty reduction. The Act requires the Millennium Challenge Corporation (MCC) to take a number of steps in selecting countries with which MCC will seek to enter into a compact, including determining the countries that will be eligible for MCA assistance for fiscal year (FY) 2015 based on (a) a country's demonstrated commitment to (i) just and democratic governance, (ii) economic freedom, and (iii) investments in its people; and (b) considering the opportunity to reduce poverty and generate economic growth in the country; and (c) the availability of funds to MCC. These steps include the submission of reports to the congressional committees specified in the Act and the publication of notices in the **Federal Register** that identify:

The countries that are "candidate countries" for MCA assistance for FY 2015 based on their per capita income levels and their eligibility to receive assistance under U.S. law and countries that would be candidate countries but for specified legal prohibitions on assistance (section 608(a) of the Act);

The criteria and methodology that the MCC Board of Directors (Board) will use to measure and evaluate the relative policy performance of the "candidate countries" consistent with the requirements of subsections (a) and (b) of section 607 of the Act in order to determine "eligible countries" from among the "candidate countries" (section 608(b) of the Act); and

The list of countries determined by the Board to be "eligible countries" for FY 2015, identification of such countries with which the Board will seek to enter into compacts, and a justification for such eligibility determination and selection for compact negotiation (section 608(d) of the Act).

This report is the first of three required reports listed above.

Candidate Countries for FY 2015

The Act requires the identification of all countries that are candidates for MCA assistance for FY 2015 and the identification of all countries that would be candidate countries but for specified legal prohibitions on assistance. Under the terms of the Act, sections 606(a) and (b) set forth the two income tests countries must satisfy to be candidates for MCA assistance.[1] However for FY 2014, those categories are defined by MCC's FY 2014 appropriations act, the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2014, Public Law 113-76, Div. K (the FY 2014 SFOAA). Specifically, the FY 2014 SFOAA used the same definitions that have been used since the FY 2012 appropriations act and defines low income candidate countries as the 75 poorest countries as identified by the World Bank and provided that a country that changes during the fiscal year from low income to lower middle income (or, vice versa) will retain its candidacy status in its former income category for the fiscal year and two subsequent fiscal years. Assuming these definitions will be used again in FY 2015, MCC is using them for purposes of this report.[2]

Under the redefined categories, a country will be a candidate for MCA assistance for FY 2015 if it:

Meets one of the following tests:

Has a per capita income that is not greater than the World Bank's lower middle income country threshold for such fiscal year ($4,125 GNI per capita for FY 2015); and is among the 75

[1] Sections 606(a) and (b) of the Act provide that a country will be a candidate for MCA assistance if it (1) has a per capita income equal to or less than the historical ceiling of the International Development Association eligibility for the fiscal year involved (the "low income category") or (2) is classified as a lower middle income country in the then most recent edition of the World Development Report for Reconstruction and Development published by the International Bank for Reconstruction and Development and has an income greater than the historical ceiling for International Development Association eligibility for the fiscal year involved (the "lower middle income category"); and is not ineligible to receive U.S. economic assistance under part I of the Foreign Assistance Act of 1961, as amended (the Foreign Assistance Act), by reason of the application of the Foreign Assistance Act or any other provision of law.

[2] If the language relating to the definition of low income candidate countries is not enacted or is changed for MCC's FY 2015 appropriations act, MCC will revisit the selection process once the FY 2015 appropriations act is enacted and will conduct the selection process in accordance with the Act and applicable provisions for FY 2015.