Total PG Requi	sted:	3,903,000,000	
Basic Class;	9Q5Q-A		2014 Inklai APQ Worksheel

FDA Ést; IMS Ext:

Company	DEA NUM	2014 Requested MQ	2013 Revised MQ	2012 Sales	2012 DEA MG Sales	% of 2012 Sams	SMULE OF BOLK LOCK! NO	TO 13 BINESSOIL	2013 Projected Exports	2013 Projectora Sanch	TO 14 Frojectes Extroits 24	13 Flowcood President	an cause y proq.	
(b)(4);(b)(7)(E)		14.500,000,000	19,283,990,000 1	2,133,621,000	53,520,189,000	0.227	684,858,014	5,113,094.000	0.000	13,370,611,000	0.000	5,357,404.000	16,262,722,667	5.000
(D)(+),(D)(1)(L)		24,000,000.000	21,799,865.000 2	9,710,268.000	63,620,169.000	0.556	2,171,019.164	10.875,598,000	0.000	33,467,533,000	2 000	11,857,568,000	21,763,644.000	28,000,000,000
MQ Totals:		48,509,000.000	41,080,858,000											26,000,005.000

2013 Final Indial APQ: 69,000,000 000
2013 Final Revised APQ: 0,000
FDA Est; (2013 Indial APQ \* FDA EsQ: 0,000

IMS Est: (2013 tritial APQ \* IMS Est):

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

D.000

Note: (b)(4) will conve	nt to hydrocodone (for sale)	PQ requested 6.f. 7,500,000.000	0.742	eeded 9,568,733.154
(b)(4) will convert to	dihydrocodeine	1270,000,038	0,750	106,866.667
	hydrocodone (for sale)	\$00,000,000,00	0,875	34,285,714.286

2014 Initial APQ Worksheets Bacic Class: FOA Eur 25,736,256 949 Total PO Requested: IMS Ert

<b>4</b>	DEA Nam	2014 Recuested MG	2013 Dendard 480	2012 Sales	2012 DEA NO Sales	% of 2012 Sales	Share of 2014 Total PO	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Cate Using CFR 50% Invent	MC.
Company	DEA MAIO						4.000	32,739	0.000	10,000	0.000	130,739	-95,278	5.000
(b)(4);(b)(7)(E)		100 000	190,900	1,78	23,368,253,976	0.000	1.969	26.122						168,000,000
(0)(+),(0)(1)(L)		148,000 00	445,000,000	106.619.000	23.368 255.978	9.005	117,423,185	137,364,000	0.000	148,030.000	0.000	77,944.000	·178, <b>3</b> 35, <b>0</b> 19	
								4,516,642 000	8,140 000	12,749,580,000	0.000	4,650,420,000	15,133,571,890	13,500,000.000
		13,500,000 003	12,610,643,000	12,167,512.000	23,385,255,978	0,521								4 000 000
		1,000,00	5.000.000	4,190,144	23.308.255.978	0.000	4,614,748	0.000	0.000	5 000 000	0 000	10,000.000	7,018,412	1,000.000
		.,	-,	.,			10 780 700 381	7,244,704,000	0,000	12,250,000,000	0.000	5,099,000,000	6,693,756,951	14,210,000.000
		14,210,000.00	15,730,716,000	9,786,850.00	23,368,255,878	0.418	10,700,780,301							
		2 and an 50		4 304 003 00	n 21 348 345 020	0.058	1.432 027 614	705, 652,000	0.000	4,070,000 000	0.000	185,000.000	3,129,697.517	3,129,607.517

. n/a - 05

3,129,607.517 30,988,612,517

2013 Final Initial APQ: 39,605,000,000 2013 Final Rayland APO: 0.000 39,805,000 000 IMS Est: (2013 Initial APCI \* IMS Est): 37,644,552,500

MQ Totals:

2014 Proposed Initial APQ: 38,900,000,000 lowered to total granted in 2012 Basic Class: 9273-0 Total PG Requested:

2014 Initial APO Worksheets

FDA Est: IMS Est:

Company	DEA Num	2014 Requested MQ 201	3 Revised NQ 2	012 Sales 2	MIZ DEA MO Sales	% of 2012 Sales   Si	here of 2014 Total PQ 2013	2 inventory 2013	Projected Exports 2013 F	Projected Sales 2014 Pr	olected Exports, 2013 Pro	ected lowertony Calc Usin	CFR 50% lovent	MO.
(b)(4);(b)(7)(E)		10.000	10.000	0.298	12.612,070.298	0.000	0.000	0.B10	0.000	2.000	0.000	9-810	-6.310	10,000
MQ Totals:		10 000	10.000											10.000

 2017 Final Inhial APQ:
 15,000

 2017 Final Revised APQ:
 0,000

 FDA Est; (2013 Initial APQ \* FDA Est):
 0,000

 MS Est; (2013 Initial APQ \* MS Est):
 0,000

2014 Proposed Initial APO:

15 800

19,000 with 25% buffer

2014 Initial APQ Worksheets

Total PO Requested: 5,007,000 FDA Est: ~314

DEA Num 2014 Requested MQ 2013 Revised MQ 2012 Sales 2012 DEA MQ Sales % of 2012 Sales % of 20 Company 23.835.010 0.000 0.111 1D.616 0.000 3.000 0.006 15.818 -11,429 5.003 (b)(4);(b)(7)(E) 5.000 5,000 0,530 57,000,000 D.000 173,000.000 -197,316.382 80,000,000 0.600 0.958 4,996.494 210,562.000 80,000,000 80,000,000 23,785,000 23,835.010 153,777 250,000 250,000 0.000 130,000 0.002 10.394 139.270 0.000 370.000 49.480 23,835,010 250.000

MQ Totals: 80,255,000 80,375,000

2013 Final antical APQ: 200,000,000
2013 Final Revised APQ: 0,000
FDA Est: (2013 Initial APQ \* EASE Est) 0,000
MMS Est: (2013 Initial APQ \* EASE Est) 0,000

Hasic Class: 9120-0

2014 Proposed Initial APQ: 80,600,000

Basic Class: Total PQ Requested: 2014 Initial APQ Workshoots

FBA Est MS EAE

Sharm of 2014 Total PQ. 2012 Inventory. 2013 Projected Exports. DEA Num 2014 Requested MO 2013 Revised MQ 2012 Sales 2012 DEA MQ Sales

1 990 3.510 2.000 4.000 0.590 0.000 (b)(4),(b)(7)(E) 2.000 2 000

MO fotals: 2 000 7.000

2013 (Final Initial APO: 2,000 2013 Final Revised APC: 0 000 FDA Est (2013 Initial APQ \* FDA Est): 0.000 IMS Est (2013 Initial APG \* IMS Est): 0.000 4 000

2014 Proposed Initial APO: 2 000

ETHYLMORPHINE

Basic Ctass: Total PG Requested:

2014 Initial APQ Worksheets 970,558,531

FDA Esc 072 MS Est

	Company	OEA Nom	2
(b)(4)	;(b)(7)(E)		ı
			l
1			l
1			
1			
1			

1.	2014 Requested MQ	2013 Revised MG	2012 Sales	2012 DEA MO Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Lising CFR 50% invent	MQ
	200,000,000	137,147,000	43,779,000	1,178,096.760	0.037	36,066.716	63,746 000						157,000,000
	210,000 000	47,699,000	49,344.760	1,178,096.780	Ø 342	40,652.006	5,739,406	60,000,000	219,000,000	0.000			123,000,000
	2000	2.000	0.000	1,178,098,780	0.000	0.000	0.223	0.000		0.000	2.223	-0.723	2 000
	31,760,000	6,900,000	5,148 800	1,178,095,780	0 004	4,241,108	1,216 000	0.000					30,670 385
	350,000.000	474,000.D3D	279,461,000	1,176,096.780	0.237	230,230 001	145,028.000	0.000	•			,	350,000 000
	5 10,000 000	852,247,000	800,384,000	1,178,096,780	0 679	659,368 671	300,901,000						
	1,640,000	. 1 0.000	0.000	1,178,096,780	0.000	0.000	0.000	0.000		* * * * * * * * * * * * * * * * * * * *	,		787,044,589
	1,000.000	45,000.000	0.000	1,178,096,780	£ 600	2.000	9.000	0.000	-,	*****	4.554	1,640,000	1,640.000
				•			4.020	9,000	1.000,000	0 000	15,000 000	-32,750.0ad	1,000.000

HD Totals:

1,604,402,000 1,562,995.000

1,460.356.973

2013 Final Initial APO: 1,687,000.000 2013 Final Revised APQ: FOA Est (2013 initial APO \* FDA Est): 1,808,464 000 (MS Eat: (2013 Hatlal APQ \* (MS Eat): 1,587,000.000

2014 Proposed Initial APQ;

1.687.000.000 2.106,750.000 with 25% buffer

Basic Class: 9200-0 Total PO Requested:

2014 Initial APQ Worksheets

4,003,000

FDA Est: IMS Est:

Company	DEA Num	2014 Requested MQ: 2013	Revised MQ 2	012 Sale+ 20	12 DEA NO SAME Y	6 of 2012 Sales   5	Share of 2014 Total PQ	2012 Inventory 201	13 Projectad Exports 2013 P	rojected Sales 2014 Pr	ojected Exports 2013 Pro	ected faventary Calc Us	ng CFR 50% Invent	MO
(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	
(6)(1),(6)(1)(2)		5.000	5.000	0.020	3.270	0.008	24,463	9.300	0,000	3.000	0.000	11,101	20,554	5.000

10 000 10.000 5.000 MD Totals:

2013 Final Initial APQ; 25.000 2013 Final Revised APQ: 0.000 FDA Est: (2013 Initial APO \* FDA Est): 0.000 MS Est: (2010 Initial APO \* IMS Est): 0.000

2014 Proposed Initial APO; 25.000

Basic Class: 9197-8					2014 1	nitial APQ Works	sheets					
Total PQ Requested:		70,108,722,142						FDA Est IMS FAC	015			
								183 CAL				
Company	DEA NUM	2014 Requestre MQ	2013 Revised #Q	2017 Sales	2012 DEA MQ Safes	% of 2012 Sales	Share of 2014 Total PQ	2012 knowntory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventor
(b)(4);(b)(7)(E)		266,000	132,500	0		0				200,000	4	D 90,00
(D)(4),(D)(1)(E)		20	20	5		0	7	63	c	10	1	) 6
		231,000	180,4\$1	17,696	56,999,043	٥	21,760	44,985	0	231,000		5,00
		7,100,000	5,722,000	G	56,999,543	0			0	3,551,433		3,548,56
		30,000,000	16,073,086	24,410,383	56,999,043	0	30,024,728	5,825,783	12,200	28,147,608	(	8,962,47
		24,000,000	24,451,038	23,305,815	56,009,043	٥	28,566,111	5,160,117	0	14,830,000		0 9,657,00
		3,600,000	0	365,519	58,999,040	9	449,588	2,514,546		1,000,000		4,483,00
		5,310,000	1,269,659	c	56,999,043	0		1,643,300	٥	2,600,000		0 5,000,00
		9,000,000	7,613,000	5,880,064	58,999,043	0	0,462,457	1,695,110	D	5,557,500	t .	943,70
MO Totals:		79,527,020	58,249,754		•		•					
2013 Final Initial APC:	79,700,000											
2013 Final Revised APG:	0.000											
FDA Eat (2013 MIDM APO * FDA Ext):	80,595,500						~					
IMS Eac (2013 Initial APD * IMS Eat):	79,750,000											
2014 Proposed Initial APC:	79,700,000											
	aa u	2500	-120	= 1 \_	PC.							
	41.4	25,000	· 4/2	۶ (۱ ۴	ou her							

952,581

9,730,123

1,964,134 3,750,000

9,000,000

Basic Class:	\$160-0
7	

2014 Initial APQ Worksheets

FOA Est:	.10
HIO C	

4,005,995,576

Company	DEA Num	2014 Requested MQ 20	113 Revised MQ	2012 Salara	2012 DEA MO Sales	% of 2012 Sales	Share of 2014 Total PG	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	102,350,000	0.50	3,509,088,484	0.000	0.000	0.000	0.000	50,000.000	0.000	60,000.000	-26,762.500	100,000,000
(5)(1),(5)(1)(2)		30 000	25.000	15 72	\$ 3,509,088.484	2.000	11.727	29,438	0.000	22 000	0,000	52.438	-11.530	20.000
		156,000,000	74,000 000	0.00	0 2,509,088,484	0.000	0.000	0.600	0 000	156,000.000	0.000	3,000.000	97,500.000	97,500,000
		535,998 000	549,743.000	575,362.604	9 3,509,068,484	0,164	403,411.413	215,808.822	0 000	447,099.000	0.000	117,999.000	294,146.195	535,995.000
		445,000,000	447,529.000	343,962,000	0 3,509,086,484	0.098	241,166.517	165,258,000	2 000	445,000,000	0.000	257,885.000	244,553,397	445,000,000
		1,170,000,000	988,463,000	901,186.CO	3,509,068,484	0.257	631,861,576	168,583,000	\$,760,000	967,450.000	0.000	477,106,000	851,106,720	1,408,907,576
		1,565,000,000	1,534,093,000	1,444,815,45	3,509,088.484	0.412	1,013,022,107	225,181.930	0.000	1,647,000.000	0.000	775,000.000	1,406,525,954	1,563,000,000
		220,000,000	93,000,000	43,567,00	0 3,509,028.484	0.012	30,546,693	37,282,000	0.000	142,400,000	0.000	20,172,200	73,551.366	153,500,000

2013 Final Initial APQ: 4,775,000.000 2013 Final Revised APQ: 0.000 FDA Est: (2013 Initial APQ \* FDA Exq; 5,281,150.000

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

2014 Proposed Initial APQ:

MQ Totals:

4,775,000,000

5,968,750 w/251. buffer

4,192,026.000 3,793,293.000

2,460,372,507

Basic Class: 9226-0

Total PO Requested:

2014 Initial APQ Workshoots

FDA Est: IMS Est

0.000

Sharm of 2014 Fotal PQ, 2012 Inventory, 2013 Projected Exports, 2013 Projected Sales, 2014 Projected Exports, 2013 Projected Inventory, Cald Using CFR 50% Inventor, MQ DEA Num 2014 Requested NO 2013 Revised NO 2012 Sales 2012 DEA NO Sales % of 2012 Sales Сетрапу 0.000 0.000 0.000 0.000 0.500 0 500 1 590 -1.000 2.000 2.000 0.000 8,000

(b)(4);(b)(7)(E) 2 000

2,000 M& Totals: 2 000 2 000

2013 Final toitle! APG: 4,000 2013 FIRM Revised APO: 0.000 FOA Est: (2013 Initial APQ \* FOA Est):

0.000 IMS Eat (2013 INIKA! APQ \* IMS EAT): 0.000

2014 Proposed Initial APC: 2.000 Basic Class: \$648-0

Total PO Requested:

2014 Initial APQ Worksheets

FDA Est:

al PO Requested;

IMS Est:

Company	DEA Num 20	014 Requested MQ 201	13 Revised MO 20	12 Sales 20	M2 DEA MO Sales	% of 2012 Sales	Shara of 2016 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Esparts	2013 Projected Inventory	Cafe Using CFR 50% levent	MQ
(b)(4);(b)(7)(E)		2,000	2,900	0.000	0.000	0.000	0.000	0.012	0,000	0.500	0.000	1.512	-1.012	2.000

Mg Totah; 2,000 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 = 40

0.000

Başle Class: 9210-0

Total PQ Requested;

0.000

2014 Initial APQ Worksheets

FOA Est:

043 Eat

Company (b)(4);(b)(7)(E)	D€A Num	2014 Requested MG 2013 2.000	Revised MQ 2 2.000	0.120	112 DEA MQ Sales 0.120	% of 2013 Saley 1.000		013 Projected Exports 0.000		s 2013 Projected Inventory 0 2.24		2747 2.000	
MQ Totals:		J 2.000	2.000								•	2.000	3
2013 Finel Inklef APO: 2013 Finel Revised APO: FOR Est: (2013 Indief APQ * FOR Est): (MS Est: (2089 Inklef APQ * WS Est):	5.000 0.000 0.000 0.000												
2014 Proposed Initial APQ:	5.000												

Basic Class: 9220-0

Total PQ Requested:

2014 Initial APQ Worksheets

FDA Est: UMS Ent:

DEA Num ' 2014 Requested NQ 2013 Revised MQ 2012 Sales : 2012 DEA MQ Sales ' % of 2012 Sales ' % of 2012 Sales ' Share of 2014 Total PQ 2012 Inventory 2013 Projected Exports 2013 Projected Sales 2014 Projected Exports 2013 Projec МО Соправу 9.500 0.000 1.500 -1,000 2.000 0.000 0.000 2,000 2.000 0.000 1,060,000 0.000 0,000 (b)(4);(b)(7)(E) 4,585.500 1,500,000 688,000 1,060,000 1.000 4,486.000 171.000 41.000 1,433.000 0.000 1,500,000 3,100,000 1,060,000

MQ Telak: 1,502.000 3,102.000 1,502.000

 2093 Final Initial APQ:
 3,800 000

 2093 Final Revised APQ:
 0,000

 FDA Est: (2013 Initial APQ.\* FDA Est):
 0,000

 RMS Est: (2013 Initial APQ.\* HMS Est):
 0,000

2014 Proposed Initial APQ:

1,600,000

2,000,000 with 25% buffer

4,488,000

Basic Class: 82 30-0 Total PQ Requested:

2,408,714.411

2014 Initial APQ Worksheets

FDA Ectr IMS Est:

	Company 13	DEA Num	2014 Requested MQ 2	013 Revised MQ	2012 Sales	2012 DEA MO Sales	% of 2012 Sales	Share of 2014 Total PO	2012 Inventory	2012 Projected Exports	2013 Projected Sales			Calc Using CFR 50% Invent	MQ
(b)(	4);(b)(7)(E)		4,000,000,000 5,000	3,109,000.000 1 7,000	735,789.000 0.396		0.798		1,344,199,060		4,000,000,000.00 000.0	000.0 000.0	1,250,000.000 10.532	3,227,356.601 3; -5.734	227,356.601 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
	Postulur		4 710 005 000	3.849.007.000										3.5	.937,381.501

MQ Totals:

2013 Final trittal APC:

4,710,005,000 3,849,007,000

5,500,000.000 0.000

2013 Final Revised APQ: FOA Est: (2013 Initial APQ \* FDA Est): 4,070,000,000

IMS Est (7013 Initial APQ - IMS Ear):

2014 Proposed Initial APO:

6,29,000 J/25% budler

Basic Class: 9233-0

Total PQ Requested:

2014 Initial APO Worksheets

I DA ERE IMS Est:

Company D	DEANUM 2	2014 Requested A	AQ 2013 Revised	ME 201	2 Sales 2012	DEA NO Sales	% of 2012 Sales		Share of 2014 Total PQ	2012 Inven	dary 201	I3 Projectad Exporta	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventor	Cate Using CFR 50% Invent	
(b)(4);(b)(7)(E)		30	00 3	000	0.000	0.000		9 000	0.000	0	000	0 000	0.200	0.000	2.80	0 -2 050	3.000
MG Totals:		30	100 3.	000													3.660

2013 Final Initial APO: 5.000
2013 Final Revised APO: 0.000
FDA Eat (2013 Initial APQ \* FDA Eat): 0.000

IMS Eat: (2013 Initial APO " IMS Eat): 0.000

2014 Proposed Initial APO;

3.000

0.000

Band Clare: \$283-0 Total FCI Requested.	1 000		2014 Initial APO Work wheets	FÇA ÇAÇ MEL Faf.				
(b)(4);(b)(7)(E)	DEA liber 2014 Pervended MQ 7,000 7,000	MCQ 28125 alon 2012 DEA WQ 3 alon 7,000 1 DES 1 DES 7,000		H4 Total PG - 1912 Enventory 1813 Project 2,000 - 7,757	ted Exports 2013 Prosected Sales 2016 Proj U DOG 2,000	ocied Exports (E13 Proyected Invertory (1913 DEA Pro 0.009 11.255	Goeted Inventory (purposy Rej Calc Uniting Com 12 257 9478	pary knownt. Cafe Using Das Invent Cafe Unling CSR 60% hause. ISO 13.257 to 75? 4.507 assets 45.007 assets 45.008
2019 Faral Bella) APC; 2019 Féral Parelmil APC; FDA Eve (1917 Indust APC)* FOA Felt; MIS Car (2017 Indust APC)* FAS Eolt;	9 000 0 1,000 0 000 0 000							

Basic Class: 9234-0

Total PQ Requested: . 0.000

2014 Initial APQ Worksheets

FDA Est:

DEA Num 2014 Requested MQ 2013 Revised MQ 2012 Sales 2012 DEA MQ Sales % of 2012 Sales 2014 Total PQ 2012 Inventory 2013 Projected Exports 2013 Projected Exports 2014 Projected Exports 201 Сотрану -2.050 3.000 0.000 0.000 0.000 0.000 0.000 0.200 0.000 2.600 0.000 3.000 (b)(4);(b)(7)(E) 3.000 3,000 MQ Totals: 3.000 3.000 2013 Final Initial APQ: 5.000 2013 Final Revised APC: 0.000 FDA Est: (2013 Inhlat APQ \* FDA Est): 0,000 IMS Ext. (2013 Initial APO \* MS Est): 0.000 2014 Proposed Initial APO: 3.000

2014 Initial APQ Worksheets

FOA Est:

-- 087

2012 Sales 2012 DEA MO Sales % of 2012 Sales Share of 2014 Total PO 2012 Inventory 2013 Projected Exports 2013 Projected Exports 2014 Projected Exports 2013 Projected Exports 2013 Projected Exports 2014 Pro DEA Num 2014 Requested MO MQ 3,272,000,000 6,007,409,826 6,007,409.826 6,544,000,000 0.000 0.000 6,375,000,000 6,321,000,000 4,976,800,000 17,835,768,563 0.279 6,016,635.061 3,316,884 000 (b)(4);(b)(7)(E) 9.236 -1.133 10.000 17,635,768,563 D 000 3.123 6 536 0.000 8,000 0.000 10 000 2.583 10 000 17,835,768,583 0.002 32,487,621 62,133 000 0.000 1,052,000 000 0.000 5,000,000 662,931.776 862,931 776 1,057,000.000 773,333.000 26 872,000 11,153,190,000 0 000 4.864.208.000 14,902,648,676 13,000,000,000 13,000,000,000 9,904,525 000 9,774,716,000 17,825,768.583 0.548 11,617,403 546 3,635,734 000 41,833 000 5,131,898,318 4,950,000,000 1,234,070,000 3,551,000,000 3,057,378,000 17,835,768,563 0.171 3,696,298,655 652,725,000 0 000 3.827,000.000 0.000 4,950,000,000

Mû Tobila: 25,378,010 000 19,939,929,000 24,620,351 602

 2013 Final finidal APQ:
 20 000,000 000

 2013 Final Revised APQ:
 0 000

 Ext;
 20,000,000 000

 IMS Ext; (2013 finitial APQ\* IMS Ext;
 24,237,600,000

Barric Clary:

Total PQ Requested:

2014 Proposed Initial APD: 25,500,000,000

31,875,000,000 with 25% buffer

21,563,078 000

METHADONE

THE FOREST SAG

1,745,460 000

2014 topical APQ Workshoets

7, of \$101\$ bates 0,000 0,000 0,427 0,183 Share of 2014 Total PG 2013 Inventory 2 Q 200 0 0 000 45,202,952 3,205,950,972 8,407,445,954 853,973,000 6,007 6,007 56+,600 067 7,706,263,333 9,361,378,239 Exports D SYS GASCO GASCO GASCO \$000 0000 23-04,07.000 364,00000 1 000 -1 14,000 000 -171,001,000 -172,001,000 -602,021,000 3 200 44,750 ha3 8,868,676 372 1,761,445 634 5 000 5 200 000 17 305 202 000 17 305 202 000 (b)(4);(b)(7)(E) 9 900 9 900 8 900 8 900 22,084,010,900 13,000,3+1,900

12,927,011 439

79 (44 brown 60 5000 -2 500 5000 1,883,753,679 1,883,753,678 1,773,774 195 7,740,744,495 1,673,734,743 11,673,734,740

Ming Oralineed 5000 41,007,7937,007 2,403,142,367 408,418,854

2019 Phony Institut APRIC 2019 Physic Revibed APRIC PDA East (2019 pentad APRIC PROA East); Best Cat: (1019 redain APRIC PROS East);

21,100,006 000 36,875,000 000 web 25% buller

Basic Class: 9300.4 Total PD Requested:

NO Totals:

2014 Initial APQ Worksheets

FDA EAL INS EAL

Company	DEA Num	2014 Requested MQ :	2013 Revised MQ	2012 Sales	2012 DEA NO Sales	% of 2012 Sales	Share of 2014 Total PO	2012 Inventory	2013 Projected Fix ports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Cate 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
(b)(4);(b)(7)(E)		44,000,000,000	42,285,090,000	34,764,093,000	47,831,774,600	0 726	4,498,389 047	99,670,020,000	0.000	45,358,948,000	0.000	13,745,160.000	401,903 191	44,000,000,000
		5,000,000	1,000,000	0.000	47,831,774,600	0.000	0.000	0.000	0.000	5,000,000	0,000	0000	4,250.000	4,250,000
		9,151,000,000	12,798,000 000	11 170 137 DOO	47,831,774 800	0.234	1,447,687,485	1,111,583 000	- 0.000	2,151,000.000	0.000	4,609,000,000	262,176.356	5,204,570,486
		5,285,000,000	1,599,975 000	441,600.000			57,266 660	0.000	0.000	5,260,000 000	0.000	0.000	4,151,602,103	4.151.602.103

57,860,422,588

 2013 Final Initial APQ:
 83,000,000 000

 2013 Final Revised APQ:
 13,000,000 000

 FDA East; (2013 Initial APQ \* FDA Eag;
 0,000

 IMS East; (2013 Initial APQ \* IMS Ext);
 0,000

2014 Proposed Infliet APQ: 73,000,000,000

91,250,000,000 with 25% buffer

6,200,016.000

61,938,900,000 60,182,065,000

nothylphenidate not complete Básic Class: 9300-8 Total PO Requested:

42,497,706 328

2014 Initial APQ Workshoets

FDA Eat: 019 IMS Eat: -021

Company -	OEA Num	ZD14 Requested MO	МО	7012 Sales	2017 DEA MQ 5444	% of 2012 Sales	Share of 2014 Total PG	2012 Inventory	2013 Projected Exports 2	013 Projected Sales 2	014 Projected Exports &	13 Projected Inventory C	aic Using CFR 50% Invent	MO
(b)(4);(b)(7)(E)		100,000	100,000	6,577	39,610,997,717	0,000	7 056	129,749	0.000	15,000	0.000	217.149	-185.929	100.000
. (0)(1),(0)(1)(2)		152,830,000	0.000	0,000		0.000	å 000	0.000	0.000	121,973,000	0.000	0.000	121,973,000	162,630.000
		6,600,000,000	4.512,500,000	2,689,583 000	39,613,997,717	0.073	3,100,169,907	0.000	0.000	6,032,085.000	0 000	547,915 000	5.522.022.384	5,600,000,000
		.,	14.625,955,000	15.310.701.000		0.462	19 645 147,491	4,168,053,000	225,000 900	13,697,160 000	0.000	6,904,820,000	23, 193,095,113	14,600,000,000
			21,698,101,000	15,447,446,000		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	21,690,101.000
		1,000,000	5,000,000	1,762 700		0.000		0.000	0.000	1,000.000	0.000	500 000	-358.048	1,000.000
		1,600,000,000	937,500 000	480,551,000		0.012		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	9 000		0.000	•	0.000	0.900	2.000,000.000	0.000	5,400,000,000	-1,000,000.000	3,000.000.000
NQ 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:

48,200,000.000

2013 Figur Revised APQ;

0 000

Est): 49,115,800,000 MS Est: (2013 Initial APQ \* IMS Est): 47,197,440,000

2014 Proposed Initial APD:

50,000,000,000

62,500,000,000 with 25% buffer

Basic Class: 9668-A Total PC Requested:

2014 Initial APQ Worksheets

I AFG HORA REG

FDA Est

Company	DEA Nurs	2014 Requested MQ 2	OI Desiros CO	2012 Sales	2012 DEA ING Sales	% of 2012 Sales	Share of 2014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Immediary	Calc Using CFR 50% Invent	MQ
(b)(4);(b)(7)(E)		6,800,000,000	5,371,701 000		• •	1.000		1,585,894,000				1,517,484.000		6.890,000.000
		3,000,000 000	832,273 000	0 000	3,713,002 000	0.000	0 000	444,132.000	0.000	3,000,000.000	0.000	0.000	1,834,093 230	3,600,000.000

MC Totals: 2.800,000.000 5.203,674.000

2013 Final Initial APQ: 2,200,000,000
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 APO:

12,250,000,000 with 25% buffer

9,600,000,000

(b)(4) will be converting the API to Nathupkine, Nativexone, and Natoxone, yields were provided but all are non-controlled substances.

1,000 000

(b)(4) with be convening the API to halozone (non-controlled substance), no convention factor given with MQ request

Basic Class: 1668-8

Total PO Requested: 4,087,500

2014 Initial APQ Worksheets

FDA Est: IMS Est;

	Company D	EA Num	2014 Requested MD	2013 Sevised NQ	2012 Sales	ZIM Z DEA MO Sales	% of 2012 Sales	Share of 2014 Total PO	2012 inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Galo 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	D.00D	1,330,813,271 1	000,000,000
ľ	(-/(-//(-/(-/		10 000	10.000	0.242	166,897.382	0.000	0.006	261.541	0.000	3.000	0.000	266,547	-266,034	10,000
-			3,000,000	2,618,000	0.000	166,607.382	0.000	0.000	534,000	\$,000	3,025,000	0.000	509,000	532,500	3,000,000
- 1			2,000.000	1,000,000	3.140	166,807.382	0.000	0.077	0.000	0.000	2,000,000	000,0	700,000	1,250,096	2,000.000
- 1															

1,005,010.000

 2013 Final Initial APQ:
 407,000,000

 2013 Final Revisad APQ:
 0,000

 FDA Est: (2013 Initial APQ \* IMS Ext):
 0,000

 IMS Est: (2013 Initial APQ \* IMS Ext):
 0,000

2014 Proposed Initial APQ:

HQ Totals:

1,010,000,000

1,262,500,000 with 25% buffer

1.005.010.000

403.528.000

Basic Class: 1010-0 Total PO Requested:

2814 Initial APQ Workshoots

FDA Est: IMS Est

DEA Num 2014 Requested Mg 2013 Revised MG 2013 Revised MG 2012 Sales 2012 DEA MG Sales % of 2014 Sales % of 2014 Total PO 2012 Inventory 2013 Projected Exports 2013 Projected Exports 2014 Projected Exports 2017 Projected Exports Company (b)(4);(b)(7)(E) 52,800,000 32,400.000 2,000.000 449,600.000 0.004 4,521.446 0.000 0 000 41,800 000 0.000 11,000,000 23,451,807 52,800.000 430,000 000 854,054,000 447,600,000 449,600,000 0.996 1,011,699,554 155,553,000 0.000 431,400 000 0.000 214,301,000 900,480.943 430,000.000

MQ Tolais: 462,899,000 886,454,000 - 886,454,000 - 482,800,000

2013 Final Initial APQ: 1,030,000,000
2013 Final Rented APQ: 0,000
FDA East: (2013 Initial APQ \* FDA East: (2013 Initial APQ \* BAS East: (2013 Initial APQ \* BAS East: (2013 Initial APQ \* BAS East: (2013 Initial APQ \* BAS

2014 Proposed Initial APQ: 500,000.000

625,000,000 with 25% buffer

OPIUM TINCTURE

Basic Class:

Total PO Requested:

2014 Initial APO Workshoots

FDA Est; IMS Est

Company \_2014 Requested MO\_2013 Revised MQ\_2012 Salas 2012 DEA MQ Salas % of 2012 Salas % of 2012 Salas Share of 2014 Total PQ\_2012 Inventory 2013 Projected Exports 2013 Projected Exports 2014 Projected Exports 2013 Projected Exports 2013 Projected Exports 2013 Projected Exports 2014 Projected Exports 2013 Projected Exports 201 (b)(4);(b)(7)(E) \$3,170.000 - 4,911.000 90,000,000 53,360,000, 55,750,000 55,750,000 1.000 0.000 56,000,000 0.000 34,000,000 77,531,500 77,531,500

MG Totals: 90,000,000 53,360,000 77,531,600

2013 Final Initial APQ: 73,000.000 2013 Final Revised APQ: 0.000 FOA Est: (2013 beltial APQ \* FOA Est); 0.000 IMS Est (2013 Within APQ " MIS Est): 0.000

2014 Proposed Initial APQ: 90,000.000

112,500.000 with 25% buffer

53,170,000

Basic Clase: 9350-0

Total PC Requested: 5.977.000 000

2014 Initial APQ Workshoots

FOA Est: (MS Est

	Company	DEA Num	2014 Requested MQ 2	DIA bestveR E103	2012 Sales	2012 DEA MQ Sales	% of 2012 Szles	Share of 7014 Total PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales	2014 Projected Exports	2013 Projected Inventory	Calc Using CFR SGS Invent	MQ
- 1			1,000,000,000	1.000.000.000	0,900	7.456,827,370	0.000	0.000	0.000			0.000	0.000	250,000.000	667,000,000
- 1	(b)(4);(b)(7)(E)		1,674,000,000	1,467,039,000	-	7.456.837.370	0,113	677,765 864	277,547,000	6.000	1,674,000 000	0000	105,000.000	1.143,381,060	1,163,057,333
			10.700.000.000	B 444,444,000			0.606	3,632,781 522	570,621,000	0,000	10,656,687.000	0.000	633,333 000	6,303,689,902	6,444,444,000
			4.235 DOC OOD	3 126 162 000		7,456,837,370	0,197		1,252,200,000			0.000	1,415,000.000	720,218 693	2,918,908.000
			480,000,000	462,716,000		7,456,837,370	0.082	490,420 460				0.000	4,000 000	741,986.575	480,000 000
												0 000	0.000	175,000,000	700,000,000
- 1			700,000.000	700,000,000	0,006	7,456,637,370	0.000	0.000	D 000	, 5.00	100.000.000	0 774		,	

14,373,409,333

2013 Fixel Initial APQ: 18,200,000 000
2013 Fixel Revised APQ: 0,000
FDA Est: (2013 Initial APQ \* FDA Est): 0,000

THIS EAR (2013 IN 1631 APIG THIS EAR): 0.1000

2014 Proposed Initial APO:

NO Totale:

18,200,000 000

22,750,000,000 with 25% buffer

18.789,000 000 15.200,361,000

tequest ID. 115535					THU PACTU	rting godi	Date Submitte		-APR-13
ame of Easic Class or List 1 (	Chemical (	onlv_	l_nor_	DEA_1891_		9ahadu'i	e/List Number	_	2
are and Address of Registrant	_					Drug_Co			9330-0
b)(4)						Quota Y	ear		2014
						DEA Reg	istration Numb	<b>ar</b> (b)(4);(	b)(7)(E)
ontact Person (b)(4);(b)(6)						Fax. No		(b)(4);	b)(6)
NOTE: All Quantities	are to be P	xbrekee	d in Ora	me of Anhy		Beas, or	Alkaloid (not as Sa	lts).	
unta History		+	20	12		13.	ly Issued by DEA	Quot	a Requeste
			3,684	,000.0	3,126	,000.0	0.0		235,000.0
roduction Data		. 2	nd Preco	ding Year	ist Prece	ding Year	Estimate for Current Year		mate for Year equested
nventory as of Dec 31		ilition	ging program in a		موديني كيجانون	्रभाकः क्र	1,415,000	- A	1,415,000
a.Bulk Controlled Substance/List 1			1	0.9 252,200.0		. 0.0		0.d	1,413,000
b.In-Process Material				0.0		0.0		0.0	
		·	1	,252,200.0		0.0	1,415,000	<b>9. q</b>	1,415,000
isposition(Sale)/Utilization a.Domestic				2,504.92		0.0	2,857,000		2,857.000
b Exports		<u> </u>	•	0.85 2,505.77		0.0	2,857,000	0.0	2,857,000
equisition/Production	•	<b></b> ├	~ : d.61			0,0	2,657,000 -577	<del>3.4</del>	
a.Domestic Sources			3	.184.006.7		0.0	4,235,000		4,235,000
			- 6	,184.006.7	· · · · · · · · · · · · · · · · · · ·	0.0	4,235,000	J. Q	4,235,000
f the Purpose is to Manufacture Anothe	r Substance(		caish th	e Following					1
Rame of Now Substance		Drug	}	2011	Amount_	Deed for th	1s Purposa 20	14	N Yield
YDRCHORPHONE		915D-0	<del>-</del>	874,020		1,140,220		7,000	85.70
•									
Product Development Dosage Form   8	trength	Unite/	Batch	# of Bato	bes De	itch Purpos	fet. Quantity	Zot. C	mpletion T
•							!		•
ransfer Registrant	<del> </del>			Explenst	on of Trai	noier			
	_						<del></del>		
,						•			
Date of Destruction	_		-	Rr Rr	planetion				
						_			
					,	•			
		1 .:	77275		9haa		Durner	I e	tal Quantit
Packaging Product Name	Strength	- Or	nita/Pkg	# 0.5	rkāe		Purpose		ret Anguitt
				•					
- · · · · · · · · · · · · · · · · · · ·							<del></del>		
emarks				<del></del> -	_				<del></del>
							•		

Request ID. 115756					RÍNG OUO	Date Submitted	25-APR-13
Name of Basic Class or List ORIPAVINE Name and Address of Registr		(only	1 per DRA-189	)	Drug Co	·	9330-0
(b)(4)					DEA Reg	ear istration Number	2014 (b)(4);(b)(7)(E)
Contact Person (b)(4);(b)(6)  Pmail Address					Fax. No	To	(b)(4);(b)(6)
NOTE: All Quest:	ltion are to be	Express	ed in Grane of An	hydrous Acid, Onot	, Base, or as Previou	Alkalcid(not as Salt	
Quota History			2012	20	13	2014	Quota Requested
			1,630,000.0		,039.0	0.0	1,674,000.0 Estimate for Year
Production Data			2nd Preceding Year	lst Prece	ding Year	Estimate for Current Year	Medicated
Inventory as of Dec 31  a.Bulk Controlled Substance/L	ion 1 Chemical	E	277,547	. of	0.0	105,000.	
b.In-Process Material				<u>.a</u>	0.0	<u> </u>	<del></del>
c. Contained in FINISHED Dona			277,547		0.0	105,000.	
Disposition(Sale)/Utilization			798,775		0.0	1,674,000.	
a.Domestic			0	. 0	0.0		
b Exports			796,77 <u>5</u>		0.0	1,674,000.	ફોરાજ કરાં છે છે.
Acquisition/Production a.Domestic Sources		Ë	797,922	. 0	0.0	1,674,000.	0 1,674,000.
			797,922	2 T T T T	0.0		
If the Furpose is to Manufacture A	nother Substanc	e(a), F	urnish the Follow	ing Informati	ion:		
Name of New Substant	te.	Drug	2011	*mount 1	Dsed for th 2012	2014	Yield
HYDROMORPHONE	<u> </u>	9150-	0		0	156,0	
DXYMORPHONE (FOR SALE)		9652-	в 0		35,053	143,0	100 45.00
							IR. Complete St
Product Development Desage Form	Strongth	Doite	/Batch # of 8	tches Ba	atch Purpos	e Mat. Quantity	Est. Completion Tim
	•						
Transfer Registrant			Explan	ation of Tra	nafer		. <del></del>
	-						
	-						
Date of Destruction				Explanation			
			-				
-							
	<u>-</u>			6 Nu		Purpose	Total Quentity
Packaging Product Name	Strang	th_	Units/Pkg # 4	f Pkgs		Agthene.	
			•			,	
-							
Romarks							
Quota is for supply of 1,000kg	(b)(4);(b)(7)	(E)			ll aleo us	e Oripavine for in	ternal conversion
Oxymorphone and Hydromorphone f	or sale to (b)	(4);(b)(7	')(E)	nd (b)(4)			
•							
			-				
1							5
1						,	

	AP	PLICATION	FOR	CUREMENTSOUOTA		Calabia (Tara)
Request ID115204	estation land and an area	<del></del>	<u> 40 200 </u>		te Submitted	01-APR-13
Name of Basic Class or I	ist 1 Chamics	l (only 1	per DKA-	250)		<u> </u>
ORIPAVINE					ug Schedule/List	2
Name and Address of Regi	strant				ug Code	. 9330-0
(b)(4)				-	ota Year	2014
				Þ	R Registration	(b)(4);(b)(7)(E)
Contact Person (b)(4);(	b)(6)				x. No	(b)(4);(b)(6)
		a Personned (v	n Grama of	<del></del>	or Alkaloid(not as S	Alta).
NOTE; AIT Qu	THETELOS APA CO D	• Wibiessed 1		cas Previously Tesues		11
Quota History		- 20	11.7	2011	2014	Quota Requested
		615,	400.0	668,000.0	0.0	476,000.0
Production Date		2nd Prece	ding Year	lat Preceding Year	Current Year Estimates	Quota Year Estimates
Inventory as of Dec 31				!	· · · · · · · · · · · · · · · · · · ·	
a.Bulk Controlled Substance/	List 1 Chemical	., }	89,060.0			
b.In-Process Material		1	0.0			
c. Contained in FINISHED Dos	age Forms	<del>}</del>	89,060.0			·
Disposition(Sale)/Utilization		_	647.0			
a.Docestic,			0.0		0.0	0.0
b Exports	***********	[	647.0			<del></del>
Acquisition/Production			420,224		476,000.1	476,000.0
a.Domestic Sources			610,324.6	0.0		
b.Importation			510,324.0	0.0	476,000.0	476,000.0
If the Purpose is to Manufactu	re Another Substa	ince(s), Furni	st the Pol	lowing Information:		
Name of New Substa	nce I	rug Code		Amount Used for	this Purpose 2014	* Yield
HYDROMORPHONE		9110-0	2011 67, 624	66,774		80.00
GXYMORPHONE (FOR SALE)		9652-8		475,610	127,50	B6.00
()mclude product form, i.e., tablets, pa		Market	Sched	3027   3	2014	Quota is Requested
		<u> </u>	Pwn	langtion of Transfer	<u> </u>	
Transfer Registrant	···					
Product Development Dosage Fo	rm Strength	Unite/Satch	# of Be	tches Batch Purpo	o Estimated Quantit	y Estimated Completion
Storage passtobment papade te	TEN DESAUGES !	,				
Date of Destruction Explanati	υn					· <del>- · · · · · · · · · · · · · · · · · ·</del>
1						
Packaging Product Name	Strongth	Units/Pkg	20 1	vkge	Purpose	Total Quantity
200,03203 120000 1						
	·					<u>.</u>
Remerks Bydromorphone production require	250 444	1.0		mutres 230 000 press in	2014. Due to equipment	constraints it le
possible not all 2013 quota will	m 256,000 grams and be consumed. If th	ide is the case	, quota vill	be surrendered later t	his year	
1						

9143-A Basic Class: Total PQ Requested:

2013 Final Initial APO:

2014 Proposed Fittal APQ:

2014 Initial APQ Worksheets 0.000

FDA Est

MS Est

DEA Nam 2014 Requested MD 2013 Revised MD 2013 Revised MD 2013 Sales 2012 DEA MQ Sales ¼ nf 2012 Sales Share of 2014 Total PQ 2012 Inventory 2013 Projected Exports 2013 Projected Sales 2014 Projected Exports 2013 Projected Sales 2014 Dea MQ Sales ¼ nf 2012 Sales Share of 2014 Dea MQ Sales 4 M 2012 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales 4 M 2014 Sales Share of 2014 Dea MQ Sales Sales 2 M 2014 Dea MQ Sales Sales Sales 2 M 2014 Dea MQ Sales Sa Company 267,369.250 7,400,000,000 7,400,000.000 5,840,045,000 6,846,859,000 6,646,859,000 1.000 0.000 2,370,141,000 0.000 7,017,544.000 0.000 2,575,098.000 (b)(4);(b)(7)(E)

MO Totals: 7,400,000.000 5,840,045.000 8,200,000,000

7,400,000,000

2013 Final Revised APQ: 0.000 FDA Eat (2013 tritlal APQ \* FDA Eat): 0.000 DAS Est: (2013 buildal APO 1 IMS Est): 0.000

7,400,000.000

9,250,000,000 with 25% buffer

АРРІ	ICATION U	FOR INDI	VIDUAL MA	NUFACTUR	ING QUOT	ALKONY (CO)		Y ALEXCE STATE
Request ID. 116051	লকাল <b>ক</b> ন্তি <sub>ই</sub>	- <u> </u>		र कर कर <b>ास्टर</b> इ.स.	age CTH Land	Date Submit		30-APR-13
Name of Basic Class or List 1 Chemi	cal (only	y 1 per 1	DRA-189)		,			
DXYCODONE (FOR CONVERSION)						/List Numbe	<u> </u>	0
Wame and Address of Registrant					Drug Cod Duota Yo		<del>-   -</del>	<u>9143-A</u> 2014
(b)(4)						istration Nu	nber(b)	
					<b>J</b>			
Contact Person(b)(4);(b)(6)  Rmail Address					Fax. No. Phone No.		(b)(	4),(b)(6)
NOTE: All Quantities are t	o be Expres	sed in Gra	ms of Anhyd	rous Acid,	Base, or	Alkaloid(not as	Belts).	
ucta History		20		Quota 201	<u>o Previous</u>	ly Issued by DE 2014	<u> </u>	Quota Requested
Angen Hyperpal	ŀ		,000.0	5,840,		0.0	<del>-   '</del>	7,400,000.0
Production Data ,	<del>- 1</del>	2nd Prece		lst Preced:		Estimate for		Sectmate for Year
		<del></del>				Current Year		Requested
Inventory as of Dec 31 a.Bulk Controlled Substance/List 1 Chem	nical		150,621.0		. 0.0	625,	098.0	625,098.
b.In-Process Material		1,	,219,520 <u>.0</u> 0.0	_	0.0	1,950,	0.00	1,950,000.
c. Contained in FINISHED Dosage Forms		2	370.141.0		0.0	2,575,		2,575,098.
Disposition(Sale)/Utilization			0.0		0.0	7,017,	544.dl	7,017,544
a.Domestic			0.0		0.0	**************************************	0.0	0.
b Exports	···· [		p.d		0,0	7.017,	544.0	7,017,544
Acquisition/Production			0.0	<u> </u>	0.0	7,400,	000.0	7,400,000
a.Domestic Sources	}	<del>-</del>	0.0		0.0	7,400,		7,400,000.
f the Purpose is to Manufactura Asother Sub	Stance (a)	Furnish the	a Following	Informatio	.v; <u>''' ©</u>	المشاطيعين ال	or storages of	1580 (44) \$1 \$14 K
Name of New Substance	Drug					le Purpose		N Yield
			2011		2012		2014	
XYMORPHONE (FOR SALE)	9652	-2	4,167,525		5,036,613	3,	017,544	\$7.00
_								
Froduct Dayslepmone Dosage Form Strengt	h Unit	s/Batch	# of Batc	ane Bat	ch Purpose	Est. Quent	ity Ret	. Completion Tix
•								
						· 		
reneder Registrant			Explanati	on of Trans	E ex			
•				•			•	
•						-		
<u> </u>			-	lamation			<del></del>	
Date of Destruction				CHELLAND				
	-						•	
•				'				-
• •								_
Fackaging Product Name St	rength	Units/Pkg	# 02 1	kga		Purpose		Total Quantity
<del></del>								
								•
					•			
• •						<u></u>		
amarko								
-								
,					-			
								•

tequest ID. 116052						Date Submitte	d	30-APR-13
lame of Basic Class or List 1	Chemical (or	nlv l per	DEA-189)		L - 41 -	/r data Number		0
XYMORPHONE (FOR SALE) ame and Address of Registran					ud Code	<u>/List_Number</u> •	<del>                                     </del>	9652-B
o)(4)	<u> </u>				ota Ye			2014
-//./						stration Numb	er(b)(4	);(b)(7)(E)
ontact Person(b)(4);(b)(6)					x. No		(b)(4	·);(b)(6)
mail Address Norg: All Quantiti	les ere to be Eve	researd in Gr	ame of Anhyd		one No.			
			012	Quotas P 2013	reviousl	y Issued by DEA		ota Requeste
ota Eistory			0,263.0	2,661,622	2.0	0.0	<del>-   •</del>	4,000,000.0
roduction Data			eding Year	lat Preceding		Estimate for	29	timate for Year Requested
eventory as of Dec 31		\$40.006A34.6	a na na naikytyn	<u>argerik ing</u>		Current Year		e 124 <u>7</u>
a. Bulk Controlled Substance/List	t 1 Chemical		325,061.0 560,781.0		0.0	1,273,45		1,273,450 250,000
b.In-Process Material			0.0	· · · · ·	0.0		0.0	C
c. Contained in FINISHED Dosage	Forms		885,842.0		0.0	1,523,45	o. c[	1,523,450
sposition(Sale)/Utilization	-		2,864,919.0		0.0	3,277,69		3,277,692
a.Domeaticb Exports			0.0		0.0	3,277,69	0.0	3,277,692
			2,864,919.0		<u> </u>		<u></u>	3,271,692
equisition/Production a,Domestic Scurces			0.0		0.0	4,000,00	_	4,000,000
• • • • • • • • • • • • • • • • • • • •		- 10	0, d		0.0	4,000.00		4,000,000
the Purpose is to Manufacture Ano		), Furnish to	he Following	Information: Amount Used	for this	- Purpose		h Yield
Name of New Substance			2011		2012	20	14	
	Sharesh I to	nite/Batch	# of Batch	en   Batch	Purpose	Est. Quantit	v Bot.	Completion Ti
Product Development Dosage Form	Strength V	MICO/BACCA	W OU Bacci				,	
					•			
Date of Destruction			Emp	lanation				
	<u> </u>							
				,				
						•		•
Packaging Product Name	strength	Unite/Pk	g # of F	kgs		Ригрове		Total Quantit
								•
emarke								
		-					<del>-</del>	
			-					
·								
<b>\</b>								
1								
<b>\</b>								

Basic Class:	9143.8
B	

2014 Initial APQ Worksheets

FOA Eat: (MS Eat: - 045

Company	DEA Num	2014 Requested MQ	MQ	2012 Sales	2012 DEA MQ Sales	i of 2012 Sales	Share of 2014 Total PG	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	D 000	0.000	. D.000	100,000,000	0.000	100,000 000	100,000 000	100,000,000
(0)(1),(0)(1)(2)		50.000	60,000	1.998	78,572,122,709	0.000	5 0 18	803 439	0.000	20.000	0.000	533,440	60.000	60.000
		675,500,000	115,835,000	2,936,000	78,672,122,706	0.000	3,685,100	12,187,000	0,000	875,500.000	0.000	20,000 000	781,043.125	761,043,125
		2,860,000,000	900,000,000	365,669 000	78,572,122,708	0 0005	458,966 856	890,207 800	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	18 099 866 000	78 872 122 708	0.230	22,717,918,640	18,073,590,000	88,954,000	23,257,329,000	3 000	8,147,670.000	19,170,091,299	19,170,091 299
		- ,				0.499	49,279,684,634	12,240,264,000	0.000	53,820,000.000	0.000	16,050,000,000	70,684,552,292	64,500,000 000
		1,000,000	5,000,000	11,190,710		0.000		29,325 000	0.000	1,000.000	0 000	35,000 000	1,000.000	1.000 000
		24,000,000,000				0.260		15 557,708 000	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			0 006	551,925,251	140,704 000		639,000,000	0 000	148,500 000	764,452.563	764,452 563

MG Totals: 117,331,560,000 92,912,758,000 92,912,758,000 91,241,448,557

2013 Pinal Initial APQ: 105,200 000,000
2013 Pinal Revised APQ: 0,000
Ent): 0,000
UNS Eat: (2013 Initial APQ \* IMS Est): 117,489,500,000

2014 Proposed Initial APQ: 119,500,000 000

149,375,000 000

0 with 25% truffer

56,744,757,717

Anticine HO4		2014 Inklut APQ Worksheets		
Total Pit Requirement	4,gm panara		FOA EIE MYS EIC	-129
		4		

7	Of a series			****													
a		6.600,000,000 (000)	7,600,000,000	4.310.0074.000	5,765,249,600	0749	2 8 120 418	žis practicenio	9,800	5,447,065,000	0,000	1,2502,972 000	-1,816,468,000 3,065,737,353	4.049,062 418	1,177,082,416	7,465 651 029	a bene bese over
(b)(4);(b)(7)(E)		1 650 000 000				0.251	1,004,059,967	446,029 000	6 000	1,710 (000,000)	11000	855,000,007	1,336,079 600 2,330,000,000	1,859,800,502	2,340,599,867	270.35F.97F	LOCATION (PERSON I
(2)(1);(2)(1)(2)				9700			0000	0 000	0000	6 000	0.007	2.500,000 cop	1,762,602,000 1,394,402,000	2,500,000,000	1,782,030,000	-1.334.990.000	1,712,600,000
		2,902,300,000	CART LESS TORS	90,0	5,703,249 002	0.000	0.00	0.44	oun	444	****	F 2-40,	1,1111111111111111111111111111111111111				.,

19,794,000,000 11,997,303,000 (12,091,000)

19,000,000 cmb 17,250,000,000 web.75% but

OXYMORPHONE (FOR CONVERSION)

Request ID. 115798				NUPACTUR	ING QUO	Date Submitte		APR-13
Name of Basic Class or List 1 Chemics OXYMORPHONE (FOR CONVERSION)	T (OU)	LY 1 Der	DBA-189)		Schodel	e/List Number	1	0
Name and Address of Registrant					Drug Co		96	52-A
(b)(4)					Quota 1			014
(0)(+)						istration Numb		
Contact Person (b)(4);(b)(6) Email Address					Phone 1	io.	(b)(4);(b)	(6)
NOTE: All Quantities are to	o Expr	ogsod in Cr.	and of Anby	<u>trous Acid,</u> Onota	Bree, or	Alkaloid(not as Sa Bly Issued by DEA	lts).	
Quote History	-	20	012	201	.3	2014		Requested
<u></u>			5,000.0	7,600,		0.0		0,000.0
Production Data			eding Year	lot Preced	ing Year	Estimate for Current Year	Req	e Lor Year Dested
Inventory as of Dec 31		C 6 1 4 1 1 5	28,600.d	A 14	0.0	1,052,932		L,052,932.
a.Bulk Controlled Substance/List 1 Chemic			0.0		B.0		). q	o.
b.In-Process Material			0.0 28,600.0		0.0		2.0	0. 1,052,932.
Disposition(Sale)/Utilization								
a.Comestic.,		<u> </u>	0.0		0.0		3.0 3.0	9,447,D68
b Exports		<u> </u>	0.0		0.0	9,447,068		9,447,068
Acquisition/Production		<del></del>	*3.*5.*	- 141	142.572.57			3- 3- W.
a.Domestic Sources			0.0		0.0	9,600.000		9,600,000.
PIDAMOROTO GOMEGERITIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII	•	3597 8.7394	0.0		0.0		). o	9,600,000
If the Purpose is to Manufacture Another Subota	ace(s),	Furnish th	he Following		n:			
Name of New Substance	Dru	1g		Amount U		nis Purpose	14	# Yield
NUROXYMORPHONE (FOR CONVERSION)	956-	A-2	4,319,604		2012 3,328,95		0,362	63.00
NOROXYMORPHONE (FOR SALE)	966		0		0	-	707	63,00
Freduct Development Dosage Form Strength	lai	te/Satch	# of Bato	hes Bat	ch Purpos	e Sec. Quantity	Hat. Com	lation Tia
Transfor Registreut			Pynlanat	on of Trans	, ofor			
						-		
Date of Destruction			£x	lenetion				
•								
Packaging Product Name Stree	arh	Units/Pk	g f of	Pkca		Purpose	Tota	al Quentity
Packaging Product Name Street			- 1	<u></u>				
						_,		
Nemarke								

2014 Initial APQ Worksheets

FDA Esti .074 Total PO Requested: 3,174,500 IMS Ext.

DEA Num 2016 Requested MQ 2013 Revised MQ 2012 States 2012 DEA MQ Sales % of 2012 States 2012 Dea MQ Sales % of 2012 States of 2014 Total PQ 2012 Inventory 2013 Projected Exports 2013 Projected Exports 2014 Projected Exports 2013 Projected Exports 2013 Projected Exports 2014 Projected Exports 2014 Projected Exports 2015 Company (b)(4);(b)(7)(E) 1,000 000 996.250 1,000,000 0,000 0.000 0.000 0.000 1,000,000 0.000 0.225 5,000 0.000 1,000,000 0.000 0.000 0.000 1.000 0.000 4.000 1.000 5.000 5,000 0.000 0,000 0.225 0.000 1,028.000 -1,483.000 1,820.000 1,620,000 1,620,000 0.000 0,225 0.000 0.000 1,938,000 0.000 1,820,000 0,000 4,000 0,000 1.000 3,968.375 5.000 5.000 D.225 0,725 1.000 3,174,500 0 000 0.003

5,000 2,830,000

MQ Totals: 2013 Final Initial APQ: 3,000,000 2013 Final Revised APG: 0,000

1,830.000

2,830,000

FDA Ect: (2013 Initial APO \* FDA Est): 3,222,000 IMS Est: (2013 twitfal APQ \* MIS Est): 0.000

9739-0

Basic Class:

3,000,000 2014 Proposed Initial APQ:

3,750 w/25% buffer

	Conserv	PC4.6-	1014 Secunda	d 100 201	1 American MAC T	M17 East 20	IZ DEA MO Seles	North Company	Share of 2018 Tatal PC	2011 Inventory	2013 Projected Exports	2019 Projected Ealer	JUNE Projected Exports	2013 Projected Investory	2013 DEA Projected investory	immetory Adp.	Calc Using Company Involv	Gest Uning Day Inwest	Cale Using (	:FR 60% Named	) HES
-			1,00			296,300	1.062.300	0.124			2,000	300 000	D-000	300.000	2,230,000	2,013.231	26 434	1 315 834		-1,600.200	1 and and
	(b)(4);(b)(7)(E)			žaca	\$.200	0.000	2.042.300	9,000	0 000		£ 000	9 200	<b>B</b> OOM	1.500	1.500	1 250	1.600	1 500		-1.000	2.000
					600,330	21.00		0.155	120,40	501.000	100 000	646,000	0.000	260,000	\$55 000	73 4 000	\$50.435	475 496		-\$4,360	<b>650.00</b> 0
				0.000			1,047.200	0.721	467 60		1740 000	1,702 000	0.020	1,718 000	1,710 000	3,121,333	7.275.600	2.217.400		-475 <b>6</b> 39	F10.000
			1 4	000	2,331,000	1,000 000	1,562,300	4721			-24-4-4	.,									

710 000 2,339,000 1,466 000 1 1,662 300 0.721 557 000 2,351,000 1,700 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,710 000 1,

### \$100 Private Indianal APPAR \$5,004 000 \$2019 Private Revoluted APPAR \$0.000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000\$\$1000 \$10000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$1000 \$10

7014 Pressured Indial APC: 5 004.00

SUFENTANIL

Ameio Ciesas - mittolió		2014 instal APQ Worksharts
Total PO Requested:	22,048,301,000	FOA Étt:
•		CCS Est:

. 0	ry - QEA Hum	2014 Pequetted MQ 2	DT S Revised MC	2012 \$444	2012 DEA NO Sales	% ad 2012 \$444	Share at 28th Total Po	2012 Inventory 2	tor i Projecta	d Erports 2	01) Project of Sales	2014 Projected Exports	2013 Projected Inventory	2013 DEA Frenched Investory	Managery Aug.	. Galc Howg Gompany Invene		Cale Using CFR \$0% Invent 180
/b\//1\·/b\/7	\/E\	387,000,000	344,000,000	0.000	13,478,272.634	0.000	t 000	0 000		5 000	400 000,000	6.000	4,000,000	-96,000,000	729,339,243	4,000,000	-16,000,000	142,000,000 142,002,000
(b)(4);(b)(7	<u>/(⊏/</u>	10,000	10 000	0.844	13,428,272 804	2,000	0.877	3.967		0.000	1.000	0.000	12,540	12,657	■.323	13814	13,614	#473 13,514
1		302,000,000	6000	12.000	13,629,272,804	0.000	0.006	0.000		0.000	392,000,000	0 000	5000 not	-202,000.000	0.000	5,000,000	-392,000,000	392,000,000, 592,000,000
		12,000,000,000	2,350,000:000	-	15,478,272,864	0.206	4,544,050 477	20,245,000		0000	13,000,000,000	0.000	21.900.000	10,0 801,851,01-	1,512,630 (80)	4,519,000 427	4,140,654.573	10,070,519 (0)   PERFECCION

2019 Final Astel APQ: 91,000,000 000
2019 Final Review APQ: 9 000
FINA Exit (2019 Inclin APQ: PEN Exit; 0 0,000
pet Exit (2019 Septem APQ: RES Exit; 0 0,000

1914 Proposed tolkal APQ:

94,000,000,000

1,600,000,000 with 25% built

Bang Člate:	9312.0

~ 31,631,308,000

2014 William ADC Workshop

FOA Eet:

	DCA Num	2814 Requested MC	MQ.	2012 Sales	2012 DEA 140 Sales S.	of 2013 Spins	Union of 2014 Total PC	2013 From tory 2	2013 Projected Expents	2013 Projected Sales	2014 Projected Exports	2913 Projected Inventory	2013 DEA Projected Streetery	in ordery Adj.	Calc Using Company house!	Calr Uning Class became d	Cate Union CFR SC% Invent	INQ.
		470,000,000	est 200 peo	62,790,00		0.001	29.9(1.473		0.000	\$70,000,000		0.000	301,136.000	780,767,333	29.011.875	824.107.A73	-464,431.154	\$70,000 FE
(b)(4);(b)(7)(E)		25,000	25 000	415		0.000	3.497	\$7 PSF	900.5	10,000		71 900	72 906	35.332	73.636	74 833	44,451	25 900
(2)(1);(2)(1)(2)		154480000	384 000,000	20,000,00		9901	17,003,436	91,718,000	0,000	1,344,000,000		50,900,000	-1,063,762,000	320,145,333	47,023 478	.1 phá anni 524	1,162,748,644	1.544,000,000
		1,200,000,000	1,200,000,000	941.400.00		4413	417.067.254	1,590,505	1,000	1,200,000,000		0.000	5,000 400	603.203.313	417,087,254	417,147.214	29.2 r 99.60s	1,200,000,000
						9.501	13,055,051,452		0,000	43,826,996,000		13,170,207,000	13,491,035,000	_	29 175,266,467	29,430,136,462	17,712,798 656	45,000,000,000
		45,000,000,000	45000,000				13,631,441,442 8 308	0.000	2.000	1,000,000		1.500,000	-833,000	2,779,000		424.894	1,635 133	2000
		2,002 300	4,167,000	19 30		6 000			0.000	9.000,000,000		4 262,600,000	1429351 900			4 050 353 374	1.675331.010	6,000,000,000
		8,100,000,000	11,064,700,000			@105		2 344,651,000				1 ATRADOCE	-16497.837.000			4879.556 744		20,000,000,000
		2000.000	1,498,513,000			0.126	4.017.078.254		8,500	20,300,000 (20)						13.837.469.207		19.500,000,000
		19,500,000,000	21,700,000,000		74,287,040,0457	0 230	7 (05.2017	3,725,400 000	0.000	19 800,000 000	0.000	17,000,000,000	9,923,400 000		10,011,100	12231,400201		

2018 Final Hardel APQ: 115,000 000.07

1019 Final Revised APQ: 000

1010 Final Revised APQ: 0.00

2014 Proposed Inniu APO: 115 (00 000 000

CONTROL MED 52% STATE

# 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-I), 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-

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(isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4), 3,4-methylenedioxyamphetamine (MDA), 3,4-methylenedioxy-n-methyleathinone (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., damphetamine 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.

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# 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-	15 g
tetramethylcyclopropyl)methanone (XLR11)	·
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-Dimethoxyphonyl)ethanamine (2C-H)	30 g
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30 g
2-(4-Iodo-2,5-dimethoxyphonyl)ethanamine (2C-I)	30 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25 g

	25.0
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	53 g
(cannabicyclohexanol or CP-47, 497 C8-homolog)	
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-(I-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-fluorofentanyi	2 g
Parahexyl	5 g
Phenomorphan	2 g
Pholeodine	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-c2,600,000 grams for methamphetamine mostly for conversion grams for methamphetamine (for sale)]	controlled, non-prescription product; on to a schedule III product; and 61,375
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)	l,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

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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 GFR 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 130B.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]
6ILLING 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.

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 reducted 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 reducted, 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, pscudoephedrine, 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 (gammahydroxybutyric acid and tetrahydrocannabinols), an additional 25% of the estimated medical. scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting established aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforescen 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-	
letramethylcyclopropy-	
I)methanone (UR-144)	15 g
[1-(5-fluoro-pentyl)-1H-indol-	
3-yi](2,2,3,3-	
tetramethylcyclopropy-	·
I)methanone (XLR11)	15 g
1-(1-	
Phenylcyclohexy-	
l)pyrrolidine	10 g
1-(5-Fluoropentyl)-3-(1-naph-	
thoyl)Indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-	
(odobenzayi)indale	
(AM694)	45 g
1-(1-(2-	
Thieny-	_
l)cyclohexyl]piperidine i	5 g

		<del></del>			
Basic class—schedule 1	Proposed 2014 quotas	Basic class—schedule I	Proposed 2014 quotas	Basic class—schedule [	Proposed 2014 quotas
t-[2-(4-Morpholinyl)ethyl]-3- (1-naphthoyl)indole (JWH-		3,4-Methylenedioxy-N- methylcathinone		Lysergic acid diethylamide (LSD)	30 g
200)	45 g	(melhylone)	50 g	Marihuana	21,000 g
1-Butyl-3-(1-naphthoyi)indole	45 g	3,4- Methylenedioxypyrovalero-		Mescaline Methaqualone	25 g 10 g
(JWH-073) 1-Cyclohexylethyl-3-(2-	************************************	ne (MDPV)	35 g	Methcathinone	25 g
methoxyphenylacely-		3-Methylfentanyl	2 g	Methyldihydromorphine Morphine Methylbromida	2 g 5 g
l)indole (SR-18 and RCS- 8)	45 g	3-Methylthiofentanyl4-Bromo-2,5-	2 g	Morphine Methylsulfonate	5 ğ
1-Hexyl-3-(1-naphthoyl)indole		dimethoxyamphetamine		Morphine-N-oxide	175 g
(JWH-019) 1-Methyl-4-phenyl-4-	45 g	(DOB)4-Bromo-2,5-	. 25 g	indazole-3-carboxamide	
propionoxypiperidine	2 g	dimethoxyphenethylamine		(AKB48)	15 g
1-Pentyl-3-(1-naph-		(2-CB)	26 g	N-Benzylpiperazine N,N-Dimethylamphelamine	25 g 25 g
thoyl)indole (JWH-018 and AM678)	45 g	4-Methoxyamphetamine 4-Methyl-2,5-	100 g	N-Ethyl-1-	_
1-Pentyl-3-(2-		dimethoxyamphetamine	2	phenylcyclohexylamine N-Ethylamphetamine	5 g 24 g
chlorophenylacetyl)indole	45 g	(DOM)	25 g	N-Hydroxy-3,4-	L7 9
(JWH-203) 1-Pentyl-3-(2-	1 739	4-Methylaminorex	<b>25</b> g	methylenedloxyamphetam-	24.5
methoxyphenylacety-		(mephedrone)	· 45 g	Noracymethadol	24 g 2 g
l)indole (JWH-250)	45 g	5-(1,1-Dimethylheptyl)-2-		Norleverphanol	52 g
thoyl)Indole (JWH-398)	45 g	[(1R,3S)-3- hydroxycyclohexyl]-phanol	68 g	Normothadone	' 2 g 18 g
1-Pentyl-3-(4-methyl-1-naph-	1 45 ~	5-(1,1-Dimethyloctyl)-2-	•	Para-fluorofentanyl	2 g
thoyl)indole (JWH~122) 1-Pentyl-3-((4-methoxy)-ben-	45 g	[(1R,3S)-3- hydroxycyclohexyl]-phenol		Parahexyl	5 g
zoyl]indole (SR-19, RCS-		(cannableyclohexano) or		PhenomorphanPholodine	2 g 2 g
4) 1-Pentyl-3-[1-(4-	45 g	CP-47, 497 C8-homolog)	53 g	Properiding	2 g
methoxynaphthoyl)]indole		5-Methoxy-3,4- methylenedioxyamphetam-		Psilocybin	30 g 30 g
(JWH-081)	45 g	ine	25 g	Psilocyn Tetrahydrocannabinols	491,000 g
2-(2,5-Dimethoxy-4-(n)- propylphenyl)ethanamine		5-Methoxy-N,N-	05 -	Thiofentanyl	2 g
(2C-P)	· 30 g	diisopropyltryptamine 5-Methoxy-N,N-	25 g	Tilidine	10 g 2 g
2-(2,5-Dimethoxy-4-		dimethyltryptamine	25 g		
ethylphenyl)ethanamine (2C-E)	30 g	Acetyl-alpha-methylfentanyl	2 g 2 g	Contractor and add of the	Proposed
2-(2,5-Dimethaxy-4-		Acetyldihydrocodeine	2 g	Basic class—schedule II	2014 quotas
methylphenyl)ethanamine (2C-D)	30 g	Allylprodine	2 g	1-Phenylcyclohexylamine	3 g
2-(2,5-Dimethoxy-4-nitro-	1	Alphacetylmethadol	2 g 25 g	1-	
phenyl)ethanamine (2C-N)	30 g	Alphameprodine	2 9	Piperdinocyclohexanecarb- onitrile (PCC)	3 g
2-(2,5- Dimethoxypheny-		Afphamethadol	2 g 2 g	4-Anilino-N-phenethyl-4-pi-	
I)ethanamine (2C-H)	<b>30</b> g	Alpha-methylfentanyl  Alpha-methylthiofentanyl	2 g	peridine (ANPP)	2,687,500 g 17,625 g
2-(4-Ch(oro-2,5- dimethoxypheny-		Alpha-methyltryptamine	_	Alfentanii	
t)ethanamine (2C-C)	30 g	Aminorex	25 g 25 g	Amobarbital	
2-(4-lode-2,5-		Benzylmorphine	2 g	Amphetamine (for conver-	18,375,000 g
dimethoxypheny- l)ethanamine (2C-I)	30 g	Betacety/methadol	2 g	Amphetamine (for sale)	49,000,000 g
2.5-Dimethoxy-4-		Beta-hydroxy-3- methylfentanyl	2 g	Carfentanil	6 g 240,000 g
ethylamphotamine (DOET) 2,5-Dimethoxy-4-n-	25 g	Bela-hydroxyfentanyl	2 g	Cocaine	68,750,000 g
propylthiophenethylamine	25 g	Betarreprodine	2 g 2 g	Codeine (for sale)	46,125,000 g
2,5-Dimethoxyamphetamine	25 g	Bulotenine	3 g	Dextropropoxyphene	19 g 100,750 g
2-[4-(Ethylthio)-2,5- dimethoxypheny-		Cathinone	26 g	Diphenoxylale	750,000 g
ljethanamine (2C-T-2)	30 g	Codeine Methylbromide Codeine-N-oxide	5 g 200 g	Ethylmorphine	127,500 g 3 g
2-[4-(Isopropylthio)-2,5- dimethoxypheny-		Desomorphine	5 g	Fentanyl	2,108,750 g
I]ethanamiine (2C-T-4)	30 g	Diethyltryptamine	25 g	Glutethimide	3 g
3,4,5- Trimethoxyamphetamine	25 g	Difenoxin	50 g 3,300,000 g	Hydrocodone (for sale)	99,625,000 g 5,968,750 g
3,4-	239	Dimethyltryptamine	25 g	(somethadone	5 9
Methylenedioxyamphetam-		Dipipanone	5g 5 g	Levo-alphacetylmethadol (LAAM)	4 g
ine (MDA)	55 g	FenethyllineGamma-hydroxybutyric acid	70,250,000 g	Levomethorphan	6 g
Methylenedioxymethamph-		Heroin	25 g	Leverphanol	2,000 g 23,750,000 g
etamine (MDMA)	50 g	Hydroxypethidine	2 g 2 g	Meperidine	6,250,000 g
ethylamphetamine (MDEA)	40 g	Ibogaine		Meperidine Intermediate-A	l 6g
	_				

Basic classschedule II .	Proposed 2014 quotas
Meperidine Intermediate-B Meperidine intermediate-C Metazocine Methadone (for sale) Methadone Intermediate Methamphetamine	11 g 6 g 6 g 31,875,000 g 38,875,000 g 38,911,375 g

[1,250,000 grams of lovo-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 conver-	_
sion)	12,250,000 g
Noroxymorphone (for sale)	1,262,500 g
Opium (powder)	112,500 g
Oplum (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 conver-	
sion)	17,250,000 g
Oxymorphone (for sale)	7,750,000 g
Pentobarbital	35,000,000 g
Phenazocine	6 9
Phencyclidine	6 g
Phenmetrazine	3 g
Phenylacetone	29,980,050 g
Racemethorphan	3 9
Remitentanil	3,750 q
Secobarbital	215,003 g
Sufentanii	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
conversion)	25,700,000 g
sale)	5,300,000 g
version)	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 1303.11 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 Doputy 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. 2013–18052 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-forprofit institutions; Business or other forprofit.

(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	
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

#### 2014 Established

Drive .	Company	Comment	Amount	Response	Proposed APO		Change
1-Pentyl-) H-indol-3-vlY2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	(b)(4)	increase APO	10	APO sufficient	151		
1-(5-fluoro-pentyl)-1H-indol-3-y[](2,2,3,3-tetramethylcyclopropyl)methanone	(-)(-)	increase APO	10	_APO sufficient_	- 15	15	
N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)		increase APO	10	APO sufficient	15[	15	
cathinone	]	inercase APO	_40	justified, increase APO	26	70	44
d-amphetamine (for sale)	]	increase APO	1.80 <u>0.000</u> 1.300.000	400 m. M. J.		- 49,000,000	
d.l-amphetamine (for sale)	1	increase APO	950,000 830,000	APQ sufficient	49,000,000	19,000,000	-
codeine (for conversion)	1	increase APO	790.000	APQ sufficient	68,750,000	68,750,000	
codeine (for sale)	1	increase APO	3.500.000 7.060.000	APO sufficient	46,125,000	46,125,000	
fénianyl		increase APO.	124 000	APQ sufficient	2,108,750	2,108,750	
hydrocodone (for sale)	]	increase APO	7.400.000	APQ sufficient	99,625,000}	99,625,000	
hydromerphone		increase APO	160,000	justified, increase APO	5,968,750	6,750,000	781.250
leyomethorphan	]	increase APO	150	justified increase APO	6	195	189
methylphenidate	1	increase APO	1 740 000	APO sufficient	96,750,000	96,750,000]	
morphine (for conversion)		increase APO	3.230.000 9.000.000	APQ sufficient	91,250,000	91,250,000	-
morphine (for sale)		increase APO	150.000 1.400.000	APO sufficient	62,500,000	62,500,000	
noroxymorphone (for conversion)	1	increase APO	10.000.000 970.000	justified, increase APQ	12,250,000	17,500,000	5,250,000
orinavine	1	increase APO	15,000,000	APO sufficient	22,750,000	22,750,000	
oxycodone (for sale)	1	increase APO	4.250.000 470.000	APQ sufficient	149,375,000	149,375,000	
oxymorphone (for conversion)	1	increase APO	13.000.000 6.211.000	justified, increase APQ	17,250,000	25,000,000	7,750,000
exymorphone (for sale)	1	increase APO	300.000 90.000	APQ sufficient	7,750,000	7,750,000	-
phenylacetone	1	increase APO	30 000,000	justified increase APO	29,980,050	67,000,000	37,019,950
tapentadol	1	increase APO	- 500 000	APO sufficient	17,500,000	17,500,000	· • • • • • • • • • • • • • • • • • • •
tetrahydrocannabino)	1	increase APO	10,000	APO sufficient	491,000	491,000	
thebaine	1	increase APO	2,225,000	APQ sufficient	145,000,000	145,900,000	
		increase APO	500.000				

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

6 24

CMEA Chemical	Company	Comment	Amoun!	Response			Change
PPA (for conversion)	(b)(4)	increase AAN	11,000,0001		25,700,000	44,800,000	19,100,000
	(-)(-)				-		

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

Laditional	Design	Considerations:	
va mittuu ai	17 F U P	C.DOSIDERATIONS:	

Drup	Response	Proposed	Revised	Change_
1-[1-(2-Thienyl)cyclohexyl)piperidine	increase APO, based on additional ref std manufactorer request	5	15	10
carfentanil	increase APO, based on additional refistd manufacterer request	6	: 19	13
eogonine	adjust to 2013 Final APO value, represents 2014 cending requests	127,500	144,000	16,500 690,000
dihydromorphine	increase APO, based on new requests - set to 2013 Final Revised value	3,300,000	3,990,000	690,000
dimethyltryptamine	increase APO, based on change in quantity requested from ref std manufacturer - (b)(4)	25	35	10
lysergic acid diethylamide	increase APO, based on change in quantity requested from ref std manufacturer -	30_	35	- 5
metazocine	increase APO, based on change in quantity requested from sef 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)
methyldeserphine	decrease APQ, based on decreasing requests for last 3 years increase APQ, based on new request from ref std manufacturer - (b)(4)		2	2
phencyclidine	increase APO, based an additional ref sid manufacturer request requests	6	19	- 1.3

Leanitibh A	Chemical	Considerations:

todatividi Çitcimen Çelebattanens.				
_	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		100_000
pseudoephedrine (for sale)	increase AAN, based on new requests	156,000,000		36,000,000

# CONFIDENTIAL

(b)(4)			

30 July 2013

Drug Enforcement Administration
Atm: 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:

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 reducted.

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,  $\binom{(b)(4)}{}$  is currently in negotiations with one of its customers to provide a bulk synthesis of Levomethorphan.  $\binom{(b)(4)}{}$  has a Letter of Intent from the customer indicating their intent to enter into a Purchase Order agreement with  $\binom{(b)(4)}{}$  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  $\binom{(b)(4)}{}$  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,  $\binom{(b)(4)}{}$  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) are submitting this comment in response to the proposed initial

0)(4)	

(b)(4)

	CONFIDENTIAL	(b)(4)		
2014 APQ for this drug class in 2013.	to cover the eventuality that the final product i	cannot be obtained		
Therefore, $(b)(4)$ is requesting that the APQ for Levomethorphan be revised to allow for a 150 gram increase to $(b)(4)$ becomethorphan 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 APO for Cathinone be revised to allow for a 40 gram increase to $(b)(4)$ Levamethorphan 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) the following five substances by requirement in the amounts list	pe adjusted as needed to ensure that (b)(4)	duction quotas for anticipated		
XLR 1 1 UR-144 AKB48 Levomethorphan Cathinone	10 g 10 g 10 g 150 g 40 g			
Please contact me at (b)(6)	you have any questions regarding	g this comment.		
Sincerely, (b)(6)		•		
Vice President Regulatory Affairs	(b)(4)	· 		

(b)(4)

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2015 36 AH 7-10

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:

[ (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

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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:

(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) Conv - 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.

> 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).

Contains Confidential and Proprietary Information

(b)(4)	
Attn: DEA Federal R	egister Representative [Docket No. DEA-378]
request for 13,000,000	that the revised aggregate be sufficient to include (b)(4)  O g AA of oxymorphone (for conversion) manufacturing quota for 2014 e submission #116698).
All of the other (b)(4)	quotas remain unchanged at this time.
Sincerely,	
Supervisor, Controlle (b)(6) (b)(4);(b)(6)	d Substance Compliance

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٨	u)	(4

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

**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.

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 <sup>[b)(4)</sup> Estimated Bulk Manufacturing Requirements
1.	Tapentadol	9780 / C-II	17,500,000 grams	500,000 grams

(cont.)

(b)(4)

Docket No. DEA-378 DEA Federal Register Representative /ODL July 26, 2013	(b)(4)
Page 2	*
Summary and Background:	
1. Tapentadol (DEA Drug Code 9780) – 500,0	)00 grams
The proposed 2014 Aggregate Production grams may not be adequate to cover for 2014.	Quota for Tapentadol of 17,500,000 projected product needs
CONFIDENTIAL BUSINESS INFORMATION	
(b)(4)	
Sincerely,	
(b)(6)	
Director, Quality Assurance and Regulatory Affair	s
(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 fo	rth in the table below for the following manufacturing
	respondence provided to the Quota Unit, which
	SS 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)		
D'	G. 1 - 4 Co	 1:
Director, Controlled	Substance Co	шћизисе

# (b)(4) Data 20 . . - 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		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	
Dihydrocodeine	112.37	-14.28%	107.21	-4.59%	75.49	-29.59%	51.46	
Diphenoxylate	480.24	三海1970%	462,59	3 67%	419.28	9.36%	** 410 18	2 2 2 2
Ephedrine	1,478.40	5.29%	1,535.42	3.86%	1,977.02	28.76%	1,949.50	-1.39%
Fentanyl - Santanyl	510.25	1:17%	539.84	5.80%	588.43	9.00%	568.65	
Hydrocodone	61,719.78	3.68%	65,108.61	5.49%	65,080.42	-0.04%	63,431.75	-2.53%
Hydromorphone	460 16	<b>8.85%</b>	1,675.24	14 73%	1,928.50	15.12%	1, 421 3 22 2 2 2 2	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%		-13.39%
Methadone : : : : : : : : : : : : : : : : : : :	7,859.04	0.11%	7,639:33	<b>`</b> ∕`≤-2.80%	7/191-03			-10.63%
Methamphetamine	14.86	-2.06%	13.86			. 5.37%		
<b>Methylphenidate</b>	18,704.32	3.39%	19,217.53	111111111111111111111111111111111111111	19,752.34	The filling to the control of the co	18,739.29	-5.13%
Morphine	28,997.24	4.40%	30,435.64	4.96%	31,015.39	-	<del></del>	
Opium	84,35	-9.23%	84.96	74 1	V		F-1	3.18%
Oxycodone	68,320.72	17.17%	70,878.97		67,940.06	· · · · · · · · · · · · · · · · · · ·	<del></del>	-7.18%
Oxymorphone :	1,653.43	31,45%	2,655.72	60.62%	31,960:18		# 1,867.25	
Pentazocine	694.40	-3.08%	839.71	20.93%	<del></del>	<u>-15.15%</u>		
Pentobarbital	8541	7-10.11%	79.12			1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		201200 12 10 10 10 10 10 10 10 10 10 10 10 10 10
Pseudoephedrine	127,452.77	-9.11%	104,473.28	-18.03%	94,447.67			5.10%
Remifentanil	<b>17:30:89</b>	5 6 <b>0 73%</b>	505	18:00%		1224 B. E. S. S. S. S. S. S. S.	the American Street or Str	( 2 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7
Secobarbital	23.20	-2.85%	20.78	<u> </u>	<del></del>	-24.59%		
Suferitanil 🙀 🚈 🚓	0.07	-14.98%	後. 第 20.05	:∄-22.81%	0.05	1:44%	1. 10.05	-::-7.94%

<sup>\*</sup>Estimates based on Jan-Jun 2013 Data

Basic Class: 1100

Total PQ Requested: 34,453,834.125

#### 2014 Initial APQ Worksheets

FOA Est: -,097 IMS Est: .01

Company	DEA Num	Drug Cod	e 2014 Requested MQ	2013 Revised MO	2012 Sules	2012 DEA MO Sales	% of 2012 Sales	Share of	2016 Total PG	2012 Inventory	2013 Projected Exports	2013 Projected Sales	Adj Aveil Calc	MD	
(b)(4);(b)(7)(E)		1100-B2	5.000	5.000	0.000	32,704,729.054	0,000		0,000	5.0B2	0.000		3.812	5.000	
(=)(-);(=)(-)(=)		1100-B2	3,000,000.000	1,245,437,000	403,393,000	32,704,729.054	0,012		421,266,532	157,532,000	Q.000.		-	2,284,223.790	
		1100-B2	2,725,500.000	2,487,000.000	2.048,177.000	32,764,729.054	0,963		2,135,929,126				_,		
		1106-B2	19,000,000.000	7,831,158.000	5,744,758,000	32,704,729,054	0.176		5,999,300.942	1,295,297.000	300,000,000				
		1100-82	10.000	10.000	0.000	32,704,720,054	0.000		0.000	0 000	0.000		7.500		
		1100-B2	194,000,000	150,000,000	0.000	32,704,729.054	0.800		0,000			•	118,500,000	75,500.000	
		1100-B2	98,590,000	24,500.000	0.000	32,704,729.054	0.000	,	\$.000				18,375.000		
		1100-B2	3,000,000.000	4,232,069,000	3,884,476.000	32,704,729,054	0,119		4,056,592,200	2,791.000				3,000,000.000	•
		1100-82	2,300,000,000	1.200,000.000	4.144,466.000	32,704,729,054			4,328,102,033				1,833,224.250		
		1100-82	1,300,000.000	402,238,000	174,287.000	32,704,729.054			182,009,436	_	•		410,246,250		**
		1100-B2	1,000 000	5,000,000		AND ADDRESS AND ADDRESS OF THE PARTY AND ADDRE	AND ASSESSMENT OF THE PROPERTY OF	But the track of the base of	1,323.346				5,069.925	1,000,000	Behard notice
		1100-A	500	0.000	of the San Company	All Same and the second of the	supply the property of the party of the	200	The second of the second	€ 5° 2° 2° 8.000		STREET,	0.000	100 100 100 100 100 100 100 100 100 100	Contract Carl
		1100-A	÷ 7,000,000,000	133,437,000	. El reinerado a de la composición dela composición dela composición de la composición dela composición de la composición dela composición de la composición de la composición dela composición de la composición dela comp	ar and the second of the secon			1181 386	320,071 000		ه وله المود " ومن بعيمه بو يون منه " المواد المود		1,707,985,482	3.37.43
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		J100-4	30 000		20.85	The section we supply the section to	- 10 000 C	7.5	0 063			21.000	* * * * * * * * * * * * * * * * * * *		
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		1100-4		24,500,000			والمراجع والمراجع والمجاهد		0.000		0.000		Activities the company of the	90 (75,000	NAME:
		CION (C)		800,000,000			Commence of the second			535,285,000				176.786.600	36 ME
		1100	and the second s	3 944 615 000	カング とうんきょうせいごう	the state of the state of the state of		1	11,022,059	26) 851 000	0.000	The second secon		.1,719.005.050 ·	
		no.	manage and a second and a second			0 22,704,729,054				279,013.000				of 032,019,610	Philippiness
		(100-C)	5 000	<ul> <li>*** * * * * * * * * * * * * * * * * *</li></ul>	化铁量像银矿矿 电影	「智さんをうだ」の一方をして一つであり	Car State Call Control		- 1 Table 1 Table 1	0.000	0.000	は無なない しょうはない はまつりん		All the second	
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		1100 C	110,000	0.000	1.75% <u>0.00</u>	0	3-3 0 000		9 7 3 9 9 1 <b>0 1000</b>	1,307	12242 1 199 <b>9 909</b>	1.300	8.480	PRESENT TONOR	

MQ Totals:

43,671,645.000 28,388.260.000

36,525,961.433

2013 Float Initial APQ: 34,100,000 000 2213 Float Revised APQ: 37,748,800,000 FDA Esti: [2013 Initial APQ-1 + FDA Esti: 30,392,300,000 IMS Esti: [2013 Initial APQ-1 + BMS Esti: 34,441,000,000

2014 Final toitial APQ:

39,200,000,000

Year DEA Name 2014 (b)(4);(b)(7)(E)	DEA Num	Requested 5	Granted	Commercial Man	APQ
2014		289,000		5 28 <b>9,0</b> 00	**************************************
	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	
T	otal Approved	611,000	599,500	599,500	2,291,000
<b>2012</b> (b)(4);(b)(7)(E)		1,729,000	1,135,000	1,135,000	
2012		380,000	318,000	318,000	
T	otal Approved	2,109,000	1,453,000	1,453,000	2,331,000
<b>2011</b> (b)(4);(b)(7)(E)		1,475,000	1,475,000	1,475,000	
2011		320,000	320,000	320,000	
т	otal Approved	1,795,000	1,795,000	1,795,000	2,331,000

BASIC CLASS:	2014 Initial Quota Worksheets	Oripavine	9330		
Company: Request: Current Year MC: Year end inventory	(b)(4) 1674.0 1467.0 277.5	(b)(4) 1000.0 1000.0 (buprenorphine pd) 0.0	(b)(4) 480.0 462.7 0.0 ((b)(4)	(b)(4) 1500.0 1040.0 570.6 (b)(4) 5800.0 2312.0 484.2	(b)(4) 700.0 700.0 2976.5 (PQ inventory)
Calculations hydromiorphone oripavine oripavine/buprenorphine de oxymorphone (sale) oxymorphone (conv)	amt needed subtance MQ: yield 346,667 156,000 0.45: 1000,000 (b)(4)	1000,000 700,000 0,700	emt needed subtance MQ yield 166.875 133.500 0.800 148.256 127.500 0.860		amt needed substance MQ yield 257
total needed	1654.444	1000.000	315.131	11604,938 2131.855 .	0.000
INITIAL MOS est need MQ: Total initial MQs:	2169.768 1665.000	1500,000	509,593 480,000	16535.551 2758.603 11605.000 2132.000	-2801.500 780.000

Total MQs: 17582.000 + others 0.005 ≈ 17582.005

**FURTHER CALCULATIONS** 

Proposed Initial APQ

18200

Barak Class: \$339-0

2014 Initial APG Worksheets 5,977,005,000

FDA Let Ma Eat:

Company	DEA Num	2014 Requested MO	2713 Revised MQ	2012 Sales	2012 DEA MQ Sales	Sales	Sture of 2	2014 Fe/4 PC	2012 Immediacy	2013 Pro	jected Exp	orts 20			2013 GEA Projected Investory			
(b)(4);(b)(7)(E)		5000	5 000	0.000	7,458,837.370	0 506		0.000	0.000		0.	.000	4 000	1 000	1.000	3,750		0.250
(D)(4),(D)(1)(L)		1,000,000,000	1,000,000,000	n bitt	7,456,137,070	0.000		-0.000	0.000		0	000	1.900,000,000	0000	0.000	750,000 000		
		1 674 02/0 000	1,467,039,000	645,573 000	7.456,637,070	D 113		677,786.431	277,547,000		4	600	1,674,000,000	1,05,000.000	70,586.000	1,300,439,500		1,308,639,500
		15 070 000 000	O COLOCADOS			0.606		3,632,784,561	\$70,621,000		10	000	14,444,444,000	1,061,733 000	-5,473,822,000	8,227,966.750	10,614,803,701	10,614,603,701
		4 235 000,000				0 (97		1,176 (02) 136	1,252,700,000		٠.	000	2,657,000,000	1,415,000,000	1,521,200,000	1.293,650 000	730,341 423	3.263,650,000
		480,000,000		811,443 000	7,456,637 370	0.082		490,420 aro	0.000		0	DEC	476,000,000	4,000 000	-13,284 000	347,037,000	741,989 067	460,000,000
		700,000,000				0.000		0.000	0.000		0	(COC)	700,000,000	6 000	0 000	575,000 000	175,000,000	525,000.000

| 2013 Final Initial APQ: | 16,200,000,000 | 2013 Final Revised APQ: | 10 TELECOR 000 | FIDA Exit (2013 format APQ \* 1 + PIDA Exit (2013 format APQ \* 1 + AFQ Exit (2013 format APQ \* 1 + AFQ

lame of Basic Class or List	1 Chemical	(only_1	per DEA-189)				·
RIPAVINE		Schedule Drug Code	List Number	2			
lame and Address of Registrant							9330-0 2014
b)(4)		DEA Regi	stration Number				
ontact Person(b)(4);(b)(6)					Fax. No_		(b)(4);(b)(6)
mail Address			4 - 5		Phone No	 	a \
NOTE: All Quantities	1es are to De	- Extrans	a th Gress or And	Queta	B Previousl	Y Issued by DEA	
uota History			2012	201	3	2014	Quota Requesta
		_	3,684,000.0	3,126,		0.0	4,235,000.0
roduction Data		] 2	nd Preceding Year	1st Preced:	ing Year	Satimate for Current Year	Estimate for Yea: Requested
nventory as of Dec 31	<del></del> .			<u> </u>	75 JE S 11	···· <del>·</del>	1. 7. 1. W
a, Bulk Controlled Substance/Lis	st 1 Chemica	1 ├—	1,252,200.0		0.0	1,415,000.0	
b.In-Process Material	,	├─	0.1		0.0	0.0	
c. Contained in FINISHED Dosage	Forms	□	1,252,200.0		0.0	1,415,000.0	1,415,00
isposition(Sale)/Utilization			2,504.9		0.0	2,857,000.0	2,857,00
a.Domestic	:	-	0.8		0.0	0.0	
b Exports			2,505.7		0.0	2,857,000.0	
equisition/Production		7.338	3 194 006		0.0	4,235,000.0	4,235,00
a.Domestic Sources		<b>-</b> -	3,184,006.		0.0	4,235,000.0	
			1 LF 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		1 8 1 PM	e e e e e e e e e e e e e e e e e e e	Mile trace and the first
f the Purpose is to Manufacture And			mish the Followin		n: and_for thic	Durnage	% Yield
Name of New Eubstance		Drug	2011	Amaune of	2017	2014	
YDROMORPHONS		9150-0	874,020		1,140,220	1,827,0	000 55.70
,							
•							
		I = 4			ch Purpose	Est. Quantity	Est. Completion T
Product Development Dosage Form	Strength	Units/S	latch   0 of Bat	CD BEC	.ch Parpose	Esc. Stantity	DDT: COMPTONIAN I
•						•	
Date of Destruction		·		splanation			
Date of Destruction		·		planation			
Date of Destruction				planation			
Date of Destruction				planation			
Date of Destruction			΄.	splanation		,	
Date of Destruction	5treng	reh U		planation  Page		Purpose	Total Quanti
	Streng	rth Ur					Total Quanti
	5treng	reb U					Total Quanti
	5treng	reb U					Total Quanti
	5treng	reb U:					Total Quanti
	Streng	reb Ur					Total Quanti
Packaging Product Name	Streng	reh U:					Total Quanti
Packaging Froduct Name	5treng	reb U:					Total Quanti
Packaging Froduct Name	5treng	reb Ur					Total Quanti
Packaging Froduct Name	Streng	rth Ur					Total Quanti
Packaging Froduct Name	Streng	rth Ur					Total Quanti
Packaging Froduct Name	Strang	rth Ur					Total Quanti
Packaging Froduct Name	Strang	rth Ur					Total Quanti
Packaging Froduct Name	Streng	rth Ur					Total Quanti
Packaging Froduct Name	Strong	rth Cr					Total Quanti
Packaging Froduct Name	Strong	reb Ur					Total Quanti
Packaging Froduct Name	Streng	reh Ur					Total Quanti
Packaging Product Name	Streng	reh Ur					Total Quanti
	Streng	rth Ur					Total Quanti
Packaging Froduct Name	Streng	rth Ur					Total Quanti
Packaging Froduct Name	Streng	rth Ur					Total Quanti
Packaging Froduct Name	Strang	rth U					Total Quanti
Packaging Froduct Name	Strang	rth Ur					Total Quanti
Packaging Product Name	Strong	rth Ur					Total Quanti

Request ID, 116697	APPLICAT	TON, LOK, THE	ĮVIDŲĄL, KAN	DPACTURING QUO	TA Date Submitted	
Name of Basic Class or List	1 Chemical	(only 1 per	DEA-189)			1
ORIPAVINE					le/List Number	9330-0
Name and Address of Registr	ent			Drug C		2014
(b)(4);(b)(7)(E)			gistration Number			
7				Pax. N		(b)(4);(b)(6)
Contact Person (b)(4);(b)(6) Email Address				Phone_	No.	
NOTE: All Quanti	ties are to be	Expressed in Gr	rame of Anhydro	Quotas Previo	Alkaloid(not so Salt	σ)
Quota Ristory			012	2013	2014	Quota Requested 15,000,000.0
			eding Year	B,444,444.0 Let Preceding Year	0.0 Escimate for	Estimace for Year
Production Data		2/10 F160			Current Year	Requested
Inventory as of Dec 31			570,621.0		1,081,733	
a.Bulk Controlled Substance/Lib.In-Process Material			0.0	0.0		<del> </del>
c. Contained in FINISHED Doses			570,621.0	0.0		
Disposition(Sale)/Utilization			0.0	0.0	14,444,444.	14,444,444.0
a,Domestic,,			0.0	0.4	0.	0 0.3
b Exports		. <u>*************</u>	0,0	<b>0.</b> 0 数据数据数 11 3	14,444,444.	14,444,444.0
Acquisition/Production		- 10/1/0 46%	0.0	0.5	15,000,000.	<u>15,000,000.0</u>
a,Domestic Sources	•		0.0		15,000,000	15,000,000.0
If the Purpose is to Manufacture A		e(s), Furnish t	he Following I			Yield
Name of New Substanc	•	Drug	2011	Amount Used for t	his Purpose 2014	
OXYMORPHONE (FOR CONVERSION)		9652-A	5,826,234	3,530,3	10,444	444 90,00
						-
Product Development Dosage Form	Strongth	Units/Batch	# of Batche	a Batch Purpo	se Ret. Quantity	Rat. Completion Time
	1					
	·····			of Transfer		<del></del>
Transfer Registrant		·	**************************************	or transfer		
Date of Destruction			Expl	nnation		
				•		
Packaging Product Name	Strengt	th Units/Pl	kg & of Pk	ga	Purpose	Total Quantity
	~. <del></del>			•		
				-		
					•	
	<del></del>					
Remarks Supplemental documentation in s	upport of this	request will	be emailed s	eparately to ODE	.Quota@usdoj.gov.	<del></del>
Pabhre Heirer morameticacton III B				- •	-	
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			4		•	••
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1						
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						•
						,

ame of Basic Class or List 1 Chemical	(only	l per DEA-189)		a_t : :	/v.a	[ .	<del></del>
RIPAVINE					List Number		<u>2</u> 0-0
ame and Address of Registrant		· · · · · · · · · · · · · · · · · · ·		<u>Drug C</u> ode Quota Yea			<u>0-0</u> 14
0)(4)					tration Number		
						(b)(4)·(b)(6	
ontact_Person (b)(4);(b)(6)		ļ		Pax. No		(b)(4);(b)(6	')
mail Address	Expresso	d in Grams of Anhyd	lrous Acid,	Bagg, or Al	kaloid(not as Salt	a).	
			Cuota	<u>a Previousl</u>	y Issued by DEA 2014		equesto
unta History	<b>├</b> -	1,630,000.0	1,467,		0.0		,000.0
roduction Data		nd Preceding Year	lat Preced		Estimate for		for Year
I ODGETER DATA					Current Year	Requi	
nventory 4s of Dec 31		277,547.0	St 5-5	0.0	105,000.0		105,000
a.Bulk Controlled Substance/List 1 Chemical		0.0		0.0	0.0	9	
b.In-Process Material		0.0 277,547.0	<del></del>	0.0	105,000.0		105,000
	<u></u>						
Disposition(Sale)/Utilization		798,775.0		0.0	1,674,000.0		674,000
b Exports	<u> </u>	0.0 798,775.0		0.0	1,674,000.0		674,000
equisition/Production	<u></u>		1. 200 . 200 . 200 . 200	2.5	5 - C - C - C - C - C - C - C - C - C -		\$ f
a,Domestic Sources		797,922.0		0.0	1,674,000,0		674,000 674,000
	<u> </u>	797,922.0	<u> </u>	1,14	1,674,000.4		74,000
f the Purpose is to Manufacture Another Substanc	e(a). Fu	rnish the Polloving	Informatio		<u> </u>	<del></del>	* Yiold
Name of New Substance	Drug	2011	Amount U	2012	2014		- 11010
TYDROMCAPHONE	9150-0	0		0	156.0		45.00
XYMORFHONE (FOR SALE)	9652-B	0		35,053	143,0	00	45.00
Product Development Desage Form Strangth	Units/	Batch   0 of Batc	hes Bat	ch Purpose	Ret. Quantity	Bat. Comp.	etion T
rengier Registrant		Explanati	on of Trans	sfer			
rensfer Registrant		Explanat	on of Trans	sfer			
rensier Registrant		Explanet	on of Trans	ofer			
rensfer Registrant				ofer			
Transfer Registrant  Date of Destruction	<u>-</u>		on of Trans	ofer			· · · · · · · · · · · · · · · · · · ·
Date of Destruction				ofer			
	·			ofer			
	·						
	·						
Date of Destruction	th Ü		planation		Putposa	Yota	l Quenti
Date of Destruction	th Ü	. Ex	planation	ofer	Putpoša	Yota	l Quanti
Date of Destruction	th Ü	. Ex	planation	ofer	Putpoša	Yota	l Quenti
Date of Destruction	th Ü	. Ex	planation	ofer	Putpoša	Yota	l Quentí
Date of Destruction	th Ü	. Ex	planation	ofer	Putpoša	Yota	l Quenti
Date of Destruction	th Ü	. Ex	planation	ofer	Putpoša	Yota	l Quenti
Date of Destruction	th Ü	. Ex	planation				
Date of Destruction  Packaging Product Name Strangl		. Ex	planation		Purpose Oripavine for integration		
Packaging Product Name Strang	F)	nite/Pkg # of	planation				
Date of Destruction  Packaging Product Name Strange  Remarks Quota is for supply of 1,000Kg to (h)(4)(h)(7)(	F)	nite/Pkg # of	Pkgs				
Date of Destruction  Packaging Product Name Strange  Remarks Quota is for supply of 1,000Kg to (h)(4)(h)(7)(	F)	nite/Pkg # of	Pkgs				
Date of Destruction  Packaging Product Name Strange  Remarks Supply of 1,000Kg to (h)(4)(h)(7)(	F)	nite/Pkg # of	Pkgs				_
Date of Destruction  Packaging Product Name Strange  Remarks Quota is for supply of 1,000Kg to (h)(4)(h)(7)(	F)	nite/Pkg # of	Pkgs				_
Packaging Product Name Strang	F)	nite/Pkg # of	Pkgs				
Packaging Product Name Strang	F)	nite/Pkg # of	Pkgs				
Packaging Product Name Strang	F)	nite/Pkg # of	Pkgs				
Date of Destruction	F)	nite/Pkg # of	Pkgs				_
Packaging Product Name Strang	F)	nite/Pkg # of	Pkgs				
Packaging Product Name Strang	F)	nite/Pkg # of	Pkgs				
Packaging Product Name Strang	F)	nite/Pkg # of	Pkgs				
Packaging Product Name Strang	F)	nite/Pkg # of	Pkgs				

APPLICE		REMOTE THE STREET SEE	******* W5/Y /	APT 1747 1 177.	Date Submitted		JUL-13
ame of Basic Class or List 1 Chemical	(only	1 per DRA-169)			Date Submitted	31-	10T-13
XYMORPHONE (FOR CONVERSION)		- DOL DOM-1071		Schedule	/List Number		.0
ame and Address of Registrant				Drug Coc		96	52-A
0)(4)				Duota Ye			014
				DEA Regi	stration Number	(b)(4);(b)	(7)(E)
ontact Person (b)(4);(b)(6) mail Address				Fax. No		(b)(4);(b)	(6)
NOTE: All Quantities are to be	o Expresse	d in Grame of Anbyd		Phone No. 3			
			Quota	a Pr <u>evious</u>	ly Issued by DEA		
uota History		2012	201		2014		Request
roduction Data	<del></del>	7,766,000.0	7,600,		0.0	.1—	00,000.0
roduction Data .	2	nd Preceding Year	1st Preced	ing Year	Estimate for Currenc Year		e for Year Jested
nventory as of Dec 31			e mary (b)		Service increases	1 1 1 1 1 1	
A.Bulk Controlled Substance/Dist 1 Chemical		28,600.0		0.0	1,000,000		893,09
b.In-Process Material		0.0		0.0	1,000,000.0		1,000,00
c. Contained in FINISHED Domage Forms	···- □	28,600.0		0.0	1,893,096.0		1,893,09
isposition(Sale)/Utilization		0.0		0.0	13,192,729.0	·	100 50
a.Comestic		0.0		0.0	13,192,729.0		1,192,72
b Exports		0.0		0.0	13,192,729.0		1,192,729
quisition/Production	V. 1	9.00	ence .	797 - 29	<ul><li>研究。* 数数 方面。</li></ul>	615 FT	100
a.Domestic Sources		0.0		0.0	13,000,000.0		,000,000
	<u> </u>	0.0(	. \ \ '* (+ 2'	0.0	13,000,000.0	1	000,000
the Purpose is to Manufacture Amother Substant	ce(s), Fur	nish the Following	Information	n:	***************************************		
Name of New Substance	Drug		Amount Va	ed for thi			* Yleld
ROXYMORPHONE (FOR SALE)		2011		2012	2014		
ROXIMORPHONE (FOR SALE) ROXIMORPHONE (FOR CONVERSION)	9668-B 9668-A	0 4,319,604		0 3,328.952	6.70° 13,186,		63,00 63.00
The second of th	7020-W	1/21/100		2,340.,	13,100,		43.00
Product Development Desage Form Strength							
	Crita/B		nes Bat	ch Purpose	Fet, Quantity	Est. Comp	letion T
spofer Ragistrant	Onita/B				Fet, Quantity	Est. Comp	letion Ti
	Onita/B				Fet, Quantity	Est. Comp	letion Ti
	Onita/B				Fet, Quantity	Est. Comp	letion Ti
	Onita/B				Fet, Quantity	Est. Comp	letion Ti
apofer Registrant	Onita/B	Explanation			Fet, Quantity	Est. Comp	letion Ti
	Onita/B	Explanation	on of Trans.		Fot, Quantity	Est. Comp	letion Ti
apofer Registrant	Onita/B	Explanation	on of Trans.		Fet, Quantity	Est. Comp	letion Ti
apofer Registrant	Onita/B	Explanation	on of Trans.		Fet, Quantity	Est. Comp	letion Ti
apofer Registrant	Onita/B	Explanation	on of Trans.		Est, Quantity	Est. Comp	letion Ti
apofer Registrant	Onita/B	Explanation	on of Trans.		Est, Quantity	Est. Comp	letion Ti
apofer Registrant		Explanation	on of Trans		Fat, Quantity		
apofer Ragistrant		Explanatí	on of Trans				
apofer Ragistrant		Explanatí	on of Trans				
apofer Ragistrant		Explanatí	on of Trans				
apofer Ragistrant		Explanatí	on of Trans				
apofer Ragistrant		Explanatí	on of Trans				
apofer Ragistrant ate of Destruction  Packaging Product Name Strengt		Explanatí	on of Trans				
apofer Registrant  ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
apofer Registrant  ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
apofer Registrant  ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
apofer Registrant  ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
apofer Registrant  ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
apofer Registrant  ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
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apofer Ragistrant ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
ate of Destruction	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
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apofer Ragistrant	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
ate of Destruction	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
ate of Destruction	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
apofer Ragistrant ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
apofer Registrant  ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		
ate of Destruction	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		letion Ti
apofer Registrant  ate of Destruction.  Packaging Product Name Strengt	th, Un	Explanation State of Post Post Post Post Post Post Post Post	on of Trans	for	Purposs		

APPLICATION	the confidence of the confidence	<del></del>		
equest ID. 116060	- 1 ppr 100\	<del></del>	Date Submitted	01-MAY-13
ame of Basic Class or List 1 Chamical (on)	LV 1 per DKA-189)	Schado	le/List Number	0
ame and Address of Registrant		Drug_C		9652-A
)(4)		Quota '	fear	2014
N-7			datration Number	(b)(4);(b)(7)(E)
PREST PERSON (b)(4);(b)(6)		FaxN		(b)(4);(b)(6)
mail Address		Рһоре ]		
HOTE: All Quantities are to be Expre	1	Quotas Previou	oly Issued by DEA	
ota History	2012	2013	2014	Quota Requeste
	1,000,000.0	1,782,600.0	0.0 Estimate for	2,500,000.0 Estimate for Year
oduction Data			Current Year	Requested
iventory as of Dec 31	0.0	<u> </u>	2,500,000.0	2,500,00
a.Bulk Controlled Substance/List 1 Chemical b.In-Process Material	0.0	0.0		
c. Contained in FINISHED Dosage Forms	0.0	0.0		2,500,00
sposition(Sale)/Utilization				
a.Domestic	0.0			
b Exports	0.0			
quisition/Production	(F) 1944 v v		2 500 000 0	7 500 00
a.Domestic Sources	0.0	<del></del>		2,500,00 2,500,00
the Purpose is to Manufacture Another Substance(a),		र्कुळार देन <u>ा</u> १८०	water - Carlotter	AV R
Name of New Substance Dru	19	Amount Used for t		% Yield
	2011	2012	2014	
,				_
Apsfer Registrant	Explanat	ion of Transfer		<del>_</del>
		TON OF TRANSPORT		
		ION OF TRANSPORT		
		ION OF Translati		
		IGN OF FEMALES		
		IGN OF FLANESCE	<del></del>	
		ION OF PLANEED		
Nate of Destruction	_ v.	planetion		
ate of Destruction	Σ.			
ate of Destruction	2.			
Oate of Destruction	Σ,			
ate of Destruction	<u> </u>			
		planetion	Purposa	Total Quanti
Packaging Product Name Strongth	Vnite/Pkg B of	planetion	Purposa	Totel Quanti
		planetion	Purposa	Totel Quanti
		planetion	Purposa	Totel Quanti
		planetion	Ригрова	Total Quanti
		planetion	Ригрова	Total Quanti
Packaging Product Name Strongth Strongth	Vnite/Pkg B of	Pkgs		
Packaging Product Name Strongth  Marka  Mark	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Distribution of the Packaging Product Name Strongth  Distribution of the Packaging Product Name Strongth  Distribution of the Packaging Product Name Strongth	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Marka  Mark	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Manarka	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Manarka	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Marka  Mark	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Marka  Mark	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Marka  Mark	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Marka  Mark	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Manarka	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Manarka	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strength  Amarka  Arrese batches © 833 kg each for validation. This can determine the converted into naloxons. The oxymorphone	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Manarka	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Froduct Name Strongth  Berongth  Berongth  Berongth  Berongth	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	
Packaging Product Name Strongth  Backaging Product Name Strongth	Vnite/Pkg B of	Pkgs converted to morox	morphone (conversion	

2014 Initial APO Worksheets

Basic Class: 9652-B Total PQ Requested;

3,441,767.250

FDA Est: IMS **E**st: . N/A -.047

	Company	DEA Num	2014 Requested MQ 2	2013 Revised MQ -	2012 Sales	2012 DEA NO Sales	% of 2012	Sales	Share of 2014 7	Fotal PQ	2012 Inventory	2013 Projected Exports	2013 Projected Sales		
- 1	(b)(4);(b)(7)(E)		· 5.000	5,000	0.000	3,570,963,674	*9	0.000	• •	0.000	0.007	0.000	4,000	3.755	5,000
	(U)(+),(U)(1)(L)		60,600		4.774	3,570,983,674	-	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	38,508,750	113,995.7 <del>9</del> 2
			980,000.000	617,680,000			-	0,080	276	5,577,871	197,838.000	D,00Q	920,000.000		604,624,339
			4,000,000,000	2, 3,400,000,000	2,863,842,000	3,570,963,674	<b>;</b> .	D.E02	. 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			0.000		634.097	8,900.000	D 000	3,000.000	10,425.000	3,000,000
- 4			3,150,000.000	955,000.000	406,349.000	3,570,963,674		0.114	. 391	1,647.412	219 085 000	0.000	1,430,000,000	860,563,750	1,430,000.000
			210,000,000	402,000.000	2,389,000	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:

8,486,065,000 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 Eat: (2013 Initial APQ \* 1 + FDA Eat): 5,500,000,000
IMS Eat: (2013 Initial APQ \* 1 + IMS Eat): 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 noncontrolled opiate antagonists ("nal-drugs" such as naloxone or naltrexone) for both the domestic and export markets.

Prepared by ODQ/ODEQ

8-29-13

Page 1 of 2

- 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).

## DEPARTMENT OF JUSTICE

## **Drug Enforcement Administration**

[Docket No. DEA-378]

Established Aggregate Production Quotas for Schedule 1 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 1 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-(5fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11), N-(1adamantyl)-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-tetramethyleyelopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethyleyelopropyl)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	15 g
(UR-144)	
[1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-	15 g
tetramethylcyclopropyl)methanone (XLR11)	1
1-(1-Phenylcyclohexyl)pyrrolidine	10 g
I-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45 g
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45 g
I-[1-(2-Thienyl)cyclohexyl]piperidine	15 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (IWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (IWH-073)	45 g
I-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)]indolc (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-lodo-2,5-dimethoxyphenyl)ethanamine (2C-l)	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-Methylenedioxymethamphctamine (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-Dimethylleptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	53 g
(cannabicyclohexanol or CP-47, 497 C8-homolog)	33 g
5-Methoxy-3,4-methylenedioxyamphetamine	25 g
5-Methoxy-N,N-diisopropyltryptamine	25 g
5-Methoxy-N,N-dimethyltryptamine	25 g
	2 g
Acetyl-alpha-methylfentanyl-	2 g
Acetyldihydrocodeine	
Acetylmethadol	
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)	
Aminorex	25 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentany!	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
Dípipanone	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-(I-adamantyl)-I-pentyl-IH-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
I-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	ll 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-cor 1,500,000 grams for methamphetamine mostly for conversion grams for methamphetamine (for sale)]	ntrolled, non-prescription product; to a schedule III product; and 61,375
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

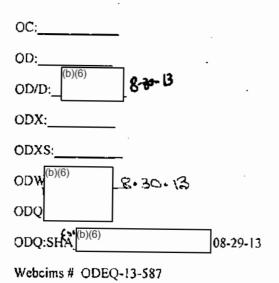
Opium (powder)	112,500 g
Opium (tincture)	625,000 g
Oripavine	22,750,000 g
Oxycodone (for conversion)	9,250,000 g
Oxycodone (for sale)	149,375,000 g
Oxymorphone (for conversion)	25,000,000 g
Oxymorphone (for sale)	7,750,000 g
Pentobarbital .	35,000,000 g
Phenazocine	6 g
Phencyclidine	19 g
Phenmetrazine	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. Havrigan, Deputy Administrator



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



To submit comments:	Send them to:
By mail	Assistant Altorney General, U.S. DOJENRD, 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, pseudoophedrine, 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 he 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)(2,2,3,3tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1H-indol-3yl](2,2,3,3tetramethylcyclopropyl)methanone (XLR11), N-(1-adamantyl)-1-pentyl-1Hindazole-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), norexymorphone (for conversion), oripavine, oxycodone (for sale), exymorphone (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, ecganine, hydromorphane, levomethorphan, lysergic acid diethylamide, metazocine, methamphetamine, dmethamphetamine (for conversion), methyldesorphine, noroxymorphone (for conversion), oxymorphone (for conversion), phencyclidine, phenylacetone, ephedrine (for conversion), ephedrine (for sale),

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

Regarding (1-Pentyl-1H-indol-3-yl)(2,2,3,3tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1H-indol-3yl)(2,2,3,3-f

yl](2,2,3,3tetramethylcyclopropyl)methanone (XLR11), N-(1-adamantyl)-1-pentyl-1Hindazole-3-carboxamide (AKB48). amphetamine (for sale), codeine (for conversion), codeine (for sale), fentanyl, hydrocodone (for sale), methylphenidate, morphine (for conversion), morphine (for sale). oripavine, exycodone (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-yi)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
1-(5-fluoro-pentyl)-1H-indol-3-yll(2,2,3,3-letramethylcyclopropyl)methanone (XLH11)	1 15
( f Dhandayalahayd) meralidina	1
I+(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	1 ""
(-(5.Fluoropeobyl):3.(2-iodohenzoyl)indole (AM694)	45
41-/2-Thienvilovclohexviloiperidine	1 15
1.42./4. Morpholipyliethyli-3-(1-paphthoyl)indole (JWH-200)	1
-Butyl-3-(1-naphthoyl)indole (JWH-073)	
-Cyclohexylethyl-3-(2-methoxyphenylacetyt)(indole (SR-18 and RCS-8)	
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	
1-Methyl-4-phenyl-4-propionoxypiperidine	1
I-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	
I-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	
I-Pentyl-3-(2-methoxyphenylacelyl)indole (JWH-250)	1
I-Pentyl-3-(4-chloro-1-naphthoyi)indole (JWH-398)	
I-Pentyl-3-(4-methyl-1-naphlhoyl)indole (JWH-122)	1
I-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	1
I-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	•
-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	] 3
2-[2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	
-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	_
-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	1
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	_
2-(4-Chloro-2,5-dimethoxyphenyl)elhanamine (2C-C)	1
2-(4-lodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	_
2,5-Dimethoxy-4-ethylamphetamine (DOET) 2,5-Dimethoxy-4-n-propyllhiophenethylamine	
2,5-Dimethoxy-4-n-propyllniopnenethylamine	
2.5-Dimethoxyamphetamine 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	
2-[4-(Ethylthio)-2,5-dimethoxyphenyljethanamine (2C-T-4)	1 3
2-[4-(Isopropylithio)-2,5-dimethoxyphenyljethaniamine (20-1-4)	
3,4,5-Trimethoxyamphetamina (MDA)	١ :
3,4-Methylenedioxymethamphetamine (MDMA)	
3,4-Mothylenedioxy-N-ethylamphetamine (MDEA)	1 '
3,4-Methylenedioxy-N-methylcathinone (methylone)	
3,4-Methylenedioxypyrovalerone (MDPV)	1 5
3,4-Methylientanyi	
2. Methyllhiofentagy	
4-Bromo-2 5-dimethoxyamphetamine (DOB)	1 -
4-Broma 2.5-dimethovyohenethylargina (2-CB)	1 4
4. Methorveronheta mine	'\
4-Methyl-9 5-dimethoxyamohelamine (DOM)	1 -
4-Methylaminorex	. 2

Basic Class—Schedule I	Established 2014 Quotas (grams)
Methyl-N-methylcathinone (mephedrone)	4
(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	6
(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohoxyl]-phenol (cannabicyclohexanol or CP-47, 497 C8-homolog)	5
Methoxy-3,4-methylenedioxyamphetamine	·2:
Methoxy-N,N-diisopropyltryptamine	2
Melhoxy-N,N-dimethyltryptamine	
celyldihydrocodgine	
celylmethadol	
lylprodine	<b>}</b> .
phacetylmethadol	
pha-ethyltryptamine	2
phameprodine	
phamethadol	
pha-methyllentanyl	
pha-methylithiotentanyl	{ 2
pha-methyltryptamine (AMT)	
enzylmorphine	· •
etacetylmethadol	
eta-hydroxy-3-methyliontanyl	
eta-hydroxyfentany	
etameorodine	
etaprodine	
utolenine	:
athinone	
odelne Methylbromide	20
esomorphice	_
etnyllryptamine	i
ienoxin	
íhydromorphine	3,990.0
methyltyptamine	1
loisanone	i
enathylline ,	70,250,0
amma-hydroxybutyric acid	
eroin	
ydroxypethidine	
ogaine	
rsergic acid diethylamide (LSD)	
arihuana	21,0
pscaline	
elhacualone	
elhcathinone	l .
ethyldesorphine ethyldihydromorphine	
ethyldihydromorphineorphine deliving a second secon	
orphine Methylsuffenate	!
orobine N-oxide	1
-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	
-Benzylpiperazine	
.N-Dimethylamphetamine	
-Fibyl-1-chenylcyclohexylamine	
-Ethylamphetamine	
-Hydroxy-3,4-methylenedioxyamphetamine	
oracymethadol	
priethadone	1
morphing the second	1
va-fluorofentany)	
rahexy	
enomorphae	
holcodine	
roperidine	
silocybin	
silocyn etrahydrocannabínols	491,0
hiofentanyl	-
liding	
imeperidine	I

, Bas		ished 20 3s (gram
Phenylcyclohexylamine		
		2,687,
		17.
mobarbital		
mphetamine (for conversion)	4	18,375,
mphetamine (for sale)	# 11/16/15/15/15/15/15/15/15/15/15/15/15/15/15/	49,000.
ocaine,	инивидительного принцения поличения	240,0
odeine (for conversion)	***************************************	68,750,
odeine (for sale)		46,125,
extropropoxyphene		
hydrocodeine	WWW. 1716.164911.1649.1649.1649.1649.1649.1649.	100,
iphenoxylate	NAMES OF THE PROPERTY OF THE P	750,
cgonine	AMINITEDIA SENTENCE PROGRAMMENTA DE CONTROL	144,
	***************************************	
entanyi	***************************************	2,108,
lutethimide		
ydrocodone (for sale)		99,625,0
	(4-1414)-(4-1414)-(4-1414)-(4-1414)-(4-1414)-(4-1414)-(4-1414)-(4-1414)-(4-1414)-(4-1414)-(4-1414)-(4-1414)-(4	6,750,
	worth Herry and the Performance of the State	
evo-alphacety(methadol (LAAM)	B / (1997) - 1941 - 1942 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 1944 - 194	
evomethorphan		
evorphanol	***************************************	2,
		23,750,
leneridine		6,250,
leperidine Intermediate-A	······································	
leperidine Intermediate-B	### ### ### ### ### ### ### ### ###	
leneridine Intermediate-C		
letazocine	***************************************	
ethadone (for sale)		31,875,
lethadone Intermediate		38,875
CHAZONO MICHICOLDIC MANAGEMENT CONTROL		
	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam	
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]	ine mos
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidale.	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]	96,750,
.250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidale	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]	96,750, 91,250,
1,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidale	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	2,811, tine mos 96,750, 91,250, 62,500, 30,
.250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidale	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500,
.250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidale	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500.
.250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidate	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidale	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamina (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidale	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidale	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidale	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidate	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500. 1,462, 112, 625, 22,750, 9,250, (49,375, 25,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidate	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500. 1,462, 112, 625, 22,750, 9,250, (49,375, 25,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidate	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate corphine (for conversion) corphine (for sale) abilione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (tincture) cipavine cycodone (for conversion) cycodone cycodone conversion) cycodone cycodon	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750, 35,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidale corphine (for conversion) corphine (for sale) abilione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (powder) conversion) coroxymorphone (for conversion) coroxymorphone (for sale) coroxymorphone (for conversion) coroxymorphone (for c	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750, 35,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate corphine (for conversion) corphine (for sale) abilione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (powder) pium (tincture) conversion) coroxymorphone (for conversion)	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, (49,375, 25,000, 7,750, 35,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate corphine (for conversion) corphine (for sale) coroxymorphone (for conversion) coroxymorphone (for conversion) coroxymorphone (for sale) coroxymorphone (for conversion)	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500. 1,462, 112, 625, 9,250, 149,375, 25,000, 7,750, 35,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate corphine (for conversion) corphine (for sale) abilione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (powder) conversion) coroxymorphone (for conversion) coroxymorphone	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]	98,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 149,375, 25,000, 7,750, 35,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate corphine (for conversion) corphine (for sale) abilione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (powder) pium (tincture) cipavine cycodone (for conversion) cycodone cycodone (for conversion) cycodone cyc	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate corphine (for conversion) corphine (for sale) abilione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (powder) pium (tincture) coroxymorphone (for conversion) cycodone cycodone (for conversion) cycodone cycodo	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 149,375, 25,000, 7,750, 35,000, 67,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidale corphine (for conversion) corphine (for sale) ablione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (powder) conversion) coroxymorphone (for sale) coroxymorphone (for conversion) coroxymorphone (for co	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750, 35,000, 3,215, 617,500,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate orphine (for conversion) orphine (for sale) abilione oroxymorphone (for conversion) oroxymorphone (for sale) pium (powder) pium (powder) pium (inclure) oroxymorphone (for conversion) oxygodone (for conversion) oxygodone (for conversion) oxymorphone (for conversion) oxymorpho	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]  1  1  1  Propo	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750, 35,000, 3,215, 67,000, 17,500,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate corphine (for conversion) corphine (for sale) gabilone coroxymorphone (for conversion) coroxymorphone (for sale) coroxymorphone (for sale) coroxymorphone (for sale) coroxymorphone (for conversion) cor	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 6 grams for methamphetamine (for sale)]  1  Class—List   Chemicals  Propo	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 7,750, 35,000, 67,000, 3,215, 6,17,500, 145,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidate corphine (for conversion) corphine (for sale) abilione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (fincture) coroxymorphone (for conversion) coroxymorphone coroxymorphone (for conversion) coroxymorphone (for conversion) coroxymorphone coroxymorphone (for conversion) coroxymorphone (for conver	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]  1  Class—List   Chemicals  Propo	96,750, 91,250, 62,500, 17,500, 1,462, 112, 625, 22,750, 49,375, 25,000, 7,750, 35,000, 67,000, 31,45,000, 145,000, 145,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 lethylphenidate corphine (for conversion) corphine (for sale) abilione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (pium (pium (for conversion) conversion) coroxymorphone (for conversion) coroxymorphone conversion) coroxymorphone (for conversion) coroxymorphone conversion) coroxymorphone coroxymorphone (for conversion) coroxymorphone coroxymorphone coroxymorphone coroxymorphone (for conversion) coroxymorphone coroxymorph	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]  1  Class—List   Chemicals  Propo	96,750, 91,250, 52,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750, 35,000, 45,000, 45,000, 45,000,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidale corphine (for conversion) corphine (for sale) abilione coroxymorphone (for conversion) coroxymorphone (for sale) pium (powder) pium (powder) pium (inclure) coroxymorphone (for conversion) cycodone (for conversion) cycodone (for conversion) cycodone (for conversion) cymorphone cycodone	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]  1  Class—List   Chemicals  Propo	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750, 35,000, 44,000, 44,800,
,250,000 grams of levo-desoxyephedrine for use in for conversion to a schedule III product; and 61,379 ethylphenidate corphine (for conversion) corphine (for sale) coroxymorphone (for conversion) coroxymorphone (for conversion) coroxymorphone (for sale) coroxymorphone (for conversion)	a non-controlled, non-prescription product; 1,500,000 grams for methamphetam 5 grams for methamphetamine (for sale)]  1  Class—List   Chemicals  Propo	96,750, 91,250, 62,500, 30, 17,500, 1,462, 112, 625, 22,750, 9,250, 49,375, 25,000, 7,750, 35,000, 3,215, 617,500,

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 angines.

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 <sup>1</sup>

### 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.
- 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 "companydirected" 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.

<sup>&</sup>lt;sup>1</sup>The Summary of Facts and Representations is based on the Applicant's representations and does not reflect the views of the Department.

							04 01
Substance	2011	2012	% Change	2013	% Change	2014*	% Change
Amphetamine (D,L)	9,703.48	10,938.95		10,928.20	-0.10%	11,921.39	
Amphetamine (D)	10,597.70	11,725.30		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 <u>.2</u> 1	75.02	-30.03%	36.22	-51.72%	6.76	-81.33%
Diphenoxyláte	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	
Fentanyi	539.85	575.07	6.53%	548.23	-4.67%	544.38	
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	
Levorphanol	0.32	1.54	378.02%	2.33	51.13%	2.53	
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	
Methadone	7,639.42	6,776.34		5,804.38		5,53 <u>1.24</u>	
Methamphetamine	13.86	14.40	3.87%	_13.09	<u> </u>	12.48	
Methylphenidate	19,212.63	19,534.84	1.68%	17,949.13	-8.12%	18,613.58	
Morphine	30,435.83	28,705.35	-5.69%	26,266.30		25,445.23	
Nalbuphine	61.42	63.60	3.55%	42.02		39.88	
Naloxone	391.27	430.32	9.98%	478.98	11.31%	497.20	<u> </u>
Naltrexone	4.56	0.00	-99.98%	0.00	-100.00%	0.00	:
Opium	84.96	81.02	-4.63%	77.44	<del></del>	77.41	
Oxycodone	70,885.82	66,702.94		60,308.91	-9.59%	59,796.79	
Oxymorphone	2,655.74	1,958.25	-26.26%			1,951.68	
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	
Pseudoephedrine	104,476.73	93,931.68	-10.09%	93,125.29	-0.86%	100,386.58	
Remifentanil	1.05	1.11	5.83%	1.16		1.20	
Secobarbital	20.78	15.67	-24.59%	11.98			
Sufentanil	0.05	0.05	-2.53%	0.05	-7.93%	0.04	-24.36%

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

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

Basic Class; 9170-B PQ Total[CM+PD]:

2,331.000

FDA Est: IMS Est:

-.059

Company	DEA NUMTI	2014 MQ Request				% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected	Exports C	alc Using CFR 30% Invent C	alt Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		2.000	2.000	9.000	702,222,000	0¢0.0	0.000	0.000		0.000	D.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	1			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 Ravised APQ:

0.000

MQ Need=PO\* 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

DIPHENOXYLATE (FOR SALE)

3

Basic Class: 9801-0 PQ Total(CM+PD):

1,104,315.000

FDA Est: .072 IMS Est: -.007

η**λ** .

Company DI	EA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PO	2013 inventory	2014 Projected Exports (	Calc Using CFR 30% Invent	Calc. Using CF	R 50% Invent	Final MO
(b)(4);(b)(7)(E)		5 000	5.000	0.000	998,926,931	0.000	0.000	0,101	0.000	-0.101	- '5	-0.101	0.000
(D)(+),(D)(1)(L)		200,000,000	151,000,000	36,960 500	998,926 931	0.037	40,659.327	53,892,000	. 0,000	-774,875		6.422.159	0,000
		97,526.000	94,776,000	58,343,393	998,926,931	D.058	64,498.698	6,032,341	72,080.000	149,695.963		161,258,877	0.000
		2.000	2,000	0.538		0.000	0 595	1.010	. 0.000	+D.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	0.000	0,000	0.000	0.000		0.000	000,0
		474,000,000		245,042.000	=	0.245		230,549,000	0.000	121,613,516		169,329,306	0.000
		810,000,000		645,039,000		0.646	713,091,440	298,686.000	95,600.000	723,932,871		849,538.050	0.000
		1,640,000	1,640,000			0.000	0.000	9,000	0,000	0.000	•	0,000	0.000
		16,000,000	18,000,000			0.004	4,930,536	17,597,000	0.000	-11,187,304		-10,319.830	0.000
		613,000	613.000	•	•	0.000		0.000	0.000	0.000		0.000	0.000
		6,500,000	6,630,000		,	0.000		0.000	500,000	500,000		500,000	D.D00
		0,000,000	0,000,000	0,000	050,520,001	2.000	•						
MQ Totals:		1,641,017.000	1,556.058.000	99 <b>8,92</b> 6.931				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=PC\* 1.5 - Revised MQ - Inventory:

-508,445,952

CFR 50%: -532,792.969

2013 Initial APO:

1,687,000.000

FDA Est = 2013 APQ \* (1 + FDA Est):

1,808,464.000

(MS Est = 2013 APO \* (1 + 1MS Est):

1,675,191.000

pending requests

82,400,00

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

0.000

FDA Est:

Company (b)(4);(b)(7)(E) MQ Totals:	DEA Num	2014 MQ Request ( 101,000,000 161,000,000	0.000 0.000	0,000 0,000	2013 Total Sales 0,000	% of 2013 Sales 0,000		014 Projected Experts C 0.000	ate Using CFR 30% Invent 0.000	Cale Using CFR 509	% invent Fi 0.000	0.000 0.000
Final Initial APQ: Proposed Revised: Final Revised APQ: MQ Need=PQ* 1.5 - Revised MQ - Inventory: 2013 Initial APQ: FDA Est = 2013 APQ * (1 + FDA Est): IMS Est = 2013 APQ * (1 + IMS Est):	0.000 110,000,000 0.000 0.000 0.000 0.000 0.000	Adjusted for (b)(	,	ial CFR 50%:	0.000							
	137,500,000	with 25% buffer										

HYDROCODONE (FOR CONVERSION)

9193-8 Basic Class: PQ Total(CM+PD):

65,322,425,000

FOA Est: IMS Est:

,015 .034

Company	DEA Num	2014 MQ Request	2814 MQ	2013 Sates	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PO	2013 Inventory	2014 Projected Exports	Cale Using CFR 30% Invent	Cale 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
(6)(4),(6)(1)(2)		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	45,068,189.355	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	\$7,602,602	12,258.000	0.000	62,625,302	69,680.752	D. 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	45,068,169,353	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	9.000	-1,751,744.255	-1,725,341.919	0.000
		24,000,000,000	22,958,367,000	18 075,428,630	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	45,068,189,355	0,913	677,535,968	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	•	0.002	150,524.518	3,645,502.000	0.000	-3,649,620,126	-3,631,383.352	0.000
NQ Totals:		79,689,445,000	56,768,511.000	45,067,568,235	i			24,539,861.044	12,200.000	60,350,358.803		0.000

11,613.551.265

Final Initial APC: Proposed Revised: 79,700,000,000

79,700,000.000 DK with pending requests

Final Revised APQ:

0.000

MQ Need=PQ\* 1.5 - Revised MQ - Inventory: 16,677,265,456

2013 Initial APO:

79,700,000,000

FDA Est = 2013 APQ \* (1 + FDA Est): 80,895,500.000

76,990,200,000 IMS Est = 2013 APQ \* (1 + IMS Est):

pending request (b)(4)

41,790,000 but really should be (for conversion)

CFR 50%:

HYDROCODONE (FOR SALE)

Basic Class: 9150-0 PQ Tetal(CM+PD);

3,313,103,000

CFR 50%:

-1,021,475.332

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 Ca	ale Using CFR 30% Invent C	ale 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	9.000	0.000	0,000,0	0.000
	30,000	30,000	2.921	3,574,775,079	0.000	2.707	49 447	0.000	-45,928	-4 <b>5.33</b> 3	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	191,828,000	128,462,930	3,574,775,079	0.036	119,059.498	35,920.698	0.000	118,858.849	145,019.408	0,000
	535,998.000	535,898 000	679,936.334	3,574,775,079	0.190	630,187.125	209,218 035	0.000	609,999.228	748,475.455	0.006
		445,000,000	334,715.000	3,574,775,078	0.094	310,213.998	251,602,000	0,000	151,676.198	219,844,248	0.000
	,	1,179,810,000		3,574,775,079	0.278	924,253,560	392,859.000	0.000	808,670,528	1,011,770,950	0,000
	.,	1,674,818,000			0.389	1,288,072.211	855,997,550	0.000	818,496.324	1,101,544.084	0.000
	220,000.000		44,542.000	•	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 Need=PQ\* 1,5 - Revised MQ - Invertory:

-1,086,879.228

2013 Initial APO:

4,775,000.000

FDA Est = 2013 APQ \* (1 + FDA Est):

5,281,150,000

1MS Est = 2013 APQ \* (1 + IMS Est):

4,604,055,000

42,065.000

2-May-14

Basic Class: 9220.
PQ Total(CM+PD):

al(CM+PO): 4 4

4,448,000

FDA Est:

IMS Est:

.084

<b>Company</b> (b)(4);(b)(7)(E)	DEA Num 2014 MQ Request 2014 MQ 2013 Sales 2013 T 2.003 2.000 0.000 3,600,003 1.598,000 1,907,000	Fotal Sales % of 2013 Sales 1,907,000 0.000 1,997,000 1.000	Share of 2014 Total PQ 0.000 4,448.000	0.000	Projected Exports Calc Usin 0 000 41,000	ng CFR 30% Invent Calc Usin 0.000 5,781,400	g CFR 50% Invent Final MC 0.000 0.000 6,035,760 0,000
MQ Totals:	3,602.000 1,600.000 1,907.000			42,000	41.000	5.781,400	0.900
Final Initial APQ: Proposed Revised: Final Revised APQ: MQ Need=PQ* 1.5 - Revised MQ - Inventory; 2013 Initial APQ: FDA Est = 2013 APQ* (1 + FDA Est); IMS Est = 2013 APQ* (1 + IMS Est);	1,603,000 3,700,000 Adjusted for (b)(4) denial 0,000 5,030,000 3,600,000 3,600,000 3,902,760	4,394.750					
	4,625 000 with 25% buffer						

LEVORPHANOL

Basic Class: 9230-0 PQ Total(CM+PD):

2,459,351,000

i

FOA Est: IMS Est:

-.28 -.113

<i>.</i>	Сотралу	DEA Num	2014 MQ Request	2014 MQ	2013 Sales .	2013 Total Sales	% of 2013	Sales	Share of 2014 Total PQ 2	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent 1	Final MQ
(b)(4);(b)(a			5.000	5,000	0.000	2,500,073,540		0.000	0.000	0,000	0.000	0.000	0.000	0.000
(0)(4),(0)(1	/(L)		4 000 000 000		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	0,000,0
			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	D.000	9,000	2,500,073,540		0.000	0.000 -	0,000	0.000	0.000	0.000	0.000
			710,000,000					0.132	323,789.612	93,082,000	95,700.000	423,544,495	489,642.785	0.003
MO Yearles			4 738 110 000	A 049 909 000	2 500 073 540					761,639.791	595,700,000	3,031,018.509		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%: -1,112,541,656

2013 Initial APO:

5,500,000.000

FDA Est = 2013 APQ \* (1 + FDA Est): 4,070,000,000

IMS Ext = 2013 APQ - (1 + IMS Ext): 4,880,150.000

pending requests

b)(4) 26,100

26,100.000

23-Apr-14

Basic Class: 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	Cate Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		131,000,000	131,000,000	0.000	47,603,753,801	0.000	0.000	0.000	- a 000	0.000	. D.000	0,000
(5)(1),(5)(1)(2)		43,480,000	43,480,000	25,980 801	47,803,753.801	0,001	2,672.611	101.581.852	0.000	-98,107,457	-91,745.689	0.000
		6,730,000,000	5.350,000,000	3,335,263,000	47,603,753,B01	0.070	343,094.168	24,303.000	3,840,950,000	4.262,669,419	5,079,330.480	0,000
		150,000,000	0.000	0.000		0.000	0.000	0.000	0,000	0.000	0.000	0.000
		44,000,000,000		35 554 556 000	47,603,753,601	0.765	3,781,348,335	12,904,910,000	0.000	-8,015,157.164	937,014.419	0.000
		5,000,000	2.875.000		47,603,753,801	0.000		69,210	0.000	-47,813	-8.636	0.000
		18,000,000,000	10,430,762,000			0.165	810 379,426	2,451,207,000	0.000	-1,397,715.045	531,214,533	0.000
		2,371,901,000	1,201,901,000		47,803,753,801	0.000	-		0.000	0.000	0.000	0.000
		1,960,000,000	0.000		47,803,753,801	0,000		• • • • • • • • • • • • • • • • • • • •		0.000	0.000	0.000
		1,900,000,000	0.003	0.000	41,002,133.001	U,UAA	0.002	5.555	2.500	.****		
MQ Totals:		73,391,381,000	61,150,018.000	47,803,753 801				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 OK with pending requests

CFR 50%:

-58,544,263,112

Final Revised APQ:

0.000

MQ Need=PQ\* 1,5 - Revised MQ - Inventory: -69,265,824.062

2013 Initial APQ:

63,000,000.000

83,000,000,000

FOA Est = 2013 APQ \* (1 + FDA Est): IMS Est = 2013 APO \* (1 + IMS Est):

63,000,000.000

pending requests

1,960,000.000 27-MAR-14 1,170,000,000 09-APR-14

MORPHINE (FOR CONVERSION)

Basic Class; PO Total(CM+PD):

40,730,343.000

FDA Est: 019 IMS Est: .031

Complify	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PO	2013 Inventory	2014 Projected Exports	Calc Using CFR 30% Invent C	aic Using CFR 50% Invent 1	FINAL MCI
(b)(4);(b)(7)(E)	DCK 115/11	5.000	5,000	0.000	35,757,656,635	0.000	0.000	0.026	0.000	-0,026	-0,026	0.000
(D)(+),(D)(1)(L)		100.000	100.000	2,195	35,757,658,635	0.000	2,500	130,578	0.000	-127.328	-126.904	0.000
		162,530,000	0.000	0.000	35.757.656.635	0.000	0.000	0.000	0.000	0.000	0.000	0.000
				52,500,080		0,001	59,801,074	157.184,176	0,000	-79,442,760	-69,307,814	0.000
		700,000,000	248,820,000			0.091	3,726,212,904	71,327,000	0.000	4,772,749,775	5,404,260,880	0.000
		6,000,000,000	4,779,867.000	3,271,287.000			14,706,467,265		/	•	18,636,374,082	0.000
		14,600,000,000	14,244,006,000	12,910,964,000		0,361	• •		0.000		0.603	0,000
		1,000,000	1,000,000	0.360	35,757,656 635	000.0	0.410				20,130,412,258	0,000
		25,550.000.000	19,333,578,000	18,047,148,000	35,757,658.635	0.449	18,278,763,830		0.000			
		1,600,000.000	703,454.000	153,724.000	35,757,656 635	0.004	175,101.834	0,000	000,0		257,308.292	
		5,400,000,000	4,200,000,000	0.000	35,757,656,635	0.000	0.000	0.020	0.000	0.002	0.000	0.000
MO Totals:		57,013,735.000	43,510,828 900	32,435,643.635				12,157,926,780	225,000.000	36,097,327.982		0.000

3.353,084.879

Final Initial APQ:

50,000,000.000

Proposed Revised:

so,000,000,000 OK with pending request

Final Revised APQ:

0.000

MQ Need=PQ\* 1.5 - Revised MQ - Inventory:

5,426,759,720

2013 Initial APCI: FOA Est = 2013 APQ \* (1 + FOA Est):

48.200,000.000 49,115,800.000

IMS Est = 2013 APQ \* (1 + IMS Est):

46,691,340.000

pending request

451,180,000 (b)(4)

2-May-14

CFR SO%;

MORPHINE (FOR SALE)

2014 Revised APQ

Basic Class: 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 PO	2013 Inventory	2014 Projected Exports	Cate Using CFR 30% Invent	Calc Using CFR 50% Invent 1	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	13,621,761.489	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	Ct 0.0	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,\$16,093	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	1,312,163.238	1,897,195,003	0.000
		480,000.000	347,037,000	91,992.000	13,621,751,480	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 Tatels:		24,082,148.000	17,749,808.000	13,621,761,480				801,297.000	0.000	5,968,809,500		0.000

Worksheels

Final Initial APQ:

18,200,000,000

Proposed Revised:

22,100,000.000 Adjusted for (b)(4)

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: FDA Est = 2013 APQ = (1 + FDA Est): IMS Est = 2013 APQ \* (1 + IMS Est):

18,200,000.000

18,200,000.000 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

Basic Class: 9143-8

PO Total(CM+PD):

82,511,169.000

FDA Est: 1MS 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	Cate Using CFR 50% Invent	Figat MO
	5.000	5.000	1,520	78,591,255.584	0,000	1.596	2.000	0.000	0.075	0.375	0.000
(b)(4);(b)(7)(E)	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	46 067 000	78,591,255,584	9,001	48,359,445	23,138,000	0,000	39,728.276	46,626.806	0,000
	20,966,000				0.000	0.000	0.000	0.000	0,000	. 0,000	0,000
	3,350,000,000				0.004	306,989.349	789,049,000	0.000	-389,962.847	-332,211.064	0.000
	24,000,000,000		14.839.041.000		0,189	15.579.171.126	14,301,862,000	88,954,000	5,040,014,464	8,970,616.157	0.000
	68.750,000.000			78,591,255.584	0,581	47,979 420 492	23,181,550,000	495,000,000	39,705,696,639	48,732,733.115	0.000
	1,000,000	1.000.000			0.011					1,261,141,100	0.000
	24.000.000.000		16,658,958,000		0.212	•	11,182,045.000		, ,	20,841,754,856	0.000
			-	•	. 0.002			•			0.000
	875,000.000	784,639,000	190,483.000	16,391,233.304	. 0.002	155,503,703	227,000,1,000	5.200	2.1,-2-11-		
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

-43,105,618,660

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

125,640.306 CFR 50%:

2013 Initial APQ;

105,200,000,000

FDA Est = 2013 APQ \* (1 + FDA Est): IMS Est = 2013 APQ \* (1 + IMS Est):

104,305,800.000

pending request

(b)(4)

14,965,000 2-May-14

OXYCODONE (FOR SALE)

Busic Class: 9739-0 PQ Total(CM+PD):

3,050,000

FDA Est: IMS Est:

.035

Company (b)(4);(b)(7)(E)	DEA Mum 2	5,000 1,232,000 5,000 5,000 1,820,000 1,540,000 5,000	2014 MQ 5.000 0.000 5.000 1,820.000 1,165.000 5,000	0.000 0.000 0.000 0.000	3 Total Sales 0.683 0.683 0.683 0.683 0.683	% of 2013 Sales 0.000 0.000 0.000 0.000 0.000	Share of 2014 Total PQ 0,000 0,000 0,000 0,000 0,000 3,050,000	0,000 0,000 0,000 2,723,000 0,000	2014 Projected Exports Ca 0.000 0.000 0.000 0.000 0.000 0.000	tic Using CFR 30% Invent C 0.000 0.000 0.000 2,723,000 0.000 3,964,167	aic Using CFR 50% Invent ( 0.000 0.000 0.000 -2,723.000 0.000 3,811,858	Final MQ 0,000 0,000 0,000 0,000 0,000 0,000
MQ Totals:  Final Initiat APQ: Proposed Revised:	3,000,000	4,607.000 djusted for (b)(4		0.683				2,723.613	0,000	1,241.187		0.000

4,700.000 Adjusted for (b)(4)

CFR 60%:

-1,911,142

Final Revised APQ: 0.000

MQ Need=PQ\* 1.5 - Revised MQ - Inventory: -1,148,813

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

Basic Class: 9050-B PQ Total(CM+PD):

25,306,205,000

CFR 50%:

-5,701,171.851

FDA 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	Cale Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MO
(b)(4);(b)(7)(E)		5.000	5.000	0.000	28,011,178.528	0,000	0,000	1.600	0.000	-1,800	-1.600	0.000
(b)(+),(b)(1)(L)		100,000	100,000	1.039	26.011.178.528	0.000	1,011	43.893	0.000	-42.579	-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	3 000
		,		•••	26,011,178.528	0.462	11,696,606,005	5,171,283,000	8,140.000	10,042,447,407	12,463,229,257	0.000
		1 ' '			26,011,178,528	0,506		5,127,800,000	D.000	11.529,704.374	14,181,635,879	0,000
		1,000,000	1.000.000		26,011,178.528	0.000		0.000	0.000	1.682	1.950	0.000
			2,554,914.000		26,011,178,528	0.027		0,000	0.000	900,059.677	1,043,352.247	0.000
MQ Totals:		40,199,105.009	33,081,197,000	26,011,178.369	•			10,755,525 693	B,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 Nead=PQ\* 1,5 - Revised MQ - Inventory:
 5,877.415,193

 2013 Initial APQ:
 39,605,000,000

2013 Initial APQ: 39,805,800.000

FDA Est = 2013 APQ \* (1 + FDA Est): 39,605,000.000

IMS Est = 2013 APQ \* (1 + IMS Est): 39,605,000.000

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

current APQ sufficient

CODEINE (FOR SALE)

Basic Class: 5501-0 PQ Total(CM+PD):

1,047,139.000

FDA Est: IMS Est: .072

	Сотраму	DEA Num	2014 MQ Request	2814 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PO	2013 Inventory	2014 Projected Exports	Cate Using CFR 38% Invent (	Calc Using CFR 50% Invent	Final MQ	•
		DEMINUM	5.000	5,800	0.000		0.000	Q.COD	0.101	0,000	-0.101	-0.101	0.000	
	(b)(4);(b)(7)(E)		200 000,000	151,000,000		998,926,931	0,037	38,743.632	53,692,000	0,000	-3,525.018	3,777,790	0.000	
-			177,178,000	-	•	998,926,931	0.058	61,159.270	6,032,341	112,080,000	185,554,710	197,082,595	0.000	,
				•	-		0.000	D.584	1,010	0.000	-0.277	-0,171	0,000	
			2.000	2.000			0.009	9,520,332	103,000	0.000	12,273 432	14.067.915	0.000	
			14,151.000	14,151,000		998,926,931			0.000	0.000	0.000	0.000	0.000	
			20,480.000	0,000		998,926.931	0.000		230,549,000		103,380,274	151,797,341	0.000	
			474,000.000	461,271.000		998,926.931	0.245					803,387,593	0.000	
			810,000,000	810,000.000		998,926.931	D.545		•		675,936.393			
			1,640.000	1,640.000	0.000	998,926.931	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		-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	D.000	0.000	0.000	,
	MO Totals:		1,714,067,001	1,636,708.000	998,926.931				606,860,457	207,680,000	962,100.248		0.000	i

 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 - leventory:
 -672,659,952

 2013 trivial APQ:
 1,687,000.000

CFR 50%: -684,912.969

2013 Ióitiki APQ: 1,687,000 000 FDA Est = 2013 APQ \* (1 + FDA Est): 1,688,464.000 IMS Est = 2013 APQ \* (1 + IMS Est): 1,667,000,000

pending requests: request grant

(b)(4) (6,600) (6,600)

new + current MQ 1,630,108

current APQ sufficient

**FENTANYL** 

Basic Class; PG Total(CM+PD):

64,310,220,000

FDA Est: -,D14 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	Cate 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	45,068,189.355	0.000	. 5.101	74.093	9.000	-57.461	-66.823	0,000
	231,000,000	175,079,000	39,742,000	45,068,189,355	0.001	56,710.020	12,258.000	0.000	61,465.025	68,565.024	0 000
	- 7,325,000	7,320.000	10,994.030	45,068,169.355	0.000	15,687.979	0.900	9.000	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	4,609,660,196	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	34,563,943,109	38,745,652,643	0.006
	3,600,000,000	1,885,910.000	148,721.000	45,066,169,355	0.003	212,218.077	2,031,970.000	D.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	25,792,811,366	3,655,635,900	0.000	29,575,018.905	33,104,235,493	0 000
	5,310,000.000	2,184,719,000	605,442.000	45,068,169,365	0.013	863,938.091	2,209,940,000	* 0.000	1,066,820,481	-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	-3,634,298,922	0.000
MQ Totals:	97,169,445,000	56,766,511.000	45,067,568.235				24,539,861,044	12,200.000	59,074,509,854		0.000

Final Initial APQ: 179,700,000.000 Proposed Revised: 79,700,000.000 0.900 Final Revised APO: 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 + IM\$ Est): 76,990,200.000 CFR 50%; 10,348,295 016

pending requests: request

18,541,633

18,541,633

new + current MQ 75,308,144

current APQ sufficient

HYDROCODONE (FOR SALE)

Basic Class; 9150-0 PQ Total(CM+PD):

3,386,794.000

FDA Est:

.072 -.036

IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 5	ales	Share of 2014 Total PO 2	2013 Inventory	2014 Projected Exports	Cate Using CFR 30% Invent	Calc Using CFR 50% Invent 1	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	9.800	0.000	0.000
(5)(4),(5)(1)(2)		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		6,000	2.767	45,447	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	148,329,601	0.000
		556,297.120	556,298.000	679,938,334	3,574,775.079		0.190	844,183,465	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	160,645.029	228,469,085	0.000
		1,390,000,000 1	1,179,810,000	997,252,000	3,574,775.079	4.7	D.279	944,811.076	392,859.000	0,000	835,395,399	1,037,467,845	0.000
		2,110,000,000 1	1,674,B18.0C0	1,389,805,400	3,574,775.079		0.389	1,316,721.888	655,997.550	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	42,199.740	31,189,000	0.000	23.670.662	32,696,175	0.000
MQ Totals:		5,043,023,120 4	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												

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

5,118,800.000 4,604,055,000

> grant request 34,438 42,065 435,182 435,182 32,289 23,351

total new

492,971

CFR 50%:

-949,661,582

new + current MQ granted 4,792,969

pending requests:

current APQ sufficient

Basic Class: PQ Total(CM+PD):

4,448.000

FDA Est:

(M\$ Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales 20	013 Total Sales	% of 2013 Sales	Share of 2014 Total PO	2013 Inventory	2014 Projected	Exports Ca	ic Using CFR 38% Invent. Calc Using CFR	: 50% Invent   F	OM Isni-
(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		0.030
Figal initial APQ:	1,600 000	1											
Proposed Revised:	3,700,000	1											
Final Revised APQ:	D.000	1							•	•			
MQ Need=PQ* 1.6 - Revised MQ - Inventory:	5,030.000	1		CFR 50%:	4,394.750								
ZO13 Initial APQ:	3,600 000	)						•					
FDA Est = 2013 APQ * (1 + FDA Est):	3,600 000	1					•						
IMS Est = 2013 APQ * [1 + IMS Est):	3,802,760	)											
											•		

(b)(4)

pending requests: request 2,002 2,002

new + current MQ granted 3,602

revised APO sufficient

• LEVORPHANOL

Basic Class: 9250-0

PQ Total(CM+PD):

18,897,110.000

FDA Est:

12	
047	

(b)(4);(b)(7)(E)	DEA Num		6,378,000,000 10,000	5,266,603 300 1,454 65,916,000 11,396,639,000	19,975,758,454 19,975,758,454 19,975,758,454 19,975,758,454	% of 2013 Sales 0 265 0,000 0,003 0,571 0,162	5,001,326,887 1,375 62,356,676 10,781,216,383	3,491,767,000 6,841 10,087,000 3,456,715,000	0.000 0.000 0.000 41,830.000		Calc Using CFR 50% Invent 4,081,592,358 -4,758 84,337,845 12,910,767,703 4,075,390,124	0,000 9,000 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: Proposed Revised: Final Revised APQ: MQ Need=PQ? 1.5 - Revised MQ - Inventory: 2013 Initial APQ: FDA Est = 2013 APQ * [1 + FDA Est]: IMS Est = 2013 APQ * [1 + IMS Est]:	25,500,000,000 25,500,000,000 0,000 -562,262,841 20,000,000,000 17,580,000,000		,	CFR 50%:	-292,60 <b>0</b> ,727							
pending requests (b)(4)	request 069,725	grant 301,736										

current APQ sufficient

new + current MQ 21,704,610

METHADONE

Worksheets

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

55,000

CFR 50%:

-17,573,275,750

FDA Est: IMS Est:

Company OEA N	m 2014 MG Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Cale Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MO
(b)(4);(b)(7)(E)	10,000	10.000	0.000	22,287,906.000	0.000	0.000	D.000	0 000	0 000	0.000	0.000
(D)(4),(D)(1)(L)	2,295,000,000	822,975,000	194,755,000	22,287,908.000	0,009	0.481	56,287,000	0,000	-66,286,375	-17,597.649	0.000
	1.5 1	-	10.780.285 000	22,287,908,000	0.484	26,602	2,170,972,000	0.000	-2, 170,937.417	\$24,132,503	0.000
				22.287,908.000		9.877	1,258,128.000	0.000	-1,258,113.160	-257,464.153	0.000
MG Jetale:	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 0.000 Final Revised APQ:

-21,317,671,500 MQ Need=PQ\* 1.5 - Revised MQ - Inventory: 26,000,000,000 2013 Initial APQ:

FOA EM = 2013 APQ \* (1 + FDA Est): 26,000,000.000 IMS Est = 2013 APQ \* (1 + IMS Est): 26,000,000,000

pending requests

request

grant

1,224,277

new + current MO

1,739,261 19,046,646

current APQ sufficient

METHADONE-INTERMEDIATE

Sasic Class: 4,917,510.000 PO Total(CM+PD):

2014 Revised APQ Workshoots

FOA Est: IMS Est:

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2015 Total Sales	% of 2013 Sales	Share of 2014 Yotal PO	2013 Inventory	2014 Projected Exports	Cate 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	25,980.601	47,803,753.601	0.001	2,672.611	101,581,652	0,000	-98,107,457	91,745.888	D.000
		6,730,000.000	5,350,000,000	3,335,263.000	47,603,753,801	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	47,603,753.601	0.000	0.000	0.000	0.000	9.000	- 0.000	0.000
		44,000,000.000	44,000,000,000	36,564,556.000	47,603,753,BC (	0.765	3,761,348.335	12,904,910,000	0.000	-8,015,157,164	937,914.419	D.000
		5,000,000	2,875.000	160,000	47,803,753.601	0,000	16.459	69.210	0.000	-47.813	-B.636	0.000
		15,500,000.000	15,500,000.000	7,877,794.000	47,803,753.601	0.165	B10,378.426	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	47,803,753,801	0.000	0,000	0.000	0.000	0.000	0.000	0.000
		1,960,000.000	1,960,000,000	0,000	47,803,753 801	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	-5,249.358.062	-	0.000

CFR 50%:

-66,743,591,112

Final Initial APQ: 73,000,000.000 Proposed Revised: 73,000,000.000 Final Rayland 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

no pending requests to consider equest granted on 7-16-14

Basic Class: 9300-8 PQ Total(CM+PD):

42,569,500,000

FDA Est:

- 083 - 031

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 201	3.Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports Cal	c Using CFR 30% Invent. Cak	c Using CFR 50% Invent   F	OM Isni
(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
(2)(1);(2)(1)(2)		100,000	. 100,000	2,195	35,757,658.635		0,000	2.613	130.576	0.000	-127.181	126,763	0.000
		162,630,000	0.000	0.000	35,767,656.635		9 000	0,000	0.000	0,000	0.000	0.000	0,000
		700,000,000	. 248,820.000	52,500,080	35,757,658 635		0.001	62,501,360	157,184,176	0,000	-75,932,409	-65,932,457	0.000
		1,692,000,000	0.000	3,322,313,000	35,757,656.635		0.093	3,954,857.385	1,260,216,000	0.000	3,881,096,600	4,493,850,981	0.000
.]		3,067,667.000	4,779,667,000	3,271,287.000	35,757,656,635.		0 091	3,894,468,068	71,327,000	0.000	4,991,481,488	5,614,579.835	0.006
		14,600,000.000	14;244,006.000	12,910,984.000	35,757,658,635	V	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	٠.	0.004	. 153,008,464	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	i				13,438,142,780	225,000,000	42,127,207.220		0,000
Final initial APQ; Proposed Revised;	50,000,000,000 50,000,000,000												

Final Revised APQ: 0.000
MQ Necd=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

pending requests: request gr

(b)(4)

451,180 - 96,471 1,692,000 1,692,000 (1,692,000) (1,692,000) CFR 50%:

5,202,318.379

total new granted

96,471

new grant + current MQ 43,607,299 -

current APQ sufficient

MORPHINE (FOR SALE)

Basic Class: 9630-0 PQ Total(CM+PD):

1,247,154,000

FDA Est:

IMS Est:

Company (b)(4);(b)(7)(E)	DEA Num		35,000,000 430,000,000	21,054,000 365,600,000	013 Total Sales 386,654,000 386,654,000 386,654,000	% of 2013 Sales 0.054 0.000	67,909,760 1,179,244,240	2013 Inventory 201 14,352.000 173,187.000 0.000	4 Projected Exports Calc 6.000 6.000 0.000	Using CFR 30% Invent 0 73,930.688 1,359,930.512 0.000	Cate Using CFR 50% Invent 75,798,700 1,392,268,300 0,000	0.DC0 0.DC0
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: Proposed Revised: Final Revised APQ: MQ Need=PQ* 1.5 - Revised MQ - Inventory: 2013 Initial APQ: FDA Est = 2013 APQ * (1 + FDA Est): IMS Est = 2013 APQ * (1 + tMS Est);	500,000,000 500,000,000 624,000,000 1,183,192,000 1,030,000,000 1,030,000,000 1,030,000,000			CFR 50%:	968,067.000			·	ena en			

previously den	led:
(b)(4)	

requested granted 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

**OPIUM TINCTURE** 

9330-0 Basic Class: PQ Total(CM+PD):

5,977,005.000

FDA Est:

Company	DEA Num	2014 MQ Request	2614 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Investory	2014 Projected Exports	Calc Using CFR 30% Invent C	ale Using CFR 50% Invent	Final MQ
		5,000	5.000	0.000	13,621,761,480	0.000	0.000	0.000	0.000	0.000	0.000	0.000
(b)(4);(b)(7)(E)		1.100.000.000				0.047	280,597,699	3,167,000	0.000	361,610.009	507,452.624	0.000
		.,,	1,674,318,000			0.013	78,323.743	253,484 000	0.000	-151,663.134	-110,953.821	0,000
		13,900,000,000				0.745	4,452,131.875	69,282,000	0,000	5,718,489,437	8,032,516.093	C.000
			3.283.650.000			O. 18B	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			0.007	40,364.577	0.000	0.000	\$2,473.950	73,453,722	0,030
		700,000,000	-	-		0.000	0.000	324,264,000	0.000	-324,254,000	-324,264.000	0.000
		430,000.000	430,000.000	0.000	13,821,761,480	0.000	0.000	0.000	0.000	0.000	9.000	0.000
MQ Totals:		J 24,297,148,000-	18,179,608.000	13,621,761.480	ı			801,297,000	0.000	6,968,809,500		000
Final Initial APQ:	18,200,000.00	0									•	
Proposed Revised:	22,100,000.00	0										
Final Revised APO:	24,500,000,00	o										

IMS Est = 2013 APQ \* (1 + IMS Est):

FDA Est = 2013 APQ \* (1 + FDA Est):

2013 Initial APQ:

pending requests:

requesting

CFR 50%:

-8,104,408.380

3,167,702 3,167,702 1,966,350 1,966,350

5,134,052 Total new grant 5,134,052

18,200,000,000

18.200,000.000

18,200,000.000

total new + current MD granted 23,313,860 5% buffer for possible other request

MQ Need=PQ\* 1.5 - Revised MQ - Inventory: -10,015,597,500

Estimated total MQ need 24,479,553 (round up for APQ)

Adjusted APQ with 25% buffer 30,625,000

**ORIPAVINE** 

Rasic Class: 9143-B PQ Total(CM+PD):

93,930,326,000

CFR SD%:

-28,831,872,410

FDA Est: - 09 1M9 Est: -.009

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Şales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PQ	2013 Inventory	2014 Projected Exports	Cate 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	0.200	0.000	0 000	0,000	0,000	0.000
		60 000	80,000	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	49,429 813	57,192.705	0,000
		20,966,000	000,000,3	9.000	78,591,255.584	0.000	0.000	0 000	0.900	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	9,189	17,735,255,001	14,301,862,000	88,954.000	6,842,923.502	11,565,921,002	0.000
		68,750,000.000	54,131,406.000	45,700,030,000	78,591,255,584	0.581	54,619,548.210	23,161,550,000	495,000,000	48,338,860.074	57,032,890.263	0,000
		1,000.000	1,000,000	866,355.240	76,591,255.584	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	24,000.009.000	16,656,858.000	78,591,255.584	D.212	19,907,876,897	11,182,045.000	6,000,000.000	20,698,194.967	23,867,018.122	0.000
		B20,000.000	784,539,000	190,483.000	78,591,255.564	0.002	227,660.573	\$37,901.000	5.000	-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	6,583,954,000	78,604,613.994		0.000

Final Initial APQ: 119,500,000,000 119,500,000.000 Proposed Ravised: Final Revised APQ: 0.000 MQ Need=PQ\* 1.5 - Revised MQ - Inventory: -24,996,904.806

2013 Initial APQ: 105,200,000 000

FDA Eut = 2013 APQ \* (1 + FDA Est): 95,732,000.000 IMS Est = 2013 APQ \* (1 + IMS Est): 104,305,800,000

> pending requests request grant 14,966 14,956 1,529,665 1,126,780 35,361 1,141,746 new grant

new + current MQ granted 116,945,376

current APQ sufficient

OXYCODONE (FOR SALE)

Basic Class: 9652-A PO Total(EM+PD):

2,059,663,000

FDA Est: IVIS Est:

Company	DEA Num	2014 VQ 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	Cald 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	0 608	1,665,050,437	1,579,762.000	0,000	584,803,569	2,076,693.047	0,000
(0)(4),(0)(1)(2)		2.751.000.000	2,751,000,000	1,493,218.000	7,793,786,000	0.192	394,612.563	269,580,000	0.000	243,316.331	596,690.203	0.000
			2,499,000.000			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	ı			1,849,442.000	0.600	828,119.990		0.000
Final Initial APQ:	20,000,000.000										•	
Proposed Revised:	20,000,000.000											
Final Revised APO:	0.000											
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-15,309,947 500			CFR 50%:	-13,676,416,750							
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				-							

no pending requests to consider

current APO sufficient

Basic Class: 9852-5
PQ Total(CM+PD):

3,153,648.000

5,754,100.000

FDA Est: IMS Est: -.185 .046

Company	DEA Num	2014 MQ Request	2014 MQ	2013 Sales	2013 Total Sales	% of 2013 Sales	Share of 2014 Total PO	2013 Inventory	2014 Projected Exports	Cate Using CFR 30% Invent	Calc Using CFR 50% Invent	Final MQ
(b)(4);(b)(7)(E)		5.000	5,000	0.000		0.000	0.000	0.007	0.000	-0.007	-0.007	0.000
(5)(4),(5)(1)(2)		60,000	60,000	4 211		0.000	3.884	215.868	0.000	-211,079	-210,210	0.000
		143,000,000		_		0.002	7,716.595	23,682,000	0.000	-13,650,427	-11,831,257	0,000
		980,000.000		-	•	0,115		211,218,000	0 000	259,234,333	344,548.262	0.000
			2.810.698.000			0,777		1,132,591,000		2,054,480,641	2,632,438.462	2,000
		3,000.000				0,012			0.000	12,700,467	21,348,922	0.000
			1,183,734,000	•		0.092			0.000	65,154,954	133,321,244	0.000
1		210,000,000		•		0.002			0.000	•	-285,671.564	0,000
		210,000.000	E ID, DOD GOD	r,205.000	0,001,002.011	0.002	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					
MQ Totals:		6,591,065,000	4,962,035.000	3.634,592,671				2,009,264,165	0.000	2,090,478.235		0.000
Final Initial APQ:	8,200,000.00	0										
Proposed Revised:	6,200,000.00	o .										
Final Revised APQ:	0.00	0										
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-2,240,827,16	5		CFR 50%;	-2,128,091,147							
2013 Initial APQ:	5,500,000.00	٥										
FDA Est = 2013 APQ * (1 + FDA Est):	4,482,500.00											

no pending requests to consider

IMS Est = 2013 APQ \* (1 + IMS Est):

(b)(4) cquest granted on 7-18-14

## Aggregate Production Quotas (all values are in grams unless Indicated otherwise)

Controlled Substance	Final Revised	Final Revised	Final Revised	Initial 2014	Proposed
	2011	2012	2013		Revised 2014
•	1 !				
Schedule I:					
Psilocybin	j ?ı	. 2	10,	30	ຸ 30
Psilocyn	2	2	12		. 30
Schedule II:	i	·	i		
Diphenoxylate	730,000	900,000	887,500	750,000	1,288,750
Ecgonine	83,000	83,000	144,000	144,900	174,379
Hydrocodone (for conversion)	0	. 0	0.	0	137,500
Levorphanol	3,600	3,600	4,500	2,000	4,62
Dripayine	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
Remifentanii	2.500	2,500	3,750	3,750	5,875
	<del>.</del> 1			•••	
grand the second of the second		:			ŧ
MATER.	: :		÷ ,=		
NOTES: As of 2013 CII values have a 25% buffer added to the calculated L	S reculrements:				-

### 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 redelegated this responsibility to the Deputy Administrator of the DEA.
- The attached Federal Register notice, prepared for your signature, proposes to adjust the calendar
  year 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 i 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 OD/ODQ/ODEQ 5/12/14 Page 1 of 2

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.

### 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 <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Paper comments that duplicate electronic submissions are

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

**FOR FURTHER INFORMATION CONTACT:** 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 <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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

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

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

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

### Legal Authority

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

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 <i>H</i> -indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15	No change
[1-(5-Fluoro-pentyl)-1 <i>H</i> -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- <i>n</i> -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)- <i>N</i> -(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)- <i>N</i> -(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)- <i>N</i> -(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- <i>n</i> -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- <i>N</i> -ethylamphetamine (MDEA)	40	No change
3,4-Methylenedioxy- <i>N</i> -methylcathinone (methylone)	50	No change
3,4-Methylenedioxypyrovalerone (MDPV)	35	No change
3-Fluoro- <i>N</i> -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- <i>N</i> -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- <i>N</i> -ethylcathinone (4-MEC)	15	No change
4-Methyl- <i>N</i> -methylcathinone (mephedrone)	45	No change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15	No change
5-(1,1-Dimethylheptyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-3-hydroxycyclohexyl]-phenol	68	No change
5-(1,1-Dimethyloctyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-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- <i>N</i> , <i>N</i> -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
<i>alpha</i> -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-1H-indazole-3-carboxamide (AKB48)	15	No change
<i>N</i> -(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (ADB-PINACA)	15	No change
<i>N</i> -(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1 <i>H</i> -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
<i>N</i> -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 <i>H</i> -indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15	No change
Quinolin-8-yl 1-pentyl-1 <i>H</i> -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	l l	
1-Phenylcyclohexylamine	3	No change
1-Piperidinocyclohexanecarbonitrile	3	No change
4-Anilino- <i>N</i> -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 Chemica	ıls	
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.

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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 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

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 reducted 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 quotes, 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 yearend 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 quotes 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-1H-indol-3-yl)(2,2,3,3-letramethylcyclopropyl)methanone (UR-144)	15	No change.
/1./5-Fluoro-nentyl)-1/-indol-3-vi)/2.2.3.3-telramethylcyclopropyl)methanone (XLHT1)	15	No change,
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15	No change, 🗸
1-(1,3-Benzodioxol-5-yt)-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-Fluoropenty }-3-(2-iodobenzoyl)indola (AM694)	45	No change.
1-[1-(2-Thienyl)cyclohexyi piperidine	15	No change.
1-[2-(4-Morpholinyl)ethyl[-3-(1-naphthoyl)indols (JWH-200)	45	No change.
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45	No change.
1-Cyclohexylethyl-3-(2-mathoxyphenylacetyl)indole (SR-18 and RCS-8)	45	No change.
1-Cyclonexyleinyi-3-tz-meinoxyonenyiacetyiintolle (3A-18 allo 103-8)	45	No change.
1-Hexyl-3-(1-naphthoyl)indole (JWH-019) 1-Methyl-4-phenyl-4-propionoxypiperidine	2	No change.
1-Methyl-4-phenyl-4-propionoxypiperione	45	No change.
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM578)	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)	30	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-Dimelhoxy-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)	15	No change.
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi- 36).		No change.
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	
2-(4-Chloro-2,5-dimethoxyphenyt)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-92)	15	No change.
2.44 lade 2.5 dimethey-pheny() other amine (2C-1)	30	No change.
2.(4-lodo-2.5-dimethoxyohenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15	No change.
2.(Methylamino)-1-phenylpentag-1-one (pentedrone)	15	No changes
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)
,5-Dimethoxyamphelamine	25	No change.
-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30	No change.
-[4-(Isopropylthio)-2.5-dimethoxyphenyllethanamine (2C-T-4)	30	No change.
4,6-Trimethoxyamphetamine	25	No change.
4-Mothylenedioxyamphetamine (MDA)	55	No change.
4-Methylenedioxymethamphetamine (MDMA)	50	No change.
4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	No change.
4-Methylonedioxy-N-methyloathinone (methylone)	50	No change.
4-Methylenedioxypyrovalerone (MDPV)	35	No change.
-Fluoro-N-methylcathinone (3-FMC)	15	No change.
-Methylfentanyl	2	No change:
-Methylthiolentanyl	2	No change.
-Bromo-2,5-dimethoxyamphetamine (DOB)	25	No change.
-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	No change.
-Fluoro-N-methylcathinone (4-FMC)	15	No change.
-Methoxyamphetamine	100 25	No change.
-Methyl-2,5-dimethoxyamphetamine (DOM)	25 25	No change.
-Mothylaminorex	15	No change:
-Methyl-Methylcathinone (4-MEC)	45	No change.
-Methyl-N-methylcathinone (mephedrone)	15	No change.
-Methyl-a-pyrrolidinopropiophenone (4-MePPP)	13 68	No change.
-(1,1-Dimethylheptyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-3-hydroxycyclohexyl]-phenol (cannablcyclohexanol or CP-47,497 C8-homo-41,1-Dimethyloctyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-3-hydroxycyclohexyl]-phenol (cannablcyclohexanol or CP-47,497 C8-homo-	53	No change.
log). -Methoxy-3,4-methylenedioxyamphetamine	25	No change.
-Methoxy-N,N-diisopropyltryptamine	25	No change.✓
-Methoxy-N,N-dimethyltryptamine	25	No change.
cetyl-aipha-methylientanyi	2	No change.
ocelyldihydrocodeina	2	No change.
cetylmethadol	2	No change.
Mypredine	2	No change, 🗸
Iphacetylmethadol	2	No change.
ipha-Ethyliryptamine	25	No change.
phameprodine	2	No change.
Iphamethador	2	No change.
Ipha-Methylfentanyl	2	No change.
Ipha-Methylthiofentanyl	2	No change.
ipha-Melhyltryplamine (AMT)	25	No change.
ipha-Pyrrolidinobutiophenone (α-PBP)	15	No change.
ipha-Pyrrolidinopentiaphenone (α-PVP)	15	No change.
minarey	25	No change.
enzylmorohine	2	No change
etacety/methadol	2	No change. 🗸
eta-Hydroxy-3-methyllentanyl	2	No change.
eta-Hydroxylentanyl	2	No change.
etameoroding	2	No change.
ntapyndine	2	No change.
lutotecine	3	No change.
Pathing ne	70	No change.
Codeine methylbromide	5	No change.
Odelne-N-oxide	200	No change.
esomorphine	5	No change.
vielhyitryptamine	25	No change.
ifenoxin	50	No change.
ihydromorphine	3,990,000	No change.
imethyltryptamine	35	No change.
ligicanone	5	No change.
enethylline	5	No change.
amma-Hydroxybutyric acid	70,250,000	No change.
eroin	25	No change.
lydromorphinol	1 2	No change.
ydroxypethidine	2	No change.
ogalne	5 i 35	No change.
ysergic acid diethylamide (LSD)		No change
farihuana	650,000	No change.
Aescaline	25	No change.
Methaqualone	10 25	No change.
Methcathinone	25	No change.✓ No change.✓
Aethyldesorphine Aethyldihydremorphine	4	No change.
	. 2	1 MO GRANGE, V

1/4 Ammos 2-6 monthly - percent - 1-4 Ammos 2-6 monthly - 1-4 Ammos 2-6 mo	Depther Novide   10   10   10   10   10   10   10   1	Basic class	Previously established 2014 quotas (g)	Proposed adjusted 2014 quotas (g)	
1	orphine-Novicle (1-Adamanyl)- perily1-H-indezole-3-carboxamide (ARH45) (1-Adamanyl)- perily1-H-indezole-3-carboxamide (ARH45) (1-Adamanyl)- perily1-H-indezole-3-carboxamide (ABP-INMCA) (1-Adamanyl)- perily1-H-indezole-3-carboxamide (ABP-INMCA) (1-Adamanyl)- perily1-indezole-3-carboxamide (ABP-INMCA) (1-Adamanyl)- perily1-indezole-3-ca	orphine methylsultonate	<u>.</u> <u>5</u>	1	
(1 Annio-3-dimethyl-1-soculars-2-yi)-i-penyl-1/Hindacoi-3-carboxanide (AB-PUBINACA)   15   16   16   17   17   17   17   17   17	(f.1.Amico_3.5 dimethyl-1- sobutan-2-yl-1- pentyl-1 /f-hidazole-3-carboxanide (ADB-PIRNACA)   15   No change   15   No chan	amhine-Mayide			
(1. Amino-3-methyl-1 coobutan-2-yi) - 1. (4-incrobensyl-1 h-indazola-3-carboxanida (AB-FUBINACA)   10		-(1-Adamantyl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide (AKB48)			
A Change	AbDinethylamphitaminn	-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)			
Seary   Sear	Isah hiypiyrovalenon (Isahyrone)   15   No change   15	-{1-Amino-3-methyl-1-oxobutan-2-yl}-1-(4-fluorobenzyl}-1H-indazole-3-carboxamide (AB-FUBI)	IACA)		
Sensity     Sens	Valenty   Internation   25   No. change   25   No. change   26   No. change   26   No. change   26   No. change   26   No. change   27   No. change   28   No. change   29	,N-Dimethylamphetamine			
Chylin phenglychonylamn	Section   Commons   Section   Sect	aphthylpyrovalerone (naphyrone)			
Entry in the Property of the Company of the Compa	Yes	-Benzylpiperazine			
No. change	Penylycyclohaylamine	-Ethyl-1-phenylcyclohexylamine			
No change	No change	-Ethylamphetamine	-		
	Schedule   1	-Hydroxy-3,4-methylenedioxyamphetamine	***************************************		
2   No change   1   No change   2   No chang	Commentation	oracymethadol			
18   No change	18	orleverphanol			
2	Schedule   1	omethadone			
	Schedule	omorphine			
Inchange	No change	ara-Fluorofentanyl			
henomorphan henomo	Phenomorphan	arahexyl		_	
No change	2   No change.   30   40   7   7   7   7   7   7   7   7   7	hegomorphan	2		
30   40   50   50   50   50   50   50   5	10   10   10   10   10   10   10   10	holcodine			
Schedule   1	Schedule   1	roperidine			
		eilambia			
Unionity   1 (-5 fluoropenty)   1 (f) fluoropenty	No change   No c	silocup			
uinolin-9-yi i-pentyl-1 I-findole-3-carcoxylate (PB-22 QUPIC)         491,000         No change-to the change-to th	No change   No c	winolin-8-v) 1-/5-fluoronentyl)-1//-indole/3-carboxylate (5-fluoro-18-22; 51-118-22)	.,		
Schedule   1	No change	minolin-8-vt 1-nentyl-1 H-indole-3-carboxylate (PB-22; QUPIC)			
	Phenylcyclohexylamine	etrahydrocannabinols			
Phenylcyclohexylamine	Phenylcyclohayylamine	hiofentanyl			
Schedule   I	Phenylcyclohexylamine   3   No change.	dine			
Phenylcyclohoxylamine	Phenylcyclohexylamine   3	rimeparidine		No changes	
Prepricting cycloritox an ecatronitrile	Prepriety control programme   3				7
Piperiolinocyclohoxaneachonitry    Anilino. N-phenethy -4-piperidine (ANPP)   17,625   No change.	Piperidinocyclohoxanecatronitrile	-Phenylcyclohexylamine			
Adillion-Michenethyl-Apiperidine (ANPP)	Anillino - A-phenethyl-4-piperidine (ANPP)	Pineridingcyclohexanecarbonitrile			
Ilentanii   1,025   No change.   1,025   No chang	Allentanii	Apiling Mahanethyl-4-ninetidine (ANEP)	2,00/,000		
Iphaprodine	Alphaprodine	lientanii	17,625		
Mochange	Amobarbital 18,375,000 No change. Morphetamine (for conversion) 18,375,000 No change. Morphetamine (for sale) 240,000 No change. Morphetamine (for sale) 240,000 No change. Morphetamine (for conversion) 240,000 No change. Morphetamine (for sale) 240,000 No change. Morphetamine (for sale) No chang	Inhantedine			
Impletamine (for conversion)         48,000,000         No change.           mphetamine (for sale)         240,000         No change.           octaine         240,000         No change.           octaine         68,750,000         No change.           odeline (for sale)         46,125,000         No change.           odeline (for sale)         100,750         No change.           intydrocodeine         100,750         No change.           intydrocodeine         750,000         1,88,750           intydrocodeine         2,108,750         No change.           intydrocodeine         2,108,750         No change.           intydrocodeine         2,108,750         No change.           intydrocodeine         144,000         174,375           No change.         No change.           intydrocodeine (for conversion)         99,825,000           intertuined (for sale)         99,825,000           intertuined (for sale)         No change.	Amphetamine (for conversion) Amphetamine (for sale) Amphetamine (for sale)  Dariontami  Cocaine  Codeine (for conversion)  Dodeine (for conversion)  Dodeine (for sale)  Destropropoxyphene  Dihydrocodeine  Diphenoxylate  Cogonine  Entlany  Silutethimide  Pentanyl  Silutethimide  Divdrocodone (for conversion)  Silutethimide  Divdrocodone (for sale)  Pentanyl  Silutethimide  Divdrocodone (for sale)  Divdrocodone (for sal	mobadatal	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1 1 2 2 2	
Marchanine (for sale)	Amphetamine (for sale)  Cardentanil  Cardentanil  Cocarien  Codeine (for conversion)  Codeine (for sale)	mohetamine (for conversion)	10,070,000		
Agricultarial   Coloration	Carientanii	mohetamine (for sale)	48,000,000		
	Cocaine   Coca	ariontanil	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1	
todeline (for conversion) dodeline (for sale) extropropoxyphene inhydrocodeine intermodiate- toperatione literatione literatio	Codeine (for conversion)   State   Codeine (for sale)   Codeine (for sale)   State   Codeine (for sal	actine	240,000		
rodeline (for sale) 48,753,000	Destropropoxyphene   100,750   No change.	odeine flot conversion)			
rektropropoxyphene inhydrocodeine 100,750 No change. 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,280,788,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750	Dextropropoxyphene   100,750   No change.   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750   1288,750	Adding (for cala)	46,125,000		
hitydrocodeline 750,000 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,288,750 1,	Dihydrocodeine	Auding (III Sale)		No change.	
piphenoxylate 734,000   174,375   174,375   No change. Stutylinorphine 2,108,750   No change. No change. No change. Stutethimide 9,6750,000   99,625,000   No change.	Diphenoxylate	extropropasymete	100,750		
cgonine thylmorphine entanyl Slutethimide (or conversion) Slutethimide (or conversion) Sydrocodone (for conversion) Sydrocodone (for sale) Sydrocodone Sydrocodone (for sale) Sydrocodone Sydroc	September   Sept		750,000	1,288,750 🗸 🐪 🗅	
thylmorphine entanyl 2,108,750 No change had by the change of the change	thylmorphine -Entanyl -Intermediate-A Meperidine Intermediate-A Meperidine Intermediate-A Meperidine Intermediate-A Meperidine Intermediate-C Metazocine Methadone (for sale) Mo change.  2,108,750 No change.	ipitelioxytate	144,000	174,375 🗠 🕠	9 5
entanyl  Silutethinide  Silutethinidehinide  Silutethinidehinide  Silutethinidehinide  Silutethinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinidehinid	Sentany	Cyclinia		No change.≅	-
Silutethimide (137,500 Victoredone (for conversion) (137,500 Victoredone (for sale) (137,500 V	Silutethimide dydrocodone (for conversion) dydrocodone (for sale) dy	Edding thing	2,108,750	No change.	
interinrinde (for conversion) 99,625,000 (6,750,000 No change.) No change. No	137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,500   137,	Citally:		No change.✓	
lydrocodone (for sale) lydromorphone somethadone evo-alphacetylmethadol (LAAM) evo-alphacetylmethadol (LAAM) evo-phanol sidexamitetamine evorphanol sidexamitetamine eperidine Intermediate-A deperidine Intermediate-B detazocine detazocine detazocine detadone (for sale)  Methadone Intermediate detapone (for sale)  Methadone Intermediate  Methadone Intermediate  Methadone (for sale)  Methadone Intermediate  Methadone Intermed	hydrocodone (for sale)  hydromorphone  somethadone  evo-alphacetylmethadol (LAAM)  evomethorphan  evomethorphan  evomethorphan  evorphanol  isdexamfatamine  deperidine  deperidine Intermediate-A  Meperidine Intermediate-A  Meperidine Intermediate-B  Meperidine Intermediate-C  Metazocine  Methadone (for sale)  99.625,000  No change.  No change.  4,625  No change.	//// / / / / / / / / / / / / / / / / /	l ō	137,500 ✓ \	w.
lydrococonic (for sale)   6,750,000   No change	Hydrococone (for sale)  6,750,000 No change.   5 No change.   195 No change.   195 No change.   195 No change.   195 No change.   196 No change.   197 No change.   198 No change.   199 No change.   190 No chang	ygrocopone (for conversion)			
systemotroprotes evo-alphacety/methadol (LAAM) evomethorphan evomethorph	No change. ✓ somethadoneevo-alphacety/methadol (LAAM)evorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanolevorphanol	ygrococone (for said)	6.750.000		
someinadorie vevo-alphacety/methadol (LAAM)  evo-alphacety/methadol (LAAM)  evo-alphacety/methadol (LAAM)  evo-alphacety/methadol (LAAM)  195  2,000  4,625  No change.	Someinadorie de la composición del la composición del la composición de la composición de la composición del la composición de la composición del la composición d	iyaromorphone			
evoraphacetymentation (CAW) evorphanol evorphanol isdexamfetamine deperidine deperidine Intermediate-A deperidine Intermediate-B deperidine Intermediate-C detazocine detazocine dethadone (for safe) dethadone Intermediate dethadon	Levo-aphracetymetriation (CASM) Levo-aphracetymetriation (CASM	iomethadone	1 4		
evorphanol sidexamfetamine deperidine deperidine Intermediate-A deperidine Intermediate-A deperidine Intermediate-B deperidine Intermediate-C detazocine detazocine detazocine detazocine detazocine dethadone (for sale) dethadone Intermediate dethadone Intermediate dethadone Intermediate dethadone Intermediate dethadone of the sale of the sal	Leverphanol	evo-alphacetylmethadol (LAAM)	195		
everpriation leperidine   11	Leverprand) Leverp	evomethorphan	2 000		100
Activishes intermediate    Separation   Sepa	Algoridine 6,250,000 No change.  Meperidine Intermediate-A 11 No change.  Meperidine Intermediate-B 6 No change.  Meperidine Intermediate-C 19 No change.  Methadone (for sate) No change.  Methadone Intermediate 38,875,000 No change.	evorphanol		1.: . /	
Mo change.  No change.	Meperidine Intermediate-A Meperidine Intermediate-B Meperidine Intermediate-B Meperidine Intermediate-C Metazocine Methadone (for sale) Methadone Intermediate  10 No change. No change.  31,875,000 No change. No change.	isdexamistamine	6 250 000	1	
Methadone Intermediate-B Methadone (for safe) Methadone Intermediate Methadone Intermediate Methadone Intermediate Methadone (for safe) Methadone Intermediate M	Adepending Intermediate-A  Althogonic Intermediate-B  Acperiding Intermediate-C  Actazocine  Actazocine  Actazocine  Actazocine  Actazocine  Actazocine  31,875,000  No change.  No change.  38,875,000  No change.	leperidine	6,230,000		
tetazocine	Methadone (for sate)  Methagone Intermediate  19 No change.  31,875,000 No change.  Methadone Intermediate  38,875,000 No change.	teperidine Intermediate-A	11		
No change.  19 No change.  Methadone (for sale)  Methadone Intermediate  Mo change.  No change.	Metazocine (for sale)	leperidine Intermediale-B			
Methadone (for sale)  Methadone Intermediate  Methadone Intermediate  Methadone Intermediate  Methadone Intermediate  Methadone Intermediate  Mo change.  No change.	Methadone (for sale)	teperidine Intermediate-C	. 10		
### defadone Intermediate	wernacone (or sale) 38,875,000 No change.	letazocine	21.875.000		
Acthorherinate 2,B11,375 No change.  2,B11,375 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)]		lethadone (for sale)	98 875 000		
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)]  Authylphenidate 96,750,000 No change.		Methadone Intermediate			
for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  Authylphenidate 96,750,000 No change.	yeinamphetamine	· · · · · · · · · · · · · · · · · · ·		!	
Aethylphenidate 96,750,000 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	1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription productions and \$1,375 grams for methamphetamine (for sales)	et; 1,500,000 grams for methan	phetamine mostly	
			40 950 000	No shoess	
I of ded don't ble sheeps 1/	Methylphenidate	Methylphenidate		No change.	

Basic class	Previously established 2014 quotas (g)	Proposed adjusted 2014 quotas (g)	
Morphine (for sale) Nabitione Noroxymorphone (for conversion) Noroxymorphone (for sale) Opium (powder) Opium (fincture) Oripavine Oxycodone (for conversion) Oxycodone (for sale) Oxymorphone (for conversion) Oxymorphone (for conversion) Oxymorphone (for sale) Pentobarbital Phonazocine Phencyclidine Phenmetrazine Phenylacetone Racemethorphan Remifentanil Secobarbital Sufentanil Sufentanil Tapentadol Thebaine	62,500,000 30,375 17,500,000 1,262,500 112,500 625,000 22,750,000 9,250,000 7,750,000 35,000,000 6 19 3 67,000,000 3,750 215,003 6,255 17,500,000 145,000,000	No change.	),9 <b>0</b> G
List I Chemicals	<u> </u>		
Ephedrine (for conversion)  Ephedrine (for sale)  Phenylpropanolamine (for conversion)  Phenylpropanolamine (for sale)  Pseudoephedrine (for conversion)  Pseudoephedrine (for sale)	1,000,000 3,000,000 44,800,000 5,300,000 5,000 192,000,000	No change. V No change. V No change. V No change. V No change. V 224,500,000 V	

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 CFŘ 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 inpotient 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 aro]
BILLING CODE P

Deug	Company	Comment	Amount	Response	Proposed APO		Chapse
4-Anilipo-phenethyl-4-paperidine (ANPP)	(b)(4)	increase APO	120,474	APO sufficient	2,150,000		
eodeine (for sale)	1~/(.)	increase APO	unknown	APO sufficient	36,900,000		
diphennxylate	7	increase APO	890,000	APQ sufficient	1,031,000	1.031.000	
hydromorphone	7	increase APO	435,182	APO sufficient	5,400,000	5,400.000	
levorphanol	7	increase APO	2,002	APO sufficient	3.700	3.700	
marphine (for conversion)	7	increase APO	5.069.238		73.000,000		
Orgavine	7	increase APO	3 167 702		22,100,000	24,500,000	2,400,000
oxycodone (for sale)	┥	increase APO	1 \$29,665		119,500,000	119,500,000	<u>-</u>
oxymorphone (for conversion)	-1	increase APO		APO sufficient	20,000,000	20,000,000	
oxymorphone (for sale)	-	increase APO	374,000	APO sufficient	6,200,000	6,200,000	
(etrahydrocannahinol 5	┥	increase APO	65,668	APO sufficient	393,000	393,000	
(Expansion Seatministry)	<del></del>						

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

Company\_

CMEA Chemical

5 11

Comment

Amount	Response	Proposed AAN	Establish AAN	Change

11

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

0

Drug Cansiderations:	Response	Pranased	Revised	Change
4-Anilino-phenethyl-4-piperidine (ANPP)	APO sufficient	see above		see above
cocaine	APO sufficient	192,000	192,000	
ecgonine	groposed revised APO increased in anticipation of grant	139,500	139.500	
durydromorphine	APO sufficient	3,990,000	3,990,000	
fentanyl	request to religioush quota APO sufficient	1 687.000	1.687.000	
ozmrna hydroxybutnie acid	APO sufficeint	56,200,000	56,200,000	
hydrocodone (for sale)	APO sufficient	79,700,000	79.700,000	
hydromorphone	2 registrant requests for increases of 32.289 ± 42.065 g, respectively	see above		<u>see abov</u>
nethadone	APO sufficeint	25,500,000	25.500,000	
methadone intermediate	APO sufficient	31,100,000	31,100,000	
meihylphenidate meihylphenidate	APO sufficient	77,400,000	77,400,000	
morphine (for sale)	APO sufficient	50,000,000	50,000,000	
opium finature	increase aPO, based on previous customer denials - 50,000	\$00,000	624,000	124
oripavine	increase APO, based on additional customer need - 1 966 350c	see above		see abov
oxycodone (for sale)	APO sufficient	see above		see abor
pentobarbital	APO sufficient	28,000,000	28,000,000	
tettalivdrocannabinols	registrant is changing sub-drug codes. APO sufficient	sce above		see abov

Additional Chemical Considerations:				
Davie	Response	Proposed	Revised	Change
enhedring (for sale)	increase AAN in response to customer demands - 1.123.500	3,000,000	4,200,008	1,200,000
		224,500,000	224,500,000	-
pseudocphedrine (for sale)	- Ol Vantilent			

2014 Proposed Revised APQ AAN Summary of proposed revised comments received as of 7-21-14

# CONFIDENTIAL

July 9, 2014

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

Subject: Ducket No. DEA-378

Dear Sus:

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

registration

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 industria, 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)(7)( E)

	(b)(4)	
1)		
,		

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:	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 the Nydrocodone request, please do not hesitate to contact

stions regarding this

Best regards,			
(b)(6)		] '	
Director, Controlled	Substan	ce Comn	lianc

	(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)

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 C	L 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

L		(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	26,422	
July 2, 2014 Revision	Procurement	CPS-Thebaine = 9670	28,579	45,600	17,021	34 410	
3413 2, 2014 REVISION	Manufacturing	Hydrocodone for Sale - 9193	22,958	41,500	18,542	34,419	

\* Confidential

\* Received w/
applications
for adjustment

(b)(4) 2014 Hydr ! Sales (Kg Base)

			(b)(4);(b	)(7)(F)				(b)(4):(b)(	7)(E)				hined
		1/1/14-4			maining	Tota	2014	1/1/14-	6/13/14	Total	1 2014	Tota	12014
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
(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	200.0		557.6				-	-	557.6	340.t
		357.0	3.0	<del>                                     </del>		-			-		-	-	_
		2,304.2	1,405.6	1,081.0		3,385.2	2,065.0	<u> </u>	_	<del>-</del>		3,385.2	2,065.0
		85.5	52.2	- 1,001.0	-	85.5	52.2					85,5	52.2
		191.5	116.8	1,000.0	<del> </del>				-	-	-	1,191.5	726.8
		165.0	100.7	825.0		990.0				-		990.0	603.9
		0.1	0.1	- \$25.5	303.3	0.1		<del> </del>	· -		Ì	0.1	0.1
		10.0	6,1			10.0			_	-	1 -	10.0	6.1
		0.1	0.0	<del> </del>		0.1			_	<u> </u>		0.1	0.0
		- 0.1		_	<del> </del>	-			0.00002	†		-	-
		0.3	0.2		<del>                                     </del>	0.3		<del></del>	•	<del>                                     </del>		0.3	0.2
		12.0	7.3		1	17.0	<del></del>	<del>} — — — — — — — — — — — — — — — — —</del>	_	1 -	-	17.0	10.4
		1,0				<del></del>				_	<del>                                     </del>	3.0	1.8
		1,0		106.0						-	-	1	
		-	<del>                                     </del>	125.0					_	-	-	125.0	
		0.0			- 10.3	0.0						0.0	
		0.1				0.1			<del>-</del> -	<del>                                     </del>		0.1	
		0.8			<del>-</del>	0.8		+	0.00003	1	1	0,8	0.5
		6,0	<del></del>		+	6.0			_	1	_	6.0	
		u,u		<del> </del>	<del>                                     </del>	1	- 311		† -	· -	<u> </u>	<del>-</del> -	-
		1,194.6		4,300.0		5,494.0		2,319.2	1,414.7	2,319,2	1,414.7	7,813.8	4,766.4
		75.0							-	-	<del> </del> -		
		0.0			- 1-	0.0			-	1		0.0	0.0
		5,0			<del></del>	5.0			_	-	-	5.0	3.1
		0.2		_	-	0.2			<del>-</del>	†		0.2	
		0.0			+	0.0			<u> </u>	1	1	0.0	
		60.0							<del>1 -</del>	-	<u> </u>		
		147.8							<del>                                     </del>	<del>                                     </del>	+		
		0.0							-		·	435.0	
		54.8	33.4	+	+ -	54.	8 33.4	<u> </u>	<del>-</del>	<del>                                     </del>		54.8	33.4
		34.8	1 33,4	400.	<del></del>				† · · · · ·	<del>-</del>	1	400.0	
		8.3	5.0		-	8.			<del> </del>	<del>-</del>	_	<del></del>	
		0.1			<del>                                     </del>	0.					1	0.1	
		- V.1	<del></del>	5.				_		1 -	-	<del></del>	
		565.8							<del>                                     </del>	1 -			
	<del></del>	8.00.0	<u> </u>	1,000.	7103			·					

7/2/2014

		(t	20	14 Hydr	۰ ع Sales (۱۹	(g Base)					(	,
(b)(4);(b)(7)(E)	0,5	0.3	· I	<del>-</del> - Т	0.5	0.3		-		<u>_</u>	0.5	0.3
(0)(+),(0)(1)(2)	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		- 1	3.9	2.4	_1			_	3.9	2.4
			Ī	- 1	-	-	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
					- 1	5 -		<u> </u>	-	-		
	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
				<u> </u>	<u> </u>	1						

<u>L</u> (b)(4)

(b)(4) Hydro	Inventory Calculations
--------------	------------------------

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 Queta
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)				_	IMATE V		ESTIMATE WITH ADDITIONAL QUOTA		
	Input to		Net output	Loss by	Input to	Output	Loss by	Input to	Output of	Loss by
Description	Step	Process Yield	of step ·	step	Step	of Step	step	Step	Step-	step
Hydrocodone for Sale - MQ			<u> </u>							
CPS Thebaine to Crude hydrocodone (CHB)	0	87.5%	0		0	0	<u>L</u>	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	(P00,L)
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)	<u> </u>	1	
Total PQ				(417)			(886)		l	(1,135)

(b)(4) Hydrod ,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

2814 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	8,020
Converted to % Yearend	-36.1%	30.8%

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

<u> </u>	AC	ACTUAL YEAR TO DATE (5/31/14)				STIMATE	ON	WITHA	L 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	<u> </u>	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	Ó	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)			Γ		L	
	Total			(1.287)			(378)			(979)

hydrot Inventory Calculations

<del></del>	With Current	With Additional
2014 CPS-Thebaine Inventory Calculations	Quota	Quota
		<del> </del>
2013 Ending Inventory	12,972	12.972
Non saleable material	<u> </u>	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:	+	<del>                                     </del>
Converted to Hydrocodone for Sale	48,211	48,211
Disposition from Import to External Manuf (AFC)	920	920
Total Dispositions	49,131	49,131
	1	<u> </u>
2014 Ending Inventory	-6,661	10,360
Converted to % Yearend	-19.4%	30.1%

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

## **PUBLIC SUBMISSION**

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

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

Contains Confidential and Proprietary Business Information

9330 Oripavine
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 Da	ita Submitted DEA	Num Company	Drug Name -	Drug Code	Quota Year Re	quested Chrota	Current Guota	Іпсгевва/Посговио	Remarks Supplemental documentation in support of this request will be smalled	
120142	10-34/-14		4-ANIUNO-N-PHENETHYL-4-PIPERIDINE (ANPP)	8333-0	2014	1,040,000.00	919,526.00	120,474.00	separately to ODE. Cuola Eusdoj gov.  Oustomer has canceled the ANPP manufacture for 2014. The request has	
120157	15-14-14		4-AMILINO-N-PHENETHYL-4-PIPERIDINE (ANPP)	8333-0	2014	0.004 1,040,000.00	6,560.00 <b>926,088.00</b>		been moved out to 2015.	
120162	16√Jul-14		ALL OTHER TETRAHYDROCANNABINOLS	7370-A	2014	11	a	11	Active ingredient material to support Process Development and $cGMP/ctinical$ material to support parent companys $(h)(4)$	
118031	5-Fob-14		ALL OTHER TETRAHYDROCANNABINOUS	7370-A	2014	15,000.00 15,015.00	0.00	15,000,00 16,011.00	product devalopment and dinical studies,	
119752	2-May-14		COCAINE	9041-0	2014	70.261.00	53,240.00	17,021.00	Please interence the attached supporting documentation for justification purposes. Regarding additional information or questions, please contact $\overline{\langle h   \gamma   G \rangle}$ antermation is located on justification. Thank you.	
119753	2-May-14		DHYDROMORPHINE	9145-0	2014	332,105.00	260,650.00	71,455.00	Planse reference the attached supporting documentation for justification purposes. Regarding adultional information or questions, please contact //h\/\G\   bifermation is located on justification. Thank you.	
120107	2-Jul-14		D:PHENOXYLATE (FOR SALE)	Q170-8	2014	890,000,00	o	890,000.00	Supplemental documentation in support of this request will be entailed separately to CDE Quota Ousdoj gov.	
119754	2-May-14		ECGONINE	9160-O	2014	79,235,12	50,220.00	29,015.12	Please reference the attached supporting documentation for justification <u>purposes.</u> Regending additional information or questions, please contact $\boxed{(b)(6)}$ Information is located on justification. Thank you.	
120158	15-Jul-14		FENTANYL	9801-0	2014	0.001	6,600.00	-6,600.00	Customer has canceled 2014 Manufacture. This production will be moved to 2015.	
120087	1-34-14		GAMMA HYDROXYBUTYRIC ACID	2010-0	2014	42,502,000.00	38,402,023.00		$\frac{(h)(4)}{2014}$ is requesting an additional 6 batches worth of quota to meet $2014$ sales for its customer.	
120124	7-Jul-14		HYDROCODONE (FOR SALE)	9193-6	2014	41,500,000.00	22,958,367,00	18,541,533.00	Process losses estimated at 2,844,000 grams. Reptaces submission refermed # 120085	
	.	(b)(4);(b)(7)(E)							[ An addi 23,000 grams of graph is needed to sun a validation compaign at an increased batch size $\frac{1}{(b)(4)}$ prow has 5 potential customers and 2014 sales are torecasted to be 109kg (97 kg as base). Due to this	
120022	20-Jun-14		HYDROMORPHONE	91 <b>50-</b> 0	2014	130,000.00	97,711.00	32,289.00	demand,  \( \frac{\lambda \chi \chi \rangle \lambda \chi} \rangle \) needs to inc.,     Please inference the attached supporting documentation for justification purposes. Regarding additional information or questions, please contact	
119755 120114	2-May-14 3-Jul-14		HYDROMORPHONE HYDROMORPHONE	9150-0 9150-0	2014 2014	233,691.00 2,110,000.00 2,473,691,00	1,674,818.00	) 435,1 <b>82.00</b>	(b)(6) Information is located on justification. Thank you.  Process losses are estimated to be 187,200 grams.	
120083	1-314-14		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 Quado; gov.	
			-		٠				[ Quota is requested to make 3 additional batches of Methadone Base. Methadone HCI year end inventory will be 1075 kg or 956,750 grams es- base. Of 2015 sales will be 1225 kg or 1,050,250 grams as base. New	
120089	· 1~Jul-14		METHADONE	9250-0	2014	5,402,000.00	4,532,275.00	869,725.00	2015 production will not be availa. ]  [Methadone intermediate is used in the manufacture of Methadone (for	
150550			METHADONE:INTERMEDIATE	9254-0	2014	6,810,800,00	5,070,739.00	0 1,739,261,00	sale). Year-end inventory of 2296 kg is being requested in order to manufacture Methodone (for sale) in January 2015. Missing from above is the 2013 actual dispositions o. ]	
120088	1-3/4-14		METHYLPHENIDATE	1724 0	2014	70,000,00			·	(b)(4);(b)(7) E)
120011	19-Jun-14		WEITHERMENDATE	17210	2077	, ,,,,,,,			Places reference the attached supporting documentation for justification	
119758	2-May-14		MORPHINE (FOR SALE)	9300-6	2014	700,000.00	248,820 00	o 461, <b>18</b> 0.00	purposes. Regarding additional information or questions, please confact $ f_h\rangle/ h $ information is located on justification. Then you will be to reduce the Monthline for selectioning quote at $ f_h\rangle/ A $ egistation by the amount of this request.	(b)(4);(b)(7) E)
120010	19-Jen-14		MORPHINE (FOR SALE)	9300-B	2014	1,692,000.00	, ,	0 1,693,000.00	Do to temporary short term constraints, we need to move production of the D Marphine (for safe) base]	
120146	11-Jul-14		MORPHINE (FOR SALE)	9300-B	2014	3,087,887,00 5,479,867.00			We are requesting a reduction in our quote of 1,892 kg, which  It is nequesting an increase in their quote of 1,892 kg.	I

120144	10-Ju-14 3-Ju-14		ORIPAVINE ORIPAVINE	9330-0 9330-0	2014 2014	13,900,000.00 5,250,000.00	3,263,650,00	Supplemental documentation in support of this request will be emailed 3,167,702.00 separately to ODE Quota Quadej gov.  Process losses are retirested at 1,380,000 grams. 2,705,000 Origaving converted to Hydromorphone (9150). Hydromorphone (9150) does not 1,966,350.00 appear on Converted Substances list but does appear on registration.
						19,150,000.00	14,015,948,00	5,134,052.00  [ Our current quote is short 36 kg from what is needed to make an additional 3 full scale batches, most of which will be said during 2014. Q1
120090	1-Jul-14	(b)(4);(b)(7)(E)	OXYCODONE (FOR SALE)	9143-B	2014	820,000.00	784,639.00	2015 sales are projected to be 440 kg or 395,000 grams as base.  35,361,00 Onycodone will be produced at -4X]  Please reterence the attached supporting documentation for justification purposes, Regarding additional information or questions, please contact
119757	2-May-14		OXYCODONE (FOR SALE)	9143-8	2014	20,966.00	6,000.00	14.966.00 ⟨⟨n⟩⟨n⟩   Information is located on justification. Thank you.  (We are requesting this increase to support(n)⟨d⟩   plans to taunct Oxycodone HCl later this year. Please note the DEA set our 2014 quots at
120030	23-Jun-14		OXYCODONE (FOR SALE)	9143-B	2014	2,894,685.00 3,735,531.00	1,365,000.00 2,155,639.00	1,365 kg, with 900 to support commercial activides and 465 kg to support 1,529,665,00 development activit) 1,579,992,00
120086	1-Jul-14		PENTOBARBITAL .	2270-0	2014	26,525,000.00	23,400,000.00	(h)(4) projected 2014 sales have increased and Q1 2015 sales are now at 5M for 4,550,000 grams as base. Sufficient inventory is needed 3,125,000.00 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:

#### List 1 Chemicals:

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

## Controlled Substances:

- OD is recommending an increase in the APQ for 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).

DEA/OD/ODO 7/23/2014 Page 1 of 1

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.

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 <i>H</i> -indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1 <i>H</i> -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
I-[1-(2-Thienyl)cyclohexyl]piperidine	15
I-[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-	1.5
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-	1.5
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-	15
NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	1.5
2-(Methylamino)-1-phenylpentan-I-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-Methylencdioxyamphetamine (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-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	53
(cannabicyclohexanol or CP-47,497 C8-homolog)	. <u>.</u>
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	
Allylprodine	2 2 2
Alphacetylmethadol	25
alpha-Ethyltryptamine	

Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
	2
alpha-Methylthiofentanyl	25
alpha-Methyltryptamine (AMT)	
alpha-Pyrrolidinobutiophenone (a-PBP)	15
alpha-Pyrrolidinopentiophenone (α-PVP)	15
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2 2
beta-Hydroxy-3-methylfentanyl	
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
Ibogáine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	650,000
Mescaline	25
Methaqualone	- 10
Methcathinone	25
Methyldesorphine	2
Methyldihydromorphine  Marshina methylbromide	
Morphine methylpromide	5
Morphine methylsulfonate	175
Morphine-N-oxide  N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15
N/1 Amino 2.2 dimethyl 1 ovehyten 2 yl) 1 nentyl 1U indezele-2-	<u> </u>
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-	15
carboxamide (ADB-PINACA)  N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-	
	15
carboxamide (AB-FUBINACA)	25
N.N-Dimethylamphetamine	15
Naphthylpyrovalerone (naphyrone)	l

N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
	52
Norlevorphanol	2
	18
Normorphine	2
para-Fluorofentanyl	
Parahexyl	5 2
Phenomorphan	2
Pholcodine	2
Properidine	40
Psilocybin	50
Psilocyn	30
Quinolin-8-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate (5-fluoro-PB-22;	15
SF-PB-22)	15
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	
Tetrahydrocannabinols	491,000
Thiofentanyl	2
Tilidine	10
Trimeperidine	Z
Schedule II	3
1-Phenylcyclohexylamine	3
1-Piperidinocyclohexanecarbonitrile	
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

T	105
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,	
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	1 10,000,000
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

00 0 1	1 and 1308.12 remain at zero.	dule I and II controlled substances included in
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, pseudosphedrine, 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 ophedrine, psoudoephodrine, 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 quotes and assessment of annual needs on or hefore 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-anilinophenethyl-4-piperidine (ANPP), codeine (for sale), diphenoxylate, hydromorphone, leverphanol, 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 ophedrine (for sale) required additional consideration and hereby further adjusts the 2014 aggregate production quota and assessment of annual needs for these substances. Regarding 4-anilinophenethyl-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 unforescen 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 quote 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, pseudosphedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as

Basic class		Final adjuste 2014
		quolas (g)
Schedule I		-
Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)		٠.
5-Fluoro-pentyl)-1/Findol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	International Control of the Control	
1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)		
1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)		
1-Phenylcyclohexyl)pyrrolidine		
5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201) 5-Fluoropentyl)-3-(2-iodobenzoyl)Indole (AM694)	* * * *	
1-(2-Thienyl)cyclohexyl]piperidine		
2-(4-Morpholinyi)ethyl]-3-(1-naphthoyl)indole (JWH-200)		
Outyl-3-(1-naphthoyf)indole (JWH-073)		
Cyclohexylethyl-3-(2-methoxyphenylacetyl)indols (SR-18 and RCS-8)		
lexyl-3-(1-naphthoyl)indole (JWH-019)		
Methyl-4-phenyl-4-propionoxypiperidine	***************************************	
Pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678)		
Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)		
entyl-3-(2-mathoxyphenylacetyl)indole (JWH-250)		
entyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)		
Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)		
entyl-3-[(4-methoxy)-benzoyl indole (SR-19, RCS-4)	***************************************	
Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)		
2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)		
2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)		
2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D) 2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	***************************************	
2,5-Dimethoxyphenyl)ethanamine (2C-H)	***************************************	
4-Bromo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOM	de: 25B: Cimbi-36\	
4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	Net 230, Oldibr-307	
4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOM	Me: 25C: Cimbi-82)	
4-lodg-2,5-dimethoxyphenyl)ethanamine (2C-I)		
4-lodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe;	25I; Cimbi-5)	
Methylamino)-1-phenylpentan-1-one (pentedrone)		
5-Dimethoxy-4-ethylamphetamine (DOET)	4	
-Dimethoxy-4-n-propylthiophenethylamine		
-Dimethoxyamphetamine		
4-(Ethylthio)-2,5-dimethoxyphenyljethanamine (2C-T-2)	***************************************	
4-(Isopropylthio)-2,5-dimethoxyphenyllethanamine (2C-T-4)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
5-Trimethoxyamphetamine		
-Methylenedioxyamphatamine (MDA)	***************************************	
-Methylenedioxymethamphetamine (MDMA)		
-Methylenedioxy-N-ethylamphetamine (MDÉA) -Methylenedioxy-N-methylcathinone (methylone)	***************************************	
-Methylenedioxypyrovaterone (MDPV)		
luoro-Mmethylcathinone (3FMC)		
Aethyllentanyl	44-1	
Methylthiofentanyl		
3romo-2,5-dimethoxyamphetaminc (DOB)		
fromo-2,5-dimethoxyphenethytamine (2–CB)	***************************************	
lugro-N-methylcathinone (4-FMC)		
Methoxyamphetamine		
Aethyl-2,5-dimethoxyamphetamine (DOM)		
Aethylaminorex	4 ) 4 T ) 4 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1 T   1	
Aethyl-N-ethylcathinone (4-MEC)		
Methyl-N-methylcathinone (mephedrone)		
Methyl-α-pyrrolidinopropiophenone (4-MePPP)		
1,1-Dimethylheptyl)-2-[(1 <i>R</i> ,3 <i>S</i> )-3-hydroxycyclohexyl]-phenol	D7 C9 homeles	
Aethoxy-3,4-methylenedioxyamphetamine	or ourionology assumation	
Aethoxy-N,N-disopropyltryplamine		
Methoxy-N,N-dimethyltryptamine		
etyl-alpha-methyllentanyi		
etyldihydrocodeine		
elylmethadol		
ylprodine		
phacetylmethadol		
pha-Ethyltryptamine		
phameprodinephameprodine		
phamethadol		

Basic class	adjuste 2014 quotas (9)
pha-Methylthiofentanyi	
pha-Methyltryptamine (AMT)	
pha-Pyrrolidinobutiophenone (α-PBP)	
pha-Pyrrolidinopentiophenone (α-PVP)	·
minorex	· [
enzylmorphine	• [
etacetylmethadol	•
ele-Hydroxy-3-methylfentanyl	•
ela-Hydroxyfentanyl	•
etaméprodine	•
elaprodineelaprodine	' <b> </b>
ulotenine	* [
allinone	<b>'</b>
odeine methylbromide	•
odeine-N-oxide	<i>'</i>
esomorphine	•
ethyltryptamine	<b>'</b>
ilenoxin	3,990
hydromorphine	
inethyltryptamine	'
pipanone	.1
enethylline	70,250
amma-Hydroxybutyric acid	
eroin	•
ydromorphinol	•
ydroxypathidine	•
ogaine	'l
sergic acid diethylamide (LSD)	·  •=^
arihuana	. 650
escaline	'l
elhaqualone	•
ethcathinone	1
ethyldasorphine	• 1
ethyldihydromorphine	• 1
orphine methylbromide	• ]
orphine methylsulfonate	- [
orphine-N-oxide	•
-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	•
(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	· [
-(1-Amino-3-methyl-1-oxobulan-2-yl)-1-(4-Iluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	<i>•</i> [
A-Dimethylamphelamine	•
aphthyloytoyalerone (naphyrone)	٠ ا
Bonzylpiperazine	·
-Ethyl-1-phenylcyclohexylamine	•
-Ethylamphetamine	*
Hydroxy-3,4-methylenedioxyamphetamine	•
oracymethadol	
orlevorphanol	•
ormelhadone	-
ormorphine	·
ara-Fiborofentanyi	·
arahexyl	.
nenomorphan	- I
holcodine	.
roperidine	- 1
silocybin	•
nyoliz	
uinolin-8-yl 1-/5-f(uoropentyl)-1/H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	I
uinolin-8-vi 1-nentvi-1/4-indole-3-carboxviate (PB-22; QUPIC)	
alrahydrocannabinols	491
longtany	
lidine	
rimeparidine	1*
Schedule II	
Phenylcyclohexylamine	
Piperidinocyclohexanecarbonitrile	"
	. 2,687

Basic class	Final adjusted 2014 quotas (g)
Amobarbital	
Amphetemine (for conversion)	18,375,
mphetamine (for sale)	49,000,
arfentani	
ocaine	240,
ordeine (for conversion)	68,750,
odeine (for sale)	46,125,
extronropayohene	400
hydrocodeine	100,
phenoxylate	1,268, 174,
cgonine	174,
hylmorphine	2,108.
ntany	2,100,
utethimide	137,
rdrocodone (for conversion)	99,625,
/drocodone (for sale)	6,750,
/dromorphone	0,100,
omethadone	
vo-alphacetylmethadol (LAAM)	
vomethorphanvorphanol	4.
vorphanoldexamietaminė	23,750
speridine	6,250
speridine intermediale-A	-,
eperidine Intermediale-B	
eperidine Intermediale-C	
etazocine	
eflacione (for sale)	31,875
ethadone intermediate	38,875
Intriductio il indirectione	
tethamphetamine	2,811, etamine mos
ethamphetamine	
ethamphetamine	etamine mos 96,750, 91,250
ethamphetamine	96,750, 91,250, 62,500
ethamphetamine	96,750, 91,250, 62,500,
ethamphetamine	96,750, 91,250, 62,500, 30, 17,500,
ethamphetamine	95,750, 91,250, 62,500, 30, 17,500,
ethamphetamine	95,750 91,250 62,500 17,500 1,262
ethamphetamine	95,750 91,250 62,500 30 17,500 1,262 112 780
ethamphetamine	95,750 91,250 62,500 30 17,500 1,262 112 780 30,625
ethamphetamine	95,750 91,250 62,500 30 17,500 1,262 112 780 30,625 9,250
ethamphetamine	95,750 91,250 62,500 17,500 1,262 112 780 30,625 9,250 149,375
ethamphetamine	95,750 91,250 62,500 30 17,500 1,262 112 780 30,625 9,250 149,375 25,000
ethamphetamine	96,750 91,250 62,500 30 17,500 1,262 780 30,625 9,250 149,376 25,000 7,750
ethamphetamine	96,750 91,250 62,500 30 17,500 1,262 780 30,625 9,250 149,376 25,000 7,750
ethamphetamine	96,750 91,250 62,500 30 17,500 1,262 780 30,625 9,250 149,376 25,000 7,750
ethamphetamine  "250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate  orphine (for conversion)  orphine (for sale)  abilione  proxymorphone (for conversion)  plum (powder)  plum (fincture)  ripavine  xycodone (for conversion)  xycodone (for conversion)  xycodone (for conversion)  xycodone (for sale)  xymorphone (for sale)	96,750 91,250 62,500 30 17,500 1,262 780 30,625 9,250 149,376 25,000 7,750
athamphetamine  250,000 grams of /evo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  athylphenidate  corphine (for conversion)  corphine (for sale)  corpymorphone (for conversion)  colum (powder)  colum (powder)  colum (incture)  colum (incture)  colum (for conversion)  corphine (for conversion)  colum (for conversion)  colum (for conversion)  corphine (for conversion)  colum (for conversion)  corphine (for conversion)	96,750 91,250 62,500 30 17,500 1,262 112 780 30,625 9,250 149,375 25,000 7,750 35,000
ethamphetamine	96,750 91,250 62,500 30 17,500 1,262 112 780 30,625 9,250 149,375 25,000 7,750 35,000
ethamphetamine  250,000 grams of /evo-desoxyephedrine for usa in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule lili product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate orphine (for conversion) orphine (for conversion) orpxymorphone (for conversion) proxymorphone (for conversion) prium (powder) pium (powder) pium (incture) pium (for conversion) xycodone (for conversion) xycodone (for conversion) xycodone (for sale) peniobarbital penazocine penengelidine penengelidine penengelidine penengelidine penengelidine penengelidine	96,750 91,250 62,500 30 17,500 1,262 780 30,625 9,250 149,376 25,000 7,750 35,000
ethamphetamine  250,000 grams of /evo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule lili product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate orphine (for conversion) orphine (for conversion) orphine (for conversion) point (powder) point (powder) point (powder) point (powder) point (incture) provymorphone (for conversion) xycodone (for conversion) xymorphone (for sale) protophone (for sale) xymorphone (for conversion) xymorphone (for sale) pendobarbital menazocine	95,750 91,250 62,500 17,500 1,262 112 780 30,625 9,250 149,378 25,000 7,750 35,000
ethamphetamine  ,250,000 grams of /evo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate	96,750 91,250 62,500 30,025 1,262 112,780 30,625 9,250 149,376,25,000 7,750 35,000
ethamphetamine  ,250,000 grams of /evo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate	96,750, 91,250, 62,500, 30, 17,500 1,262, 112, 780, 30,625, 9,250, 149,375, 25,000, 7,750, 35,000
ethamphetamine  ,250,000 grams of /evo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate	96,750 91,250 62,500 30 17,500 1,262 112 780 30,625 9,250 149,375 25,000 7,750 35,000
ethamphetamine  250,000 grams of /evo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule [II product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate orphine (for conversion) orphine (for conversion) oroxymorphone (for conversion) oroxymorphone (for sale) oium (powder) oium (lincture) inpavine sycodone (for conversion) sycodone (for conversion) sycodone (for conversion) symorphone (for conversion) encoparities enc	96,750 91,250 62,500 30,17,500 1,262 780 30,625 9,250 149,375 25,000 7,750 35,000
ethamphetamine  ,250,000 grams of /evo-desoxyephedrine for usa in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate orphine (for conversion) orphine (for conversion) oroxymorphone (for conversion) oroxymorphone (for conversion) opium (powder) opium (fincture) opium (fincture) opium (for conversion) xycodone (for conversion) xycodone (for conversion) xymorphone (for sale) opiobarbital nenazocine nenmetrazine nenmetrazine nenmetrazine nenmetrazine memilentanii accobarbital uppentadol nebaline  List   Chemicals	96,750 91,250 62,500 30 17,500 1,262 112 780 30,625 9,250 149,375 25,000 7,750 35,000 45,750 145,000
ethamphetamine  ,250,000 grams of /evo-desoxyephedrine for usa in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule lil product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate orphine (for conversion) orphine (for sale) abilione proxymorphone (for conversion) proxymorphone (for sale) plum (powder) plum (powder) plum (inclure) propavine xycodone (for conversion) xyroodone (for sale) xyroophone (for sale) entobarbital enenazocine heneyclidine henemetrazine heneylacteone acemethorphan emilentanii escobarbital urientanii escobarbital escoparbital urientanii escoparbital escoparbita	96,750 91,250 62,500 17,500 1,262 112 780 30,625 9,250 149,375 25,000 7,750 35,000 45,750 5 17,500 145,000
ethamphetamine  ,250,000 grams of /evo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate	95,750 91,250 62,500 30,625 112 780 30,625 9,250 149,375 25,000 7,750 35,000 45,750 17,500 145,000
ethamphetamine  ,250,000 grams of /evo-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphe for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate	96,750 91,250 62,500 30 17,500 1,262 112 780 30,625 9,250 149,375 25,000 7,750 35,000 45,750 145,000 145,000 4,200 44,800
ethamphetamine  250,000 grams of <i>levo-</i> desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetor conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]  ethylphenidate	95,750 91,250 62,500 30,625 112 780 30,625 9,250 149,375 25,000 7,750 35,000 45,750 17,500 145,000

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]

BULING CODE 4410–08–P

# 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 onter 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

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 or the fiscal year involved (the "lower middle income category"); and is not inoligible to receive U.S. economic assistance under part I of the Foreign Assistance Act of 1901, as amended (the Foreign Assistance Act of 1901, as amended (the Foreign Assistance Act of any other provision of large.

\*If the language relating to the definition of low income candidate countries is not enacted or is changed for MCC's FY 2015 appropriations and, 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.