2012 Established Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish limits on the production of schedules I and II controlled substances. This responsibility has since been delegated to the Administrator of the Drug Enforcement Administration (DEA).
- The regulations require that DEA revise the aggregate production quota (APQ) annually after review of pertinent information provided from various sources including DEA-registered manufacturers and the Food and Drug Administration (FDA).
- The attached Federal Register seeks to establish the APQ for 2012. A table summarizing the APQ and the changes made to the proposed established value are attached for reference.
- OD is recommending an increase in the APQ for **alfentanil**. This increase is based on increased exportation requirements.
- OD is recommending an increase in the APQ for **dihydrocodeine.** This increase is based on increased manufacturing requirements.
- OD is recommending an increase in the APQ for **diphenoxylate**. This increase is based on increased sales.
- OD is recommending an increase in the APQ for **hydromorphinol.** This increase is based on the increased need for reference standards.
- OD is recommending an increase in the APQ for **lisdexamfetamine**. This increase is based on increased exportation requirements.
- OD is recommending an increase in the APQ for **meperidine**. The increase is due to increased sales.
- OD is recommending an increase in the APQ for **meperidine intermediate A**. This increase is based on the increased need for reference standards.
- OD is recommending an increase in the APQ for **meperidine intermediate B**. This increase is based on the increased need for reference standards.
- OD is recommending an increase in the APQ for **meperidine intermediate C**. This increase is based on the increased need for reference standards.
- OD is recommending an increase in the APQ for **morphine-N-oxide**. This increase is based on the increased need for reference standards.
- OD is recommending an increase in the APQ for **nabilone**. The increase is to support product development efforts.

- OD is recommending an increase in the APQ for **pentobarbital.** The increase is due to increased sales and because (b)(4) now properly assesses their quota at the initial manufacturing stage vs. the final finished product. The majority of this increase is accounting for their manufacturing losses.

- OD is recommending an increase in the APQ for **properidine.** This increase is based on the increased need for reference standards.

- OD is recommending an increase in the APQ for **tapentadol**. This increase is to support product development efforts. Currently Tapentadol ether is manufactured outside the US, the product development efforts will allow a shift to domestic manufacturing.

Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Initial	Final Revised	Proposed Initial	Initial
N,N-Dimethylamphetamine	2	2	2	2	2
N-Ethylamphetamine	2	2	2	2	2
N-Hydroxy-3,4-Methylenedioxyamphetamine	2	2	2	2	2
Schedule I:	**2010**	**2011**	**2011**	**2012**	**2012**
Noracymethadol	2	2	2	2	2
Norlevorphanol	52	52	52	52	52
Normethadone	2	2	2	2	2
Normorphine	16	18	18	18	18
Para-fluorofentanyl	2	2	2	2	2
Phenomorphan	2	2	2	2	2
Pholcodine	2	2	2	2	2
Psilocybin	2	2	2	2	2
Psilocyn	2	2	2	2	2
Tetrahydrocannabinols	264,000	393,000	393,000	393,000	393,000
Thiofentanyl	2	2	2	2	2
Tilidine	10	10	10	10	10
Trimeperidine	2	2	2	2	2
Controlled Substance	**Final Revised**	**Initial**	**Final Revised**	**Proposed Initial**	**Initial**
Schedule II:	**2010**	**2011**	**2011**	**2012**	**2012**
1-Phenylcyclohexylamine	2	2	2	2	2
1-Piperidinocyclohexanecarbonitrile	0	2	2	2	2
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,100,000	2,500,000	1,800,000	1,800,000	1,800,000
Alfentanil	8,000	8,000	12,800	11,600	15,000
Alphaprodine	2	2	2	2	2
Amobarbital	3	40,007	40,007	40,007	40,007
Amphetamine (for conversion)	7,500,000	7,500,000	8,500,000	8,500,000	8,500,000
Amphetamine (for sale)	18,600,000	18,600,000	25,300,000	25,300,000	25,300,000
Carfentanil	200	0	0	0	0
Cocaine	247,000	247,000	216,000	216,000	216,000
Codeine (for conversion)	65,000,000	65,000,000	65,000,000	65,000,000	65,000,000
Codeine (for sale)	39,605,000	39,605,000	39,605,000	39,605,000	39,605,000
Dextropropoxyphene	92,000,000	92,000,000	7	7	7
Dihydrocodeine	800,000	800,000	255,000	255,000	400,000
Diphenoxylate	827,000	827,000	730,000	500,000	900,000
Ecgonine	83,000	83,000	83,000	83,000	83,000
Ethylmorphine	2	2	2	2	2
Fentanyl	1,428,000	1,428,000	1,428,000	1,428,000	1,428,000
Glutethimide	2	2	2	2	2
Hydrocodone (for sale)	55,000,000	55,000,000	59,000,000	59,000,000	59,000,000
Hydromorphone	3,455,000	3,455,000	3,455,000	3,455,000	3,455,000
Isomethadone	11	11	2	4	4
Levo-alphacetylmethadol (LAAM)	3	3	3	3	3
Levomethorphan	5	5	2	2	2
Levorphanol	10,000	10,000	3,600	3,600	3,600
Lisdexamfetamine	9,000,000	9,000,000	10,400,000	10,400,000	12,000,000
Meperidine	6,600,000	6,600,000	5,500,000	5,200,000	5,500,000
Meperidine Intermediate-A	3	3	3	3	5
Meperidine Intermediate-B	7	7	7	7	9
Meperidine Intermediate-C	3	3	3	3	5
Metazocine	1	5	5	5	5
Methadone (for sale)	20,000,000	20,000,000	20,000,000	20,000,000	20,000,000
Methadone Intermediate	26,000,000	26,000,000	26,000,000	26,000,000	26,000,000
Methamphetamine	3,130,000	3,130,000	3,130,000	3,130,000	3,130,000
levo-desoxyephedrine	750,000	750,000	750,000	750,000	750,000
methamphetamine (for conversion)	2,331,000	2,331,000	2,331,000	2,331,000	2,331,000
methamphetamine (for sale)	49,000	49,000	49,000	49,000	49,000
Methylphenidate	50,000,000	50,000,000	56,000,000	56,000,000	56,000,000
Morphine (for conversion)	83,000,000	83,000,000	70,000,000	83,000,000	83,000,000
Morphine (for sale)	39,000,000	39,000,000	39,000,000	39,000,000	39,000,000
Nabilone	9,002	10,502	10,502	10,502	20,502
Noroxymorphone (for conversion)	9,000,000	9,000,000	7,200,000	7,200,000	7,200,000
Noroxymorphone (for sale)	41,000	401,000	401,000	401,000	401,000
Opium (powdered)	230,000	230,000	63,000	63,000	63,000
Opium (tincture)	1,500,000	1,500,000	1,000,000	1,000,000	1,000,000

Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Initial	Final Revised	Proposed Initial	Initial
Oripavine	15,000,000	15,000,000	8,000,000	8,000,000	9,600,000
Oxycodone (for conversion)	5,600,000	5,600,000	5,600,000	5,600,000	5,600,000
Oxycodone (for sale)	105,500,000	105,500,000	98,000,000	98,000,000	9,800,000
Schedule II:	2010	2011	2011	2012	2012
Oxymorphone (for conversion)	12,800,000	12,800,000	12,800,000	12,800,000	12,800,000
Oxymorphone (for sale)	3,070,000	3,070,000	3,070,000	5,500,000	3,070,000
Pentobarbital	28,000,000	28,000,000	34,000,000	31,000,000	34,000,000
Phenazocine	1	5	5	5	5
Phencyclidine	14	24	24	24	24
Phenmetrazine	2	2	2	2	2
Phenylacetone	12,500,001	8,000,000	8,000,000	8,000,000	16,000,000
Properidine					2
Racemethorphan	2	2	2	2	2
Remifentanil	2,500	2,500	2,500	2,500	2,500
Secobarbital	67,000	260,002	336,002	336,002	336,002
Sufentanil	7,000	7,000	5,000	5,000	5,000
Tapentadol	1,000,000	1,000,000	403,000	243,000	5,400,000
Thebaine	126,000,000	126,000,000	116,000,000	116,000,000	11,600,000

Drug	Proposed APQ	Establish APQ	Change
3,4-Methylenedioxy-N-methylcathinone (methylone)	-	8.0	8.0
3,4-Methylenedioxypyrovalerone (MDPV)	-	8.0	8.0
4-Methyl-N-methylcathinone (mephedrone)	-	8.0	8.0
alfentanil	11,600.0	15,000.0	3,400.0
dihydrocodeine	255,000.0	400,000.0	145,000.0
diphenoxylate	500,000.0	900,000.0	400,000.0
gamma hydroxybutyric acid	29,000,000.0	47,000,000.0	18,000,000.0
hydromorphinol	2.0	54.0	52.0
lisdexamfetamine	10,400,000.0	12,000,000.0	1,600,000.0
meperidine	5,200,000.0	5,500,000.0	300,000.0
meperidine - intermediate A	3.0	5.0	2.0
meperidine - intermediate B	7.0	9.0	2.0
meperidine - intermediate C	3.0	5.0	2.0
morphine-N-oxide	605.0	655.0	50.0
nabilone	10,502.0	20,502.0	10,000.0
pentobarbital	31,000,000.0	34,000,000.0	3,000,000.0
phenylacetone	8,000,000.0	16,000,000.0	8,000,000.0
properidine	-	2.0	2.0
tapentadol	243,000.0	5,400,000.0	5,157,000.0

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA # 358E]

Controlled Substances:
Established Aggregate Production Quotas for 2012

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

ACTION: Notice.

SUMMARY: This notice establishes the initial 2012 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

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

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

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

The 2012 aggregate production quotas represent those quantities of Schedule I and II controlled substances that may be produced in the United States in 2012 to provide adequate supplies of each substance for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve

stocks. 21 U.S.C. 826(a) and 21 CFR 1303.11. These quotas do not include imports of controlled substances for use in industrial processes.

On October 21, 2011, a notice entitled "Controlled Substances: Proposed Aggregate Production Quotas for 2012" was published in the Federal Register (76 FR 65537). That notice proposed the 2012 aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. All interested persons were invited to comment on or object to the proposed aggregate production quotas on or before November 21, 2011.

Sixteen responses (eleven from DEA registered manufacturers, and five from other members of the public) were received within the published comment period, offering comments on a total of 37 Schedule I and II controlled substances. Several comments discussed the national prescription drug abuse epidemic and urged DEA to reduce quotas for prescription painkillers and opioids. Addressing prescription drug abuse requires a multi-faceted approach which includes education, treatment, and enforcement.

The quota system is specifically designed to operate within the statutory framework of the CSA, in conjunction with other controls to enable DEA to monitor the movement of controlled substances and certain chemicals into and through the closed system of distribution to help prevent diversion of such substances into the illicit market. Through the quota system, DEA limits the amount of those substances and chemicals manufactured each year to those quantities that will provide for the estimated medical, scientific, research, and industrial needs, lawful export requirements, and the establishment and maintenance of reserve stocks for the United States. All aspects of the closed system of distribution must work together to reduce or eliminate the diversion of controlled substances.

Other commenters stated that the proposed aggregate production quotas for alfentanil, amphetamine (for sale), codeine (for conversion), codeine (for sale), dihydrocodeine, dihydromorphine, diphenoxylate, hydrocodone (for sale), hydromorphinol, levorphanol, lisdexamfetamine, meperidine, meperidine intermediate A, meperidine intermediate B, meperidine intermediate C, methadone, methadone intermediate, methamphetamine, methylphenidate, morphine (for conversion), morphine (for sale), morphine-N-oxide, nabilone, noroxymorphone (for conversion), noroxymorphone (for sale), opium (tincture), oripavine, oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), pentobarbital, phenylacetone, properidine, sufentanil, tapentadol, 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.

In determining the aggregate production quotas, DEA has taken into consideration the above comments along with the factors set forth at 21 CFR 1303.11(b), in accordance with 21 U.S.C. 826(a), and other relevant factors including the consideration of 2011 manufacturing quotas, current 2011 sales and inventories, 2012 export requirements, additional applications for quotas, as well as information on research and product development requirements. Based on this information, DEA determined that adjustments to the proposed aggregate production quotas for alfentanil, dihydrocodeine, diphenoxylate, hydromorphinol, lisdexamfetamine, meperidine, meperidine intermediate A, meperidine intermediate B, meperidine intermediate C, morphine-N-oxide, nabilone, pentobarbital, phenylacetone, properidine, and tapentadol are warranted. This notice reflects those adjustments.

When DEA published the Proposed Aggregate Production Quotas for 2012 on

October 21, 2011, that notice proposed that all Schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.21 but not specifically referenced in that notice be established at zero. That reference extended to the three synthetic cathinones (4-methyl-N-methylcathinone; 3,4-methylenedioxy-N-methylcathinone; and 3,4,methylenedioxypyrovalerone) that were temporarily placed in Schedule I pursuant to the final order also published on October 21, 2011, at 76 FR 65371. No comments were received within the published comment period regarding the proposed quota for the three synthetic cathinones, however, DEA has determined, based on the information described above, that an increase from the proposed quota of zero is warranted for all three substances. This notice reflects those adjustments.

Regarding amphetamine (for sale), codeine (for conversion), codeine (for sale), dihydromorphine, hydrocodone (for sale), levorphanol, methadone, methadone intermediate, methamphetamine, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), noroxymorphone (for sale), opium (tincture), oripavine, oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), sufentanil, and thebaine, DEA has determined that the proposed initial 2012 aggregate production quotas are sufficient to meet the current 2012 estimated medical, scientific, research, and industrial needs of the United States. This notice finalizes these aggregate production quotas at the same amounts as proposed.

In accordance with 21 U.S.C. 826 and 21 CFR 1303.11, the Administrator hereby determines that the 2012 aggregate production quotas for the following controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Established 2012 Quotas
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	22 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	8 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g
3,4-Methylenedioxypyrovalerone (MDPV)	8g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g
4-Methyl-N-methylcathinone (mephedrone)	8 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
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	2 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g

Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	4 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	50 g
Dihydromorphine	3,608,000 g
Dimethyltryptamine	7 g
Gamma-hydroxybutyric acid	47,000,000 g
Heroin	20 g
Hydromorphinol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	5 g
Methaqualone	10 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	2 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Established 2012 Quotas
1-Phenylcyclohexylamine	2 g
1-piperdinocyclohexanecarbonitrile	2 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g
Alfentanil	15,000 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	8,500,000 g
Amphetamine (for sale)	25,300,000 g
Cocaine	216,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	7 g
Dihydrocodeine	400,000 g
Diphenoxylate	900,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	59,000,000 g
Hydromorphone	3,455,000 g
Isomethadone	4 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	3,600 g
Lisdexamfetamine	12,000,000 g
Meperidine	5,500,000 g
Meperidine Intermediate-A	5 g
Meperidine Intermediate-B	9 g
Meperidine Intermediate-C	5 g
Metazocine	5 g
Methadone (for sale)	20,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]	
Methylphenidate	56,000,000 g
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	39,000,000 g
Nabilone	20,502 g
Noroxymorphone (for conversion)	7,200,000 g

Noroxymorphone (for sale)	401,000 g
Opium (powder)	63,000 g
Opium (tincture)	1,000,000 g
Oripavine	9,800,000 g
Oxycodone (for conversion)	5,600,000 g
Oxycodone (for sale)	98,000,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	5,500,000 g
Pentobarbital	34,000,000 g
Phenazocine	5 g
Phencyclidine	24g
Phenmetrazine	2 g
Phenylacetone	16,000,000 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	336,002 g
Sufentanil	5,000 g
Tapentadol	5,400,000 g
Thebaine	116,000,000 g

The Administrator further determines 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. All aggregate production quotas are subject to adjustment pursuant to 21 CFR 1303.13.

Dated:

Michele M. Leonhart
Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXL:_____
ODXS:_____
CC:_____
CCR:_____
ODW:_____
ODQ:CAS_____
ODEQ:(b)(6) 12-02-11
S:\ODQ\Fed Reg\2012 Established Aggregate Production Quota
Webcims # ODE-11-654
(DFN: 630-08 – Quotas)

2011 Final Rev | Comments

Drug	Company	Comment	Amount	Response	Proposed APQ	Establish APQ	Change
alfentanil	(b)(4)	increase APQ	3,500.0	exports to Europe increasing	11,600.0	15,000.0	3,400.0
amphetamine (for sale)		increase APQ	3,200,000.0	APQ sufficient at this time	25,300,000.0	25,300,000.0	-
		increase APQ	1,911,000.0				
codeine (for conversion)		increase APQ	1,100,000.0	APQ sufficient at this time	65,000,000.0	65,000,000.0	-
		increase APQ	36,000,000.0				
codeine (for sale)		increase APQ	24,537,000.0	APQ sufficient at this time	39,605,000.0	39,605,000.0	-
dihydrocodeine		increase APQ	280,000.0	increase APQ	255,000.0	400,000.0	145,000.0
dihydromorphine		increase APQ	300,000.0	APQ sufficient at this time	3,608,000.0	3,608,000.0	-
diphenoxylate		increase APQ	15,000.0	increase APQ	500,000.0	900,000.0	400,000.0
		increase APQ	950,000.0				
hydrocodone (for sale)		increase APQ	3,020,000.0	no change	59,000,000.0	59,000,000.0	-
		increase APQ	4,698,000.0				
		increase APQ	31,000,000.0				
hydromorphinol		increase APQ	1.0	(b)(4) ref std; increase APQ	2.0	54.0	52.0
		increase APQ	50.0				
levorphanol		increase APQ	6,100.0	APQ sufficient at this time	3,600.0	3,600.0	-
lisdexamfetamine		increase APQ	18,263.0	exports to Europe increasing	10,400,000.0	12,000,000.0	1,600,000.0
meperidine		increase APQ	26,800.0	increase APQ to match 2011 Final APQ	5,200,000.0	5,500,000.0	300,000.0
		increase APQ	2,100,000.0				
		increase APQ	93,000.0				
meperidine - intermediate A		increase APQ	1.0	(b)(4) ref std; increase APQ	3.0	5.0	2.0
meperidine - intermediate B		increase APQ	1.0	ref std; increase APQ	7.0	9.0	2.0
meperidine - intermediate C		increase APQ	1.0	ref std; increase APQ	3.0	5.0	2.0
methadone		increase APQ	805,000.0	APQ sufficient at this time	20,000,000.0	20,000,000.0	-
methadone intermediate		increase APQ	1,500,000.0	APQ sufficient at this time	26,000,000.0	26,000,000.0	-
methamphetamine		increase APQ	8,000.0	APQ sufficient at this time	3,130,000.0	3,130,000.0	-
methylphenidate		increase APQ	2,150,000.0	APQ sufficient at this time	56,000,000.0	56,000,000.0	-
		increase APQ	7,400,000.0				
morphine (for conversion)		increase APQ	900,000.0	APQ sufficient at this time	83,000,000.0	83,000,000.0	-
		increase APQ	46,000,000.0				
morphine (for sale)		increase APQ	23,000,000.0	APQ sufficient at this time	39,000,000.0	39,000,000.0	-
morphine-N-oxide		increase APQ	50.0	ref std; increase APQ	605.0	655.0	50.0
nabilone		increase APQ	10,000.0	prod dev; increase APQ	10,502.0	20,502.0	10,000.0
noroxymorphone (for conversion)		increase APQ	4,800,000.0	APQ sufficient at this time	7,200,000.0	7,200,000.0	-
noroxymorphone (for sale)		increase APQ	1,200,000.0	not enough information to consider	401,000.0	401,000.0	-
opium (tincture)		increase APQ	1,000,000.0	APQ sufficient at this time	1,000,000.0	1,000,000.0	-
oripavine		increase APQ	7,000,000.0	APQ sufficient at this time	9,800,000.0	9,800,000.0	-
oxycodone (for conversion)		increase APQ	7,000,000.0	no change	5,600,000.0	5,600,000.0	-
oxycodone (for sale)		increase APQ	70,900,000.0	no change	98,000,000.0	98,000,000.0	-
oxymorphone (for conversion)		increase APQ	4,230,000.0	APQ sufficient at this time	12,800,000.0	12,800,000.0	-
		increase APQ	7,000,000.0				
oxymorphone (for sale)		increase APQ	1,398,000.0	APQ sufficient at this time	5,500,000.0	5,500,000.0	-
		increase APQ	4,000,000.0				
pentobarbital		increase APQ	25,000.0	increase APQ to match 2011 Final APQ	31,000,000.0	34,000,000.0	3,000,000.0
phenylacetone		increase APQ	18,000,000.0	pd efforts to validate domestic manufacturing	8,000,000.0	16,000,000.0	8,000,000.0
properidine		increase APQ	1.0	drug code 9644 - schedule I narcotic	-	2.0	2.0
sufentanil		increase APQ	300.0	APQ sufficient at this time	5,000.0	5,000.0	-
		increase APQ	2,100.0				
tapentadol		increase APQ	120,000.0	pd efforts to validate domestic manufacturing	243,000.0	5,400,000.0	5,157,000.0
		increase APQ	5,100,000.0				
		increase APQ	72,000.0				
thebaine		increase APQ	753,000.0	APQ sufficient at this time	116,000,000.0	116,000,000.0	-

Number of registrants/entities commenting: 15 (five non-registrants)
Number of drugs commented on: 37 (five were for reduction of all opioid drugs)

Additional Considerations:

Drug	Response	Proposed	Revised	Change
phenylacetone	(b)(4) plans to shift from importation to domestic manufacturing once FDA approval is granted for their manufacturing process in 2012	8,000,000.0	16,000,000.0	8,000,000.0
tapentadol	(b)(4) currently imports bulk material to utilize for fdf stateside, patent is expiring so other manufacturers are also requesting material for their pd efforts. (b)(4) is waiting for determination for precursor may need 2,000kg less. (b)(4) will not sell in 2012 but hold in inventory until FDA approval	243,000.0	5,400,000.0	5,157,000.0
gamma hydroxybutyric acid	(b)(4) are requesting material for product development efforts	29,000,000.0	47,000,000.0	18,000,000.0
3,4-Methylenedioxy-N-methylcathinone	temporarily controlled as Schedule 1 on Oct 21, 2011 - ref stds will be required by (b)(4)	-	8.0	8.0
3,4-Methylenedioxypyrovalerone (MDPV)	temporarily controlled as Schedule 1 on Oct 21, 2011 - ref stds will be required by	-	8.0	8.0
4-Methyl-N-methylcathinone (mephedrone)	temporarily controlled as Schedule 1 on Oct 21, 2011 - ref stds will be required by	-	8.0	8.0

(b)(4)

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ODE

2011 NOV 21 PM 2:53

Drug Enforcement Administration
Office of Diversion Control
Attn: DEA Federal Register Representative/OD
8701 Morrissette Drive
Springfield, VA 22152

November 14, 2011

Re: **Docket Number DEA-358**

Dear Sir or Madame:

This comment is in response to Federal Register Docket Number DEA-358, the Proposed Aggregate Production Quotas for 2012 as published on October 21, 2011. **This letter contains Confidential Business Information highlighted with red print, to be redacted prior to online publication or posting.**

The proposed aggregate production quota listed for Noroxymorphone (for sale) is 401,000 grams. Our firm requests that this quota be increased to at least **1,200,000 grams**, which is the quantity our firm expects to manufacture during 2012.

Our firm is under contract to (b)(4) a multinational pharmaceutical firm, to manufacture the bulk Active Pharmaceutical Ingredient (API) **for mPEG-Naloxol,** also known as **NKTR-118**. This material has been deemed by DEA to be a derivative of noroxymorphone (drug code 9668), pursuant to a Controlled Status Determination letter from DEA dated July 17, 2010.

We have received a letter of intent from (b)(4) indicating that they expect to purchase 1,200 kilograms of NKTR-118 oxalate salt from (b)(4) during 2012. A copy of that letter is attached.

At a conversion rate of 0.88, 1,200 kg of **oxalate salt** equates to 1,056 kilograms of base. We are requesting that the aggregate be increased to allow the manufacturing of that quantity of material, as well as a small percentage of overage, to provide for a year-end inventory to meet requirements for the first quarter of 2013, as well as a quantity required for sampling and production losses.

(b)(4)

(b)(4)

Drug Enforcement Administration
November 14, 2011

Your consideration of this request is appreciated. If you have any questions, or require further information, please telephone me at (b)(6) or contact me via e-mail at (b)(4);(b)(6)

Sincerely,

(b)(6)

DEA Regulatory Specialist

attachment: a/s

(b)(4)

(b)(4)

(b)(4)

Södertälje 11 November, 2011

(b)(4) is having the compound NKTR-118 oxalate in an R&D clinical programme, and preparations for commercial manufacturing of the Drug Product are on-going.
We intend to have 1200 kgs of NKTR-118 oxalate under drug code for noroxymorphone manufactured at (b)(4) (b)(4) in 2012.

Regards,

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

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

53 074-S

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2011 NOV 18 AM 6:35

CONFIDENTIAL

SENT VIA E-MAIL

November 16, 2011

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

Subject: Docket No. DEA-358

Dear Sirs:

I, (b)(4);(b)(6) manufacturing registration (b)(4);(b)(7)(E) am submitting this comment on the 2012 Proposed Aggregate Production Quota for various products as published in the October 21, 2011 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) Alfentanil by 3,500 grams as base; (ii) Amphetamine (for sale) by 3,200,000 grams as base; (iii) Codeine (for conversion) by 1,100,000 grams as base; (iv) Dihydromorphine by 300,000 grams as base; (v) Diphenoxylate by 15,000 grams as base; (vi) Hydrocodone by 3,020,000 grams as base; (vii) Meperidine by 26,800 grams as base; (viii) Methamphetamine by 8,000 grams as base; (ix) Methylphenidate by 2,150,000 grams as base; (x) Sufentanil by 300 grams as base; (xi) Hydromorphinol by 1 gram as base; (xii) Pethidine Intermediate A by 1 gram a base; (xiii) Pethidine Intermediate B by 1 gram as base; (xiv) Pethidine Intermediate C by 1 gram as base; and (xv) Properidine by 1 gram as base. As noted herein, this first paragraph of this letter contains personal identifying and confidential business information and should be redacted in its entirety from any public docket.

We feel the proposed quantities for the material mentioned above is not sufficient to provide for adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements, and that the quotas should be increased to cover our needs. The appropriate DEA Form 189 will be or have been submitted pertaining to the items for which we submitted comments.

Very truly yours

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CONFIDENTIAL

2011 NOV 18 AM 6:35

SENT VIA E-MAIL

November 16, 2011

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

Subject: Docket No. DEA-358

Dear Sirs:

I, (b)(4);(b)(6) manufacturing registration (b)(4);(b)(7)(E) am submitting this comment on the 2012 Proposed Aggregate Production Quota for various products as published in the October 21, 2011 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) Meperidine by 93,000 grams as base; (ii) Methadone by 805,000 grams as base; (iii) Methadone Intermediate by 1,500,000 grams as base; and (iv) Morphine (for conversion) by 900,000 grams as base. As noted herein, this first paragraph of this letter contains personal identifying and confidential business information and should be redacted in its entirety from any public docket.

We feel the proposed quantities for the material mentioned above is not sufficient to provide for adequate supplies for the medical, scientific, research and industrial needs of the United States, and for the lawful export requirements, and that the quotas should be increased to cover our needs. The appropriate DEA Form 189's will be or have been submitted pertaining to the items for which we submitted comments.

Very truly yours

(b)(4)

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2011 NOV 16 AM 9:02

DEA Headquarters
Attn: DEA Federal Register Representative/OD
8701 Morrissette Drive
Springfield, VA 22152

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

November 11, 2011

Subject: Docket No. DEA-358 – Morphine-N-oxide

Dear Federal Register Representative,

By the end of November, (b)(4);(b)(7)(E) will be requesting to be registered as a manufacturer of Morphine-N-oxide. We are providing comment to the proposed aggregate production quota for 2012 for Morphine-N-oxide.

(b)(4) is requesting the aggregate be increased by at least 50 grams to allow sufficient aggregate for (b)(4) to be granted 50 grams of manufacturing quota in order to manufacture Morphine-N-oxide as a reference standard to be used in the analysis primarily of Morphine Sulfate but also other opiate drug products and drug substances. Morphine-N-oxide is a potential known impurity in Morphine Sulfate and possibly other opiates.

(b)(4) respectfully requests that the 2012 aggregate production quota for Morphine-N-oxide be increased by at least 50 grams to allow for our request.

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

Sincerely,

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

DEA Compliance Manager

(b)(4)

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ODE

2011 NOV 16 AM 9:02

DEA Headquarters
Attn: DEA Federal Register Representative/OD
8701 Morrissette Drive
Springfield, VA 22152

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

November 11, 2011

Subject: Docket No. DEA-358 - Hydromorphinol

Dear Federal Register Representative,

(b)(4) is a registered manufacturer (b)(4);(b)(7)(E) of Hydromorphinol. We are providing comment to the proposed aggregate production quota for 2012 for Hydromorphinol.

(b)(4) is requesting the aggregate be increased by at least 50 grams to allow sufficient aggregate for (b)(4) to be granted 50 grams of manufacturing quota in order to manufacture Hydromorphinol as a reference standard to be used primarily in the analysis of Oxymorphone but also other opiate drug product and drug substances. Hydromorphinol is a potential known impurity in Oxymorphone and our Oxymorphone customers have already requested this reference standard.

(b)(4) respectfully requests that the 2012 aggregate production quota for Hydromorphinol be increased by at least 50 grams to allow for our request.

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

Sincerely,

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

DEA Compliance Manager

CONFIDENTIAL BUSINESS INFORMATION

(b)(4)

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2011 NOV 21 PM 4:32

18 November 2011

DEA Federal Register Representative/OD
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA-358
Proposed Revised Aggregate Production Quotas for 2012
Tapentadol (9780)

CONFIDENTIAL BUSINESS INFORMATION

(b)(4) requests that the DEA revise the 2012 aggregate production quota to establish at least 1200 kg of 2011 Tapentadol aggregate manufacturing quota. (b)(4),(b)(7)(E) is developing tapentadol hydrochloride to support several generic pharmaceutical companies who plan to file generic versions of this active pharmaceutical ingredient (API). The goal for these companies is to submit Abbreviated New Drug Applications (ANDA) in late 2012. To support this development schedule, manufacturing quota in excess of the Proposed Aggregate Production Quota for 2012 (Docket DEA-358) will be required.

(b)(4) anticipates two manufacturing campaigns in 2012. The first will conclude in January 2012. This campaign is a continuation of production started in December 2011. (b)(4) had hoped to complete this campaign in 2011, but manufacturing delays will require a portion of this production to slip into January 2012. The second campaign is planned for March-April 2012. This will allow API to be formulated and stability studies completed to support ANDA submission in Q4 2012. (b)(4) anticipates manufacturing requirement ~900 kg (900,000 grams) in 2012 to meet these needs.

Customers have provided the following forecasts for Tapentadol HCl demand in 2012:
CONFIDENTIAL BUSINESS INFORMATION

Customer	Demand base form (kg)
(b)(4)	154.8
	258.0
	129.0
	116.1
	77.4
	172.0
TOTAL	907.3

(b)(4)

(b)(4)

The customer forecasts total 907.3 kg (base); the 243 kg proposed 2012 aggregate quota will not be sufficient to support these customers. (b)(4) requests that the DEA revise the 2012 aggregate production quota to establish at least 1200 kg of Tapentadol aggregate manufacturing quota. (b)(4) has only requested 120 kg of quota for 2012 but due to the latest numbers forecasted by our customers, we will be submitting an increased 2012 quota request to support our planned 2012 campaigns.

This aggregate quota increase is essential to support the development of generic drug version of this drug in accordance with U.S. Drug Price Competition and Patent Term Restoration Act of 1984.

Thank you for your consideration of this request.

Respectfully yours,

(b)(6)

Director of US Operations

(b)(4)

PUBLIC SUBMISSION

As of: November 21, 2011
Received: November 21, 2011
Status: Pending_Post
Tracking No. 80f70865
Comments Due: November 21, 2011
Submission Type: Web

Docket: DEA-2011-0014
Controlled Substances: Proposed Aggregate Production Quotas for 2012

Comment On: DEA-2011-0014-0001
Controlled Substances: Proposed Aggregate Production Quotas for 2012

Document: DEA-2011-0014-DRAFT-0006
Comment on FR Doc # 2011-27283

Submitter Information

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

General Comment

The attached file constitutes (b)(4) comments on the Proposed Initial Aggregate Production Quotas for 2012, as published in the Federal Register on October 21, 2011, FR Vol. 76.

(b)(6)
Supervisor, Controlled Substance Compliance
(b)(4);(b)(6)

Attachments

2012 Initial Aggregate Comment (b)(4);(b)(7)(E)

(b)(4)

(b)(4)

November 21, 2011

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

Attn: DEA Federal Register Representative [Docket No. DEA-358]

This letter constitutes (b)(4) comments on the Proposed Initial Aggregate Production Quotas for 2012, as published in Federal Register on October 21, 2011, FR Vol. 76, No. 204, pages 65537-65540.

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

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

9050 Codeine (for conversion)

(b)(4) requests that the initial aggregate be sufficient to include its request for 36,000,000 grams AA of Codeine (for conversion) manufacturing quota for 2012.

9120 Dihydrocodeine

(b)(4) requests that the initial aggregate be sufficient to include its request for 280,000 grams AA of Dihydrocodeine manufacturing quota for 2012.

9170 Diphenoxylate

(b)(4) requests that the initial aggregate be sufficient to include its request for 950,000 grams AA of Diphenoxylate manufacturing quota for 2012.

9193 Hydrocodone (for sale)

(b)(4) requests that the initial aggregate be sufficient to include its request for 31,000,000 grams AA of Hydrocodone (for sale) manufacturing quota for 2012.

9220 Levorphanol

(b)(4) requests that the initial aggregate be sufficient to include its request for 6,100 grams AA of Levorphanol manufacturing quota for 2012.

9230 Meperidine

(b)(4) requests that the initial aggregate be sufficient to include its request for 2,100,000 grams AA of Meperidine manufacturing quota for 2012.

1724 Methylphenidate

(b)(4) requests that the initial aggregate be sufficient to include its request for 7,400,000 grams AA of Methylphenidate manufacturing quota for 2012.

9300 Morphine (for conversion)

(b)(4) requests that the initial aggregate be sufficient to include its request for 46,000,000 grams AA of Morphine (for conversion) manufacturing quota for 2012.

9300 Morphine (for Sale)

(b)(4) requests that the initial aggregate be sufficient to include its request for 23,000,000 grams AA of Morphine (for Sale) manufacturing quota for 2012.

9668 Noroxymorphone (for conversion)

(b)(4) requests that the initial aggregate be sufficient to include its request for 4,800,000 grams AA of Noroxymorphone (for conversion) manufacturing quota for 2012.

9630 Opium Tincture

(b)(4) requests that the initial aggregate be sufficient to include its request for 1,000,000 grams AA of Opium Tincture manufacturing quota for 2012.

9330 Oripavine

(b)(4) requests that the initial aggregate be sufficient to include its request for 7,000,000 grams AA of Oripavine manufacturing quota for 2012.

9143 Oxycodone (for conversion)

(b)(4) requests that the initial aggregate be sufficient to include its request for 7,000,000 grams AA of Oxycodone (for conversion) manufacturing quota for 2012.

9652 Oxymorphone (for conversion)

(b)(4) requests that the initial aggregate be sufficient to include its request for 7,000,000 grams AA of Oxymorphone (for conversion) manufacturing quota for 2012.

9652 Oxymorphone (for sale)

(b)(4) requests that the initial aggregate be sufficient to include its request for 4,000,000 grams AA of Oxymorphone (for sale) manufacturing quota for 2012.

9740 Sufentanil

(b)(4) requests that the initial aggregate be sufficient to include its request for 2,100 grams AA of Sufentanil manufacturing quota for 2012.

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

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

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

PUBLIC SUBMISSION

As of: November 16, 2011
Received: November 16, 2011
Status: Posted
Posted: November 16, 2011
Tracking No. 80f6dc41
Comments Due: November 21, 2011
Submission Type: Web

Docket: DEA-2011-0014
Controlled Substances: Proposed Aggregate Production Quotas for 2012

Comment On: DEA-2011-0014-0001
Controlled Substances: Proposed Aggregate Production Quotas for 2012

Document: DEA-2011-0014-0002
Comment on FR Doc # 2011-27283

Submitter Information

Name: Ada Giudice-Tompson
Address:
452 Athabasca Drive
4100 Galt Ocean Drive
Fort Lauderdale, Florida 33308 U.S.A., Ontario, Canada, L6A 3S2
Email: adatompson@rogers.com
Phone: 905 417-3153

General Comment

RE: Docket No. DEA-358
Controlled Substances: Proposed Aggregate Production Quotas for 2012

As a bereaved mother who lost my only child Michael to a prescribed opioid I offer these comments on the DEA's proposed aggregate production quotas for Schedule I and II opioids in 2012:

- End the epidemic of death and addiction caused by prescription opioid drugs by ensuring that opioids are regulated, marketed and prescribed to patients who are terminally ill or short term for severe pain; not for long term use.
- The destruction we have witnessed clearly highlights the inherent dangers of opioids. To focus on the misuse of opioids is to continue to cloak them in a veil of legitimacy.

It is the responsibility and duty of the DEA to significantly reduce the quotas for Schedule I and II drugs and avoid the overproduction and saturation of the market which has contributed to this epidemic of legally prescribed Heroin-like drugs.

Sincerely

Ada Giudice-Tompson

November 6, 2011

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

RE: Docket No. DEA-358
Controlled Substances: Proposed Aggregate Production Quotas for 2012

On behalf of Advocates for the Reform of Prescription Opioids, Inc. (ARPO), I offer these comments on the DEA's proposed aggregate production quotas for Schedule II opioids in 2012. ARPO formed earlier this year with the goal of ending the epidemic of death and addiction caused by prescription opioid drugs by ensuring that opioids are regulated, marketed, prescribed and used in an evidence-based manner. Many of our members are bereaved parents who lost a child to prescription opioids. In my case, I lost my eighteen year-old daughter Emily after she consumed one OxyContin pill given to her by a relative. Others in our group are struggling with an addicted family member; the majority of these cases began due to an injury that led to an opioid prescription.

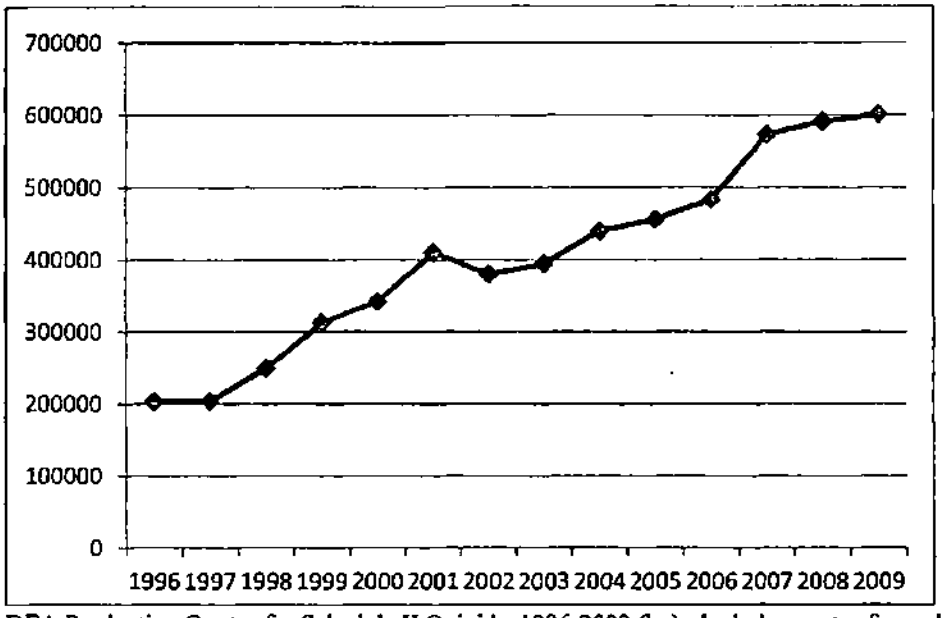
The United States and other developed countries around the world are currently in what has been termed a prescription drug epidemic. The term, "epidemic", has been used by Office of National Drug Control Policy Director Gil Kerlikowske, the Centers for Disease Control, National Insitute on Drug Abuse Director Nora Volkow, SAMHSA, coroners and others to refer to the prescription drug crisis we are currently facing. In her remarks before a Congressional subcommittee earlier this year, DEA Administrator Michele Leonhart stated that "Prescription drug abuse is a serious problem. Reducing prescription drug abuse is vital to the health and welfare of the American people." (Leonhart 2011)[1]. Of some 35,450 deaths in the United States in 2008, more than 20,000 of these deaths were attributed to prescription drugs, and of those 14,800 deaths were attributed to prescription opioids (CDC 2011).

According to the DEA website, the mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States. In fulfillment of this mission, DEA establishes production quotas for Schedule I and II drugs every year. In her Congressional remarks earlier this year, Administrator Leonhart stated that "DEA establishes manufacturing and procurement quotas each year for schedule I and II controlled substances in order to avoid the overproduction of these substances, for the purpose of reducing the risk of diversion to illicit traffic. Accordingly, the quota system serves the vital purpose of reducing the risk of diversion" (Leonhart 2011). If this is indeed the objective of the quota system, the

[1] Administrator Leonhart also stated: "The economic impact on the United States from the non-medical use of prescription opioids in 2006 was estimated at $53.4 billion".

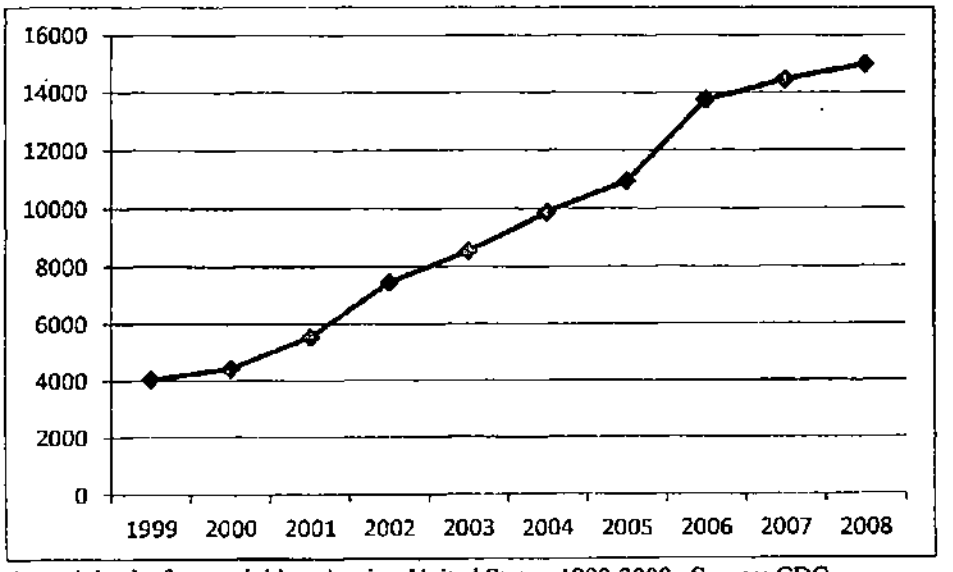
following information casts serious doubt on the effectiveness of DEA's administration of its quota system.

Here is a graph showing the steady increase in DEA production quotas for most Schedule II opioids:



DEA Production Quotas for Schedule II Opioids, 1996-2009 (kg). Includes quotas for codeine, fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, opium, oxycodone, oxymorphone and thebaine. Source: DEA website.

In the United States during roughly this same time period, deaths from prescription opioids have risen in parallel with the increase in supply:

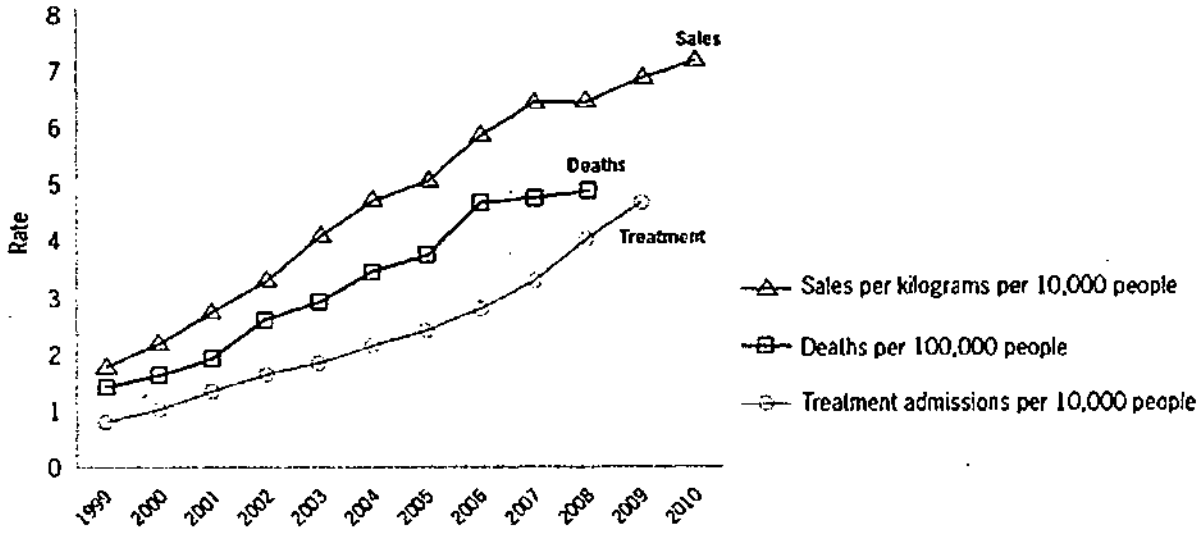


Annual deaths from opioid analgesics, United States, 1999-2008. Source: CDC.

These two trend lines are clearly very highly correlated (Pearson correlation coefficient = 0.94 for years 1999-2008), providing evidence of the close relationship between the supply of prescription opioids, as represented by the DEA quotas, and deaths from these same drugs.

Following is a graph from the Centers for Disease Control that shows that the rate of deaths and treatment admissions attributed to prescription opioids have steadily risen in lock step with sales of prescription opioids in the United States:

Rates of prescription painkiller sales, deaths and substance abuse treatment admissions (1999-2010).



SOURCE: CDC Vital Signs, November 2011. CDC references: National Vital Statistics System, 1999-2008; Automation of Reports and Consolidated Orders System (ARCOS) of the Drug Enforcement Administration (DEA), 1999-2010; Treatment Episode Data Set, 1999-2009

These graphics vividly establish that deaths and addictions from prescription opioids have continued to rise unabated as DEA production quotas have been increased. It is abundantly clear that the steadily increasing supply of opioids that is made possible through DEA's production quotas is driving the prescription opioid epidemic.

The time has come for DEA to finally recognize that its production quotas enable the production of drugs that kill and addict thousands of Americans and other citizens throughout the world each year. Thus, **DEA is directly responsible for enabling the American drug production system to mass produce huge quantities of narcotics that are killing people and destroying lives.** To consider only the benefits that these medications provide is to ignore a major public health problem that is being driven by DEA's drug quota policies. With all of the problems brought on by the mass production of oxycodone in this country, a 2012 proposal to allow the production of 103,600 kg (114 tons), a 1,747% increase over the amount produced in 1996, the year OxyContin first came on the market, is unconscionable and reflects a complete disregard for the loss of life that this drug has caused.

According to CDC, in 2010 about 12 million Americans aged 12 or older (about one in twenty) reported using prescription opioids nonmedically, enough to medicate every American adult around the clock for a month (CDC 2011). This constitutes proof that these powerful and deadly narcotics have over-saturated our society. The DEA has approved these massive increases in the legal supply of prescription opioids without evidence that these narcotics are safe or effective for chronic noncancer pain. Rather than taking the drug companies' or FDA's word for it, why does DEA not conduct its own investigation on the efficacy of these drugs and how the drug companies propose to use them? A good place to begin your investigation is the website of Physicians for Responsible Opioid Prescribing (PROP) at: http://www.responsibleopioidprescribing.org/. Our own website also provides up to date medical research on prescription opioids: http://www.rxreform.org/.

The time has come for DEA to do the right thing – it must **roll back the production quotas** to save lives.

Sincerely,

Peter W. Jackson

Peter W. Jackson, President
Advocates for the Reform of Prescription Opioids
www.rxreform.org

References:

CDC 2011. CDC Vital Signs. http://www.cdc.gov/VitalSigns/PainkillerOverdoses/#LatestFindings

CDC 2011. Vital Signs: Overdoses of Prescription Opioid Pain Relievers – United States, 1999-2008. Morbidity and Mortality Weekly Report, November 2, 2011. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6043a4.htm?s_cid=mm6043a4_w

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PUBLIC SUBMISSION

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Docket: DEA-2011-0014
Controlled Substances: Proposed Aggregate Production Quotas for 2012

Comment On: DEA-2011-0014-0001
Controlled Substances: Proposed Aggregate Production Quotas for 2012

Document: DEA-2011-0014-0004
Comment on FR Doc # 2011-27283

Submitter Information

Name: Jeremy S Mirabile
Address:
301 Justice Lane
Bunnell, FL, 32110
Phone: 386-236-1748
Fax: 386-236-1823
Organization: Stewart-Marchman-Act Behavioral Healthcare

General Comment

Docket No DEA-358
As Deputy Medical Director for Addictions for the Stewart-Marchman-Act Behavioral Healthcare and the Director of the Vince Carter Sanctuary I am asking that you significantly cut back the production quotas for 2012.

The market is already flooded with these drugs of which a significant percentage then becomes available on the street.

I

PUBLIC SUBMISSION

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Controlled Substances: Proposed Aggregate Production Quotas for 2012

Comment On: DEA-2011-0014-0001
Controlled Substances: Proposed Aggregate Production Quotas for 2012

Document: DEA-2011-0014-0005
Comment on FR Doc # 2011-27283

Submitter Information

Name: Trudy Duffy
Address:
1011 Faulkner St
New Smyrna Beach, FL,

General Comment

Re: Docket No. DEA-358 Controlled Substances
A recent Center for Disease Control report states "Enough prescription painkillers were prescribed in 2010 to medicate every American adult around the clock for a month."

We are living in the midst of a public health tragedy stemming from the damage inflicted on society by the use and oversupply of prescription opioids. The quota system, which should serve to reduce the risk of diversion, could have either helped to avoid or reduce this epidemic. The rising level of public awareness and the lack of government oversight to date gives the DEA an opportunity to become an active participant in curbing this epidemic. Reports generated by the CDC, USDHHS and NIH are all clear indicators of an oversaturation of the market with deadly consequences. In 9/11 terms, "the system is blinking red".

I live in Florida where excessive unit doses are shipped. The manufacturers are aware of the oversupply, diversion and their culpability. The epidemic begins with production and in the past reducing manufacturing quotas cut abuse successfully for other drugs. Is the influence of the pharm companies driving the decision? Prescription opiods sanctioned by the government, over-promoted and highly prescribed, with known potential for abuse and diversion is a public health tragedy. The DEA must take action now. To not do so is unthinkable.

In Volusia County, Florida a recent Drug Task Force Forum attracted over 300 participants. Our

courts, jails, hospitals and treatment facilities are now recognizing the ramifications of opioid addiction and are overwhelmed. Too many are suffering and too many have died.

I urge you to read the data. You have the power and the responsibility to make a difference.

PUBLIC SUBMISSION

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Docket: DEA-2011-0014
Controlled Substances: Proposed Aggregate Production Quotas for 2012

Comment On: DEA-2011-0014-0001
Controlled Substances: Proposed Aggregate Production Quotas for 2012

Document: DEA-2011-0014-0006
SG Comment 2011-11-19

Submitter Information

Name: S G
Address:
Myrtle Beach, SC,

General Comment

NOVEMBER 19, 2010

TO THE DRUG ENFORCEMENT ADMINISTRATION
ATTENTION: DEA FEDERAL REGISTER REPRESENTATIVE/OD
8701 MORRISSETTE DRIVE SPRINGFIELD,VA 22152

The proposal to allow the continued massive production quotas for 2012 of Schedule II opioids, such as 103,600 kg of oxycodone, needs to be urgently re-assessed, especially in light of the mounting death toll caused by this and other prescription narcotics. As documented by the CDC, the growing volume of opioid-related mortality is clearly related to the volume of opioid sales and prescribing, which have been excessive and inappropriate across the nation, especially for chronic noncancer pain. The promotion and marketing of OxyContin and other opioids for expanded use well beyond that of cancer pain, was based upon false premises in the absence of scientific validation, and done for commercial and political objectives and motivations. It is unfortunate that the DEA was swayed by the myths and misinformation spread by the opioid drug companies and a misguided pain 'management' industry dangerously overly-focused on narcotics.

Over the past ten years, the risky practice of opioid overprescribing has lead to an epidemic and public health crisis of addiction, abuse, crime, overdose and death

throughout the nation with no end in sight. Diversion of widely available and accessible prescription opioids has had a catastrophic effect on our youth, while providing many opioid-dependent and addicted patients with illegal sources of income and facilitating involvement in related criminal activities, which have significantly increased during these hard economic times.The death toll continues to rise, with over 6000 prescription opioid-related deaths in the state of Florida alone during 2010, with oxycodone accounting for about one-third of these, as per data from the Office of the Florida Medical Examiners.

A group of medical experts have put together a website of medical information for physicians, containing multiple evidence-based studies including the recent CDC data, which seeks to reverse the dangerous practices and misconceptions about prescription opioids which underlie the disastrous consequences stemming from the massive overuse and oversupply of prescription narcotics, such as oxycodone. The link to this website can be accesssed at: www.responsibleopioidprescribing.org. It is apparent from the videos of this site that leaders in the pain management community have now re-assessed and reversed their initially misinformed attitudes about opioid prescribing, and now acknowledge the very clear risks of widespread, nonselective opioid use for chronic noncancer pain, especially at higher doses, and the lack of evidence for their long-term effectiveness.

It is hoped that the DEA will re-evaluate its position on production quotas for Schedule II opioids, and return to the initial approach it had ten years ago when it closed down the Comprehensive Pain Clinic of Myrtle Beach, SC, one of the nation's first 'pill mills'. If it had followed-up and adhered to the same strategy over the ensuing years, the current opioid epidemic with its mounting toll of addiction and death and the massive proliferation of the Florida 'pill-mills' [which are now spreading to other states], could have been significantly curtailed.

Sincerely,

SG
Myrtle Beach, SC
11/19/11

2012 Establish Initial Aggregate Production Quotas

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

- The attached Federal Register notice, prepared for your signature, established initial year 2012 aggregate production quotas (APQ) for schedules I and II controlled substances for which the United States has medical, scientific, industrial, export and reserve stock requirements. Also attached is a list of the 2010 and proposed 2011 APQs for these substances for comparison.

- Expeditious publication of this notice is necessary to ensure that quota is available at the beginning of 2012 for manufacturing. The following points provide brief explanations of the changes from the proposed APQ values:

Schedule I substances

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

- The APQ for **gamma hydroxybutyric acid** was increased to support new product development and validation efforts.

Schedule II substances

- The APQ for **alfentanil** and **lisdexamfetamine** were increased to support increased exportation requirements.

- The APQ for **meperidine intermediate A, meperidine intermediate B,** and **meperidine intermediate C** were increased due to additional applications received to support the manufacturing of diagnostic kits and or reference standards.

- The APQ for **nabilone** and **tapentadol** were increased to support new product development and validation efforts which would allow for the domestic manufacturing of these substances.

- The APQ for **dihydrocodeine, diphenoxylate, meperidine, pentobarbital** and **phenylacetone** were increased due to additional applications received to support the manufacturing efforts.

- The APQ for **noroxymorphone (for sale)** was not increased to support new manufacturing of NKTR-118, or mPEG-Naloxol which falls under the basic drug class noroxymorphone.

Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Initial	Final Revised	Proposed Initial	Initial
Schedule I:	2010	2011	2011	2012	2012
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	0	0	45	45	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	0	0	45	45	45
1-Methyl-4-phenyl-4-propionoxypiperidine	0	2	2	2	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	0	0	45	45	45
2,5-Dimethoxyamphetamine	2	2	2	2	2
2,5-Dimethoxy-4-Ethylamphetamine (DOET)	2	2	2	2	2
2,5-Dimethoxy-4-(n)-propylthiophenethylamine	0	2	2	2	2
3-Methylfentanyl	2	2	2	2	2
3-Methylthiofentanyl	2	2	2	2	2
3,4-Methylenedioxyamphetamine (MDA)	20	22	22	22	22
3,4-Methylenedioxy-N-Ethylamphetamine (MDEA)	10	15	15	15	15
3,4-Methylenedioxy-N-methylcathinone (methylone)					8
3,4-Methylenedioxymethamphetamine (MDMA)	20	22	22	22	22
3,4-Methylenedioxypyrovalerone (MDPV)					8
3,4,5-Trimethoxyamphetamine	2	2	2	2	2
4-Bromo-2,5-Dimethoxyamphetamine (DOB)	2	2	2	2	2
4-Bromo-2,5-Dimethoxyphenethylamine (2-CB)	2	2	2	2	2
4-Methoxyamphetamine	77	77	77	77	77
4-Methylaminorex	2	2	2	2	2
4-Methyl-2,5-Dimethoxyamphetamine (DOM)	2	2	2	2	2
4-Methyl-N-methylcathinone (mephedrone)					8
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	0	0	68	68	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	0	0	53	53	53
5-Methoxy-3,4-Methylenedioxyamphetamine	2	2	2	2	2
5-Methoxy-N,N-diisopropyltryptamine	0	2	2	2	2
Acetyl-alpha-methylfentanyl	2	2	2	2	2
Acetyldihydrocodeine	2	2	2	2	2
Acetylmethadol	2	2	2	2	2
Allylprodine	2	2	2	2	2
Alphacetylmethadol	2	2	2	2	2
Alpha-ethyltryptamine	2	2	2	2	2
Alphameprodine	2	2	2	2	2
Alphamethadol	2	2	2	2	2
Alpha-methylfentanyl	2	2	2	2	2
Alpha-methylthiofentanyl	2	2	2	2	2
Alpha-methyltryptamine (AMT)	2	2	2	2	2
Aminorex	2	2	2	2	2
Benzylmorphine	2	2	2	2	2
Betacetylmethadol	2	2	2	2	2
Beta-hydroxy-3-methylfentanyl	2	2	2	2	2
Beta-hydroxyfentanyl	2	2	2	2	2
Betameprodine	2	2	2	2	2
Betamethadol	2	2	2	2	2
Betaprodine	2	2	2	2	2
Bufotenine	3	3	3	3	3
Cathinone	3	4	4	4	4
Codeine-N-Oxide	602	602	602	602	602
Diethyltryptamine	2	2	2	2	2
Difenoxin	3,000	3,000	50	50	50
Dihydromorphine	3,608,000	3,608,000	3,608,000	3,608,000	3,608,000
Dimethyltryptamine	3	7	7	7	7
Gamma-hydroxybutyric acid	52,156,000	3,000,000	5,772,000	29,000,000	47,000,000
Heroin	20	20	20	20	20
Hydromorphinol	2	2	2	2	54
Hydroxypethidine	2	2	2	2	2
Ibogaine	1	5	5	5	5
Lysergic Acid Diethylamide	15	16	16	16	16
Marihuana	21,000	21,000	21,000	21,000	21,000
Mescaline	5	5	5	5	5
Methaqualone	7	10	10	10	10
Methcathinone	4	4	4	4	4
Methyldihydromorphine	2	2	2	2	2
Morphine-N-oxide	605	605	605	605	655
N-Benzylpiperazine	2	2	2	2	2

Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised 2009	Final Revised 2010	Initial 2011	Final Revised 2011	Proposed Initial 2012
Schedule I:					
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	0	0	0	45	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	0	0	0	45	45
1-Methyl-4-phenyl-4-propionoxypiperidine	0	0	2	2	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	0	0	0	45	45
2,5-Dimethoxyamphetamine	2	2	2	2	2
2,5-Dimethoxy-4-Ethylamphetamine (DOET)	2	2	2	2	2
2,5-Dimethoxy-4-(n)-propylthiophenethylamine	0	0	2	2	2
3-Methylfentanyl	2	2	2	2	2
3-Methylthiofentanyl	2	2	2	2	2
3,4-Methylenedioxyamphetamine (MDA)	25	20	22	22	22
3,4-Methylenedioxy-N-Ethylamphetamine (MDEA)	10	10	15	15	15
3,4-Methylenedioxymethamphetamine (MDMA)	20	20	22	22	22
3,4,5-Trimethoxyamphetamine	2	2	2	2	2
4-Bromo-2,5-Dimethoxyamphetamine (DOB)	2	2	2	2	2
4-Bromo-2,5-Dimethoxyphenethylamine (2-CB)	2	2	2	2	2
4-Methoxyamphetamine	27	77	77	77	77
4-Methylaminorex	2	2	2	2	2
4-Methyl-2,5-Dimethoxyamphetamine (DOM)	2	2	2	2	2
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	0	0	0	68	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	0	0	0	53	53
5-Methoxy-3,4-Methylenedioxyamphetamine	2	2	2	2	2
5-Methoxy-N,N-diisopropyltryptamine	5	0	2	2	2
Acetyl-alpha-methylfentanyl	2	2	2	2	2
Acetyldihydrocodeine	2	2	2	2	2
Acetylmethadol	2	2	2	2	2
Allylprodine	2	2	2	2	2
Alphacetylmethadol	2	2	2	2	2
Alpha-ethyltryptamine	2	2	2	2	2
Alphameprodine	2	2	2	2	2
Alphamethadol	2	2	2	2	2
Alpha-methylfentanyl	2	2	2	2	2
Alpha-methylthiofentanyl	2	2	2	2	2
Alpha-methyltryptamine (AMT)	0	2	2	2	2
Aminorex	2	2	2	2	2
Benzylmorphine	2	2	2	2	2
Betacetylmethadol	2	2	2	2	2
Beta-hydroxy-3-methylfentanyl	2	2	2	2	2
Beta-hydroxyfentanyl	2	2	2	2	2
Betameprodine	2	2	2	2	2
Betamethadol	2	2	2	2	2
Betaprodine	2	2	2	2	2
Bufotenine	3	3	3	3	3
Cathinone	3	3	4	4	4
Codeine-N-Oxide	602	602	602	602	602
Diethyltryptamine	2	2	2	2	2
Difenoxin	3,000	3,000	3,000	50	50
Dihydromorphine	3,132,000	3,608,000	3,608,000	3,608,000	3,608,000
Dimethyltryptamine	3	3	7	7	7
Gamma-hydroxybutyric acid	24,200,000	52,156,000	3,000,000	5,772,000	29,000,000
Heroin	20	20	20	20	20
Hydromorphinol	2	2	2	2	2
Hydroxypethidine	2	2	2	2	2
Ibogaine	1	1	5	5	5
Lysergic Acid Diethylamide	10	15	16	16	16
Marihuana	4,500,000	21,000	21,000	21,000	21,000
Mescaline	7	5	5	5	5
Methaqualone	5	7	10	10	10
Methcathinone	4	4	4	4	4
Methyldihydromorphine	2	2	2	2	2
Morphine-N-oxide	605	605	605	605	605
N-Benzylpiperazine	2	2	2	2	2
N,N-Dimethylamphetamine	7	2	2	2	2
N-Ethylamphetamine	2	2	2	2	2
N-Hydroxy-3,4-Methylenedioxyamphetamine	2	2	2	2	2

Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Final Revised	Initial	Final Revised	Proposed Initial
Schedule I:	**2009**	**2010**	**2011**	**2011**	**2012**
Noracymethadol	2	2	2	2	2
Norlevorphanol	52	52	52	52	52
Normethadone	2	2	2	2	2
Normorphine	16	16	18	18	18
Para-fluorofentanyl	2	2	2	2	2
Phenomorphan	2	2	2	2	2
Pholcodine	2	2	2	2	2
Psilocybin	7	2	2	2	2
Psilocyn	7	2	2	2	2
Tetrahydrocannabinols	312,500	264,000	393,000	393,000	393,000
Thiofentanyl	2	2	2	2	2
Tilidine	0	10	10	10	10
Trimeperidine	2	2	2	2	2
Controlled Substance	**Final Revised**	**Final Revised**	**Initial**	**Final Revised**	**Proposed Initial**
Schedule II:	**2009**	**2010**	**2011**	**2011**	**2012**
1-Phenylcyclohexylamine	2	2	2	2	2
1-Piperdinocyclohexanecarbonitrile	2	0	2	2	2
4-Anilino-N-phenethyl-4-piperidine (ANPP)	0	1,100,000	2,500,000	1,800,000	1,800,000
Alfentanil	8,000	8,000	8,000	12,800	11,600
Alphaprodine	2	2	2	2	2
Amobarbital	3	3	40,007	40,007	40,007
Amphetamine (for conversion)	7,500,000	7,500,000	7,500,000	8,500,000	8,500,000
Amphetamine (for sale)	17,000,000	18,600,000	18,600,000	25,300,000	25,300,000
Carfentanil	0	200	0	0	0
Cocaine	247,000	247,000	247,000	216,000	216,000
Codeine (for conversion)	65,000,000	65,000,000	65,000,000	65,000,000	65,000,000
Codeine (for sale)	39,605,000	39,605,000	39,605,000	39,605,000	39,605,000
Dextropropoxyphene	106,000,000	92,000,000	92,000,000	7	7
Dihydrocodeine	1,200,000	800,000	800,000	255,000	255,000
Diphenoxylate	947,000	827,000	827,000	730,000	500,000
Ecgonine	83,000	83,000	83,000	83,000	83,000
Ethylmorphine	2	2	2	2	2
Fentanyl	1,428,000	1,428,000	1,428,000	1,428,000	1,428,000
Glutethimide	2	2	2	2	2
Hydrocodone (for sale)	55,500,000	55,000,000	55,000,000	59,000,000	59,000,000
Hydromorphone	3,340,000	3,455,000	3,455,000	3,455,000	3,455,000
Isomethadone	2	11	11	2	4
Levo-alphacetylmethadol (LAAM)	3	3	3	3	3
Levomethorphan	5	5	5	2	2
Levorphanol	10,000	10,000	10,000	3,600	3,600
Lisdexamfetamine	8,200,000	9,000,000	9,000,000	10,400,000	10,400,000
Meperidine	8,600,000	6,600,000	6,600,000	5,500,000	5,200,000
Meperidine Intermediate-A	3	3	3	3	3
Meperidine Intermediate-B	7	7	7	7	7
Meperidine Intermediate-C	3	3	3	3	3
Metazocine	1	1	5	5	5
Methadone (for sale)	25,000,000	20,000,000	20,000,000	20,000,000	20,000,000
Methadone Intermediate	26,000,000	26,000,000	26,000,000	26,000,000	26,000,000
Methamphetamine	3,130,000	3,130,000	3,130,000	3,130,000	3,130,000
levo-desoxyephedrine	680,000	750,000	750,000	750,000	750,000
methamphetamine (for conversion)	2,405,000	2,331,000	2,331,000	2,331,000	2,331,000
methamphetamine (for sale)	45,000	49,000	49,000	49,000	49,000
Methylphenidate	50,000,000	50,000,000	50,000,000	56,000,000	56,000,000
Morphine (for conversion)	100,000,000	83,000,000	83,000,000	70,000,000	83,000,000
Morphine (for sale)	36,300,000	39,000,000	39,000,000	39,000,000	39,000,000
Nabilone	9,002	9,002	10,502	10,502	10,502
Noroxymorphone (for conversion)	9,000,000	9,000,000	9,000,000	7,200,000	7,200,000
Noroxymorphone (for sale)	10,000	41,000	401,000	401,000	401,000
Opium (powdered)	230,000	230,000	230,000	63,000	63,000
Opium (tincture)	1,250,000	1,500,000	1,500,000	1,000,000	1,000,000
Oripavine	15,000,000	15,000,000	15,000,000	8,000,000	8,000,000
Oxycodone (for conversion)	4,500,000	5,600,000	5,600,000	5,600,000	5,600,000
Oxycodone (for sale)	94,000,000	105,500,000	105,500,000	98,000,000	98,000,000

Aggregate Production Quotas

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Final Revised	Initial	Final Revised	Proposed Initial
Schedule II:	2009	2010	2011	2011	2012
Oxymorphone (for conversion)	12,000,000	12,800,000	12,800,000	12,800,000	12,800,000
Oxymorphone (for sale)	2,570,000	3,070,000	3,070,000	3,070,000	5,500,000
Pentobarbital	28,000,000	28,000,000	28,000,000	34,000,000	31,000,000
Phenazocine	1	1	5	5	5
Phencyclidine	20	14	24	24	24
Phenmetrazine	2	2	2	2	2
Phenylacetone	250,001	12,500,001	8,000,000	8,000,000	8,000,000
Racemethorphan	2	2	2	2	2
Remifentanil	500	2,500	2,500	2,500	2,500
Secobarbital	67,000	67,000	260,002	336,002	336,002
Sufentanil	10,300	7,000	7,000	5,000	5,000
Tapentadol	0	1,000,000	1,000,000	403,000	243,000
Thebaine	126,000,000	126,000,000	126,000,000	116,000,000	116,000,000

Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-358P]

Controlled Substances:
Proposed Aggregate Production Quotas for 2012

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

ACTION: Notice with request for comment.

SUMMARY: This notice proposes initial year 2012 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

DATES: Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-358" on all electronic and written correspondence. DEA encourages that all comments be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov website 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: Christine A. Sannerud, Ph.D., Chief, UN Reporting and Quota Section, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 307-7184.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

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

Background

Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100.

The proposed year 2012 aggregate production quotas represent those quantities of Schedule I and II controlled substances that may be produced in the United States in 2012 to provide adequate supplies of each substance for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes.

In determining the proposed 2012 aggregate production quotas, the DEA has taken into account the criteria that DEA is required to consider in accordance with 21 U.S.C. 826(a) and 21 CFR 1303.11. DEA proposes the aggregate production quotas for 2012 by considering (1) total net disposal of the class by all manufacturers during the current and two preceding years; (2) trends in the national rate of net disposal of the class; (3) total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation; (4) projected demand for such class as indicated by procurement quotas requested pursuant to 21 CFR 1303.12; and (5) other factors affecting the medical, scientific, research, and

industrial needs in the United States, lawful export requirements, and reserve stocks, as the Administrator finds relevant. Other factors DEA considered include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information.

The Administrator, therefore, proposes that the year 2012 aggregate production quotas for the following Schedule I and II controlled substances, expressed in grams of anhydrous acid or base, be established as follows:

Basic Class – Schedule I	Proposed 2012 Quotas
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
2,5-Dimethoxyamphetamine	2 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	22 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g
3,4,5-Trimethoxyamphetamine	2 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g
4-Methoxyamphetamine	77 g
4-Methylaminorex	2 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 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
5-Methoxy-3,4-methylenedioxyamphetamine	2 g
5-Methoxy-N,N-diisopropyltryptamine	2 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	2 g

Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	2 g
Aminorex	2 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	4 g
Codeine-N-oxide	602 g
Diethyltryptamine	2 g
Difenoxin	50 g
Dihydromorphine	3,608,000 g
Dimethyltryptamine	7 g
Gamma-hydroxybutyric acid	29,000,000 g
Heroin	20 g
Hydromorphinol	2 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	5 g
Methaqualone	10 g
Methcathinone	4 g
Methyldihydromorphine	2 g
Morphine-N-oxide	605 g
N-Benzylpiperazine	2 g
N,N-Dimethylamphetamine	2 g
N-Ethylamphetamine	2 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g

Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Proposed 2012 Quotas
1-Phenylcyclohexylamine	2 g
1-piperdinocyclohexanecarbonitrile	2 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g
Alfentanil	11,600 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	8,500,000 g
Amphetamine (for sale)	25,300,000 g
Cocaine	216,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	7 g
Dihydrocodeine	255,000 g
Diphenoxylate	500,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	59,000,000 g
Hydromorphone	3,455,000 g
Isomethadone	4 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	5 g
Levorphanol	3,600 g
Lisdexamfetamine	10,400,000 g
Meperidine	5,200,000 g
Meperidine Intermediate-A	3 g
Meperidine Intermediate-B	7 g
Meperidine Intermediate-C	3 g
Metazocine	5 g
Methadone (for sale)	20,000,000 g
Methadone Intermediate	26,000,000 g
Methamphetamine	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled,	

non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]	
Methylphenidate	56,000,000 g
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	39,000,000 g
Nabilone	10,502 g
Noroxymorphone (for conversion)	7,200,000 g
Noroxymorphone (for sale)	401,000 g
Opium (powder)	63,000 g
Opium (tincture)	1,000,000 g
Oripavine	9,800,000 g
Oxycodone (for conversion)	5,600,000 g
Oxycodone (for sale)	98,000,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	5,500,000 g
Pentobarbital	31,000,000 g
Phenazocine	5 g
Phencyclidine	24g
Phenmetrazine	2 g
Phenylacetone	8,000,000 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	336,002 g
Sufentanil	5,000 g
Tapentadol	243,000 g
Thebaine	116,000,000 g

The Administrator further proposes that aggregate production quotas for all other Schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 be established at zero. Pursuant to 21 CFR 1303.13, upon consideration of the relevant factors, the Administrator of the DEA may adjust the 2012 aggregate production quotas as needed.

Comments

Pursuant to 21 CFR 1303.11, any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this Notice, the Administrator may hold a public hearing on one or more issues raised. In the event

the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the Federal Register. After consideration of any comments and after a hearing, if one is held, the Administrator will publish in the Federal Register a final order determining the 2012 aggregate production quota for the basic class of controlled substance.

Dated:

Michele M. Leonhart
Administrator

OC:_____
OD:_____
OD/D:_____
ODX:_____
ODXS:_____
CC:_____
CCR:_____
ODW:_____
ODQ:CAS_____
ODEQ:(b)(6)
S:\ODE\Fed Reg\2012 Proposed Aggregate Production Quota
Webcims # ODE-11-

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION, OFFICE OF DIVERSION CONTROL
ARCOS 3 - REPORT
TOP 25 DRUG SELLERS BY DRUG CODE

Date: 8/10/2012
Business Activity: MANUFACTURER (E)
Drug Name: METHADONE(9250B)
State:
Zip:
Transaction Year: 2011 - 2011

Division / Office Name: ALL Divisions / ALL Offices
Report By: Total Grams
Display Limit: 25

Rank	Business Activity	Drug Name	Seller's Dea No	Seller's Name	City	State	Division Name	Office Name	Total Grams	Quantity manufactured in 2011	2010 Inventory
1	MANUFACTURER(E)	METHADONE(9250B)	(b)(4);(b)(7)(E)	(b)(4)		MO	ST. LOUIS	ST LOUIS	10,265,821.256	10,741,796	3,436,241
2	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	ALBANY	8,872,836.290		
3	MANUFACTURER(E)	METHADONE(9250B)				OH	DETROIT	COLUMBUS	4,699,176.92		
4	MANUFACTURER(E)	METHADONE(9250B)				VA	WASHINGTON DC	RICHMOND	3,836,302.487	4,815,201	1,463,006
5	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	CAMDEN	2,153,886.454	1,869,609	878,788
6	MANUFACTURER(E)	METHADONE(9250B)				FL	MIAMI	TAMPA	2,066,045.033		
7	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	ALBANY	333,189.936		
8	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	NEW YORK	169,398.456		
9	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	NEWARK	24,858.909		
10	MANUFACTURER(E)	METHADONE(9250B)				MN	CHICAGO	MINNEAPOLIS	8,327.715		
11	MANUFACTURER(E)	METHADONE(9250B)				SC	ATLANTA	COLUMBIA	5,078.769		
12	MANUFACTURER(E)	METHADONE(9250B)				NC	ATLANTA	GREENSBORO	4,972.327		
13	MANUFACTURER(E)	METHADONE(9250B)				OK	DALLAS	OKLAHOMA CITY	3,266.343		
14	MANUFACTURER(E)	METHADONE(9250B)				CO	DENVER	DENVER	3,173.412		
15	MANUFACTURER(E)	METHADONE(9250B)				GA	ATLANTA	ATLANTA	1,897.836		
16	MANUFACTURER(E)	METHADONE(9250B)				AL	NEW ORLEANS	MOBILE	1,343.445		
17	MANUFACTURER(E)	METHADONE(9250B)				TX	HOUSTON	HOUSTON	1,087.680		
18	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	1,085.158		
19	MANUFACTURER(E)	METHADONE(9250B)				MN	CHICAGO	MINNEAPOLIS	920.338		
20	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	894.400		
21	MANUFACTURER(E)	METHADONE(9250B)				OH	DETROIT	DETROIT	775.579		
22	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	511.580		
23	MANUFACTURER(E)	METHADONE(9250B)				GA	ATLANTA	ATLANTA	441.217		
24	MANUFACTURER(E)	METHADONE(9250B)				TN	ATLANTA	KNOXVILLE	345.030		
25	MANUFACTURER(E)	METHADONE(9250B)				OK	DALLAS	TULSA	237.472		

estimated 2012 PQ
32,997,731.874
inventory allowance (30%)
42,897,051.436

estimated 2012 MQ
32,516,020.414
inventory allowance (30%)
42,270,826.538

quantity of methadone intermediate required for PQ and PQ inventory
52,763,373.267
required for MQ only
39,994,705.109

		Manufactured	Inventory
PQ Summary	16,498,865.937		
MQ Summary	16,258,010.207	17,426,606	5,778,035

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION, OFFICE OF DIVERSION CONTROL
ARCOS 3 - REPORT
TOP 25 DRUG SELLERS BY DRUG CODE

Date: 8/10/2012
Business Activity: MANUFACTURER (E)
Drug Name: METHADONE(9250B)
State:
Zip:
Transaction Year: 2012 - 2012
Division / Office Name: ALL Divisions / ALL Offices
Report By: Total Grams
Display Limit: 25

Rank	Business Activity	Drug Name	Seller's Dea No	Seller's Name	City	State	Division Name	Office Name	Total Grams		Last Report
1	MANUFACTURER(E)	METHADONE(9250B)	(b)(4);(b)(7)(E)	(b)(4)		MO	ST. LOUIS	ST LOUIS	7,477,185.286	Bulk Manufacturer	30-Jun
2	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	ALBANY	3,972,349.594		
3	MANUFACTURER(E)	METHADONE(9250B)				VA	WASHINGTON DC	RICHMOND	3,401,650.162	Bulk Manufacturer	30-Jun
4	MANUFACTURER(E)	METHADONE(9250B)				OH	DETROIT	COLUMBUS	3,188,499.395		
5	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	CAMDEN	1,302,496.832	Bulk Manufacturer	30-Jun
6	MANUFACTURER(E)	METHADONE(9250B)				FL	MIAMI	TAMPA	1,276,453.318		
7	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	NEW YORK	159,896.662		
8	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	ALBANY	134,930.078		
9	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	NEWARK	28,978.560		
10	MANUFACTURER(E)	METHADONE(9250B)				SC	ATLANTA	COLUMBIA	8,203.536		
11	MANUFACTURER(E)	METHADONE(9250B)				NC	ATLANTA	GREENSBORO	5,061.052		
12	MANUFACTURER(E)	METHADONE(9250B)				OK	DALLAS	OKLAHOMA CITY	1,604.654		
13	MANUFACTURER(E)	METHADONE(9250B)				CO	DENVER	DENVER	1,408.800		
14	MANUFACTURER(E)	METHADONE(9250B)				TN	ATLANTA	KNOXVILLE	1,326.842		
15	MANUFACTURER(E)	METHADONE(9250B)				GA	ATLANTA	ATLANTA	1,051.601		
16	MANUFACTURER(E)	METHADONE(9250B)				TX	HOUSTON	HOUSTON	727.147		
17	MANUFACTURER(E)	METHADONE(9250B)				MN	CHICAGO	MINNEAPOLIS	694.949		
18	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	658.954		
19	MANUFACTURER(E)	METHADONE(9250B)				AL	NEW ORLEANS	MOBILE	556.317		
20	MANUFACTURER(E)	METHADONE(9250B)				OH	DETROIT	DETROIT	423.337		
21	MANUFACTURER(E)	METHADONE(9250B)				IL	CHICAGO	CHICAGO	310.969		
22	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	NEWARK	289.973		
23	MANUFACTURER(E)	METHADONE(9250B)				CA	LOS ANGELES	LOS ANGELES	96.729		
24	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	91.955		
25	MANUFACTURER(E)	METHADONE(9250B)				MS	NEW ORLEANS	NEW ORLEANS	62.963		

estimated 2012 PQ
17,567,351.120
Inventory allowance (30%)
22,837,556.456

estimated 2012 MQ
24,362,664.560
Inventory allowance (30%)
31,671,463.928

quantity of methadone intermediate required for PQ and PQ inventory
28,090,194.441
required for MQ only
29,966,077.409

PQ Summary	8,783,675.560
MQ Summary	12,181,332.280

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION, OFFICE OF DIVERSION CONTROL
ARCOS 3 - REPORT
TOP 25 DRUG SELLERS BY DRUG CODE

Date: 8/10/2012
Business Activity: MANUFACTURER (E)
Drug Name: METHADONE(9250B)
State:
Zip:
Transaction Year: 2012 - 2012
Division / Office Name: ALL Divisions / ALL Offices
Report By: Total Grams
Display Limit: 25

Rank	Business Activity	Drug Name	Seller's Dea No	Seller's Name	City	State	Division Name	Office Name	Total Grams		Last Report
1	MANUFACTURER(E)	METHADONE(9250B)	(b)(4);(b)(7)(E)	(b)(4)		MO	ST. LOUIS	ST LOUIS	7,477,185,288	Bulk Manufacturer	30-Jun
2	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	ALBANY	3,972,349,594		
3	MANUFACTURER(E)	METHADONE(9250B)				VA	WASHINGTON DC	RICHMOND	3,401,650,162	Bulk Manufacturer	30-Jun
4	MANUFACTURER(E)	METHADONE(9250B)				OH	DETROIT	COLUMBUS	3,188,499,395		
5	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	CAMDEN	1,302,498,832	Bulk Manufacturer	30-Jun
6	MANUFACTURER(E)	METHADONE(9250B)				FL	MIAMI	TAMPA	1,276,453,318		
7	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	NEW YORK	159,896,862		
8	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	ALBANY	134,930,078		
9	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	NEWARK	28,978,560		
10	MANUFACTURER(E)	METHADONE(9250B)				SC	ATLANTA	COLUMBIA	8,203,535		
11	MANUFACTURER(E)	METHADONE(9250B)				NC	ATLANTA	GREENSBORO	5,061,052		
12	MANUFACTURER(E)	METHADONE(9250B)				OK	DALLAS	OKLAHOMA CITY	1,604,554		
13	MANUFACTURER(E)	METHADONE(9250B)				CO	DENVER	DENVER	1,406,680		
14	MANUFACTURER(E)	METHADONE(9250B)				TN	ATLANTA	KNOXVILLE	1,326,842		
15	MANUFACTURER(E)	METHADONE(9250B)				GA	ATLANTA	ATLANTA	1,051,801		
16	MANUFACTURER(E)	METHADONE(9250B)				TX	HOUSTON	HOUSTON	727,147		
17	MANUFACTURER(E)	METHADONE(9250B)				MN	CHICAGO	MINNEAPOLIS	694,949		
18	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	656,954		
19	MANUFACTURER(E)	METHADONE(9250B)				AL	NEW ORLEANS	MOBILE	556,317		
20	MANUFACTURER(E)	METHADONE(9250B)				OH	DETROIT	DETROIT	423,337		
21	MANUFACTURER(E)	METHADONE(9250B)				IL	CHICAGO	CHICAGO	310,965		
22	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	NEWARK	289,973		
23	MANUFACTURER(E)	METHADONE(9250B)				CA	LOS ANGELES	LOS ANGELES	96,729		
24	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	91,955		
25	MANUFACTURER(E)	METHADONE(9250B)				MS	NEW ORLEANS	NEW ORLEANS	62,963		

PQ Summary:	8,783,675,560
MQ Summary	12,181,332,260

2011

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION, OFFICE OF DIVERSION CONTROL
ARCOS 3 - REPORT
TOP 25 DRUG SELLERS BY DRUG CODE

Date: 8/10/2012
Business Activity: MANUFACTURER (E)
Drug Name: METHADONE(9250B)
State:
Zip:
Transaction Year: 2011 - 2011

Division / Office Name: ALL Divisions / ALL Offices
Report By: Total Grams
Display Limit: 25

Rank	Business Activity	Drug Name	Seller's Dea No	Seller's Name	City	State	Division Name	Office Name	Total Grams	Quantity manufactured in 2011	2010 Inventory
1	MANUFACTURER(E)	METHADONE(9250B)	(b)(4);(b)(7)(E)	(b)(4)		MO	ST. LOUIS	ST LOUIS	10,265,829,256	10,741,796	3,436,241
2	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	ALBANY	8,873,836,299		
3	MANUFACTURER(E)	METHADONE(9250B)				OH	DETROIT	COLUMBUS	4,599,178.92		
4	MANUFACTURER(E)	METHADONE(9250B)				VA	WASHINGTON DC	RICHMOND	3,836,302.497	4,815,201	1,463,006
5	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	CAMDEN	2,153,886.454	1,869,609	878,788
6	MANUFACTURER(E)	METHADONE(9250B)				FL	MIAMI	TAMPA	2,068,045.03		
7	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	ALBANY	333,189.93		
8	MANUFACTURER(E)	METHADONE(9250B)				NY	NEW YORK	NEW YORK	159,395.46		
9	MANUFACTURER(E)	METHADONE(9250B)				NJ	NEW JERSEY	NEWARK	24,858.99		
10	MANUFACTURER(E)	METHADONE(9250B)				MN	CHICAGO	MINNEAPOLIS	8,327.71		
11	MANUFACTURER(E)	METHADONE(9250B)				SC	ATLANTA	COLUMBIA	5,078.76		
12	MANUFACTURER(E)	METHADONE(9250B)				NC	ATLANTA	GREENSBORO	4,972.32		
13	MANUFACTURER(E)	METHADONE(9250B)				OK	DALLAS	OKLAHOMA CITY	3,266.34		
14	MANUFACTURER(E)	METHADONE(9250B)				CO	DENVER	DENVER	3,173.41		
15	MANUFACTURER(E)	METHADONE(9250B)				GA	ATLANTA	ATLANTA	1,897.83		
16	MANUFACTURER(E)	METHADONE(9250B)				AL	NEW ORLEANS	MOBILE	1,343.44		
17	MANUFACTURER(E)	METHADONE(9250B)				TX	HOUSTON	HOUSTON	1,067.88		
18	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	1,065.15		
19	MANUFACTURER(E)	METHADONE(9250B)				MN	CHICAGO	MINNEAPOLIS	920.33		
20	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	894.40		
21	MANUFACTURER(E)	METHADONE(9250B)				OH	DETROIT	DETROIT	775.57		
22	MANUFACTURER(E)	METHADONE(9250B)				MA	BOSTON	BOSTON	511.58		
23	MANUFACTURER(E)	METHADONE(9250B)				GA	ATLANTA	ATLANTA	448.21		
24	MANUFACTURER(E)	METHADONE(9250B)				TN	ATLANTA	KNOXVILLE	345.03		
25	MANUFACTURER(E)	METHADONE(9250B)				OK	DALLAS	TULSA	237.47		

		Manufactured	Inventory
PQ Summary	16,498,865.937		
MQ Summary	16,258,010.207	17,426,606	5,778,035

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION, OFFICE OF DIVERSION CONTROL

ARCOS 3 - REPORT

TOP 100 DRUG DISTRIBUTORS BY DRUG CODE

Date:	8/24/2012
Business Activity:	MANUFACTURER (E)
Drug Name:	HYDROCODONE(9193)
Buyer Business Activity:	
Buyer State / Zip:	ALL States / ALL Zips
Transaction Year:	2012 - 2012
Buyer Division / Office:	ALL Divisions / ALL Offices
Report By:	Total Grams
Display Limit:	100

Rank	Drug Name	Distributor's Dea No	Distributor's Name	Distributor's City	State	Distributor's Division	Distributor's Office	Total Grams Sold	Current Quota
1	HYDROCODONE(9193)	(b)(4);(b)(7)(E)	(b)(4)		TN	ATLANTA	KNOXVILLE	113,822	
2	HYDROCODONE(9193)				NY	NEW YORK	LONG ISLAND	31,771	3 649 Above - 10
3	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	24,086	
4	HYDROCODONE(9193)				OK	DALLAS	OKLAHOMA CITY	23,227	
5	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	18,434	
6	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	16,008	
7	HYDROCODONE(9193)				GA	ATLANTA	ATLANTA	13,140	
8	HYDROCODONE(9193)				TX	HOUSTON	HOUSTON	12,777	
9	HYDROCODONE(9193)				NY	NEW YORK	ALBANY	10,927	
10	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	7,805	
11	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	6,578	
12	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	6,403	
13	HYDROCODONE(9193)				CO	DENVER	DENVER	5,648	
14	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	4,978	
15	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	4,926	
16	HYDROCODONE(9193)				AL	NEW ORLEANS	MOBILE	4,671	
17	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	3,972	
18	HYDROCODONE(9193)				OH	DETROIT	DETROIT	3,760	
19	HYDROCODONE(9193)				MN	CHICAGO	MINNEAPOLIS	3,044	
20	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	2,496	
21	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	1,886	
22	HYDROCODONE(9193)				AZ	PHOENIX	PHOENIX	1,861	
23	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	1,660	
24	HYDROCODONE(9193)				FL	MIAMI	MIAMI	1,321	
25	HYDROCODONE(9193)				TN	ATLANTA	KNOXVILLE	1,141	
26	HYDROCODONE(9193)				VA	WASHINGTON DC	RICHMOND	753	
27	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	448	
28	HYDROCODONE(9193)				OK	DALLAS	TULSA	433	
29	HYDROCODONE(9193)				OK	DALLAS	TULSA	374	
30	HYDROCODONE(9193)				MO	ST. LOUIS	ST LOUIS	182	
31	HYDROCODONE(9193)				CA	SAN FRANCISCO	OAKLAND	154	
32	HYDROCODONE(9193)				CA	SAN FRANCISCO	OAKLAND	122	
33	HYDROCODONE(9193)				KY	DETROIT	LOUISVILLE	120	
34	HYDROCODONE(9193)				CA	SAN FRANCISCO	SAN FRANCISCO	104	
35	HYDROCODONE(9193)				OH	DETROIT	COLUMBUS	49	
36	HYDROCODONE(9193)				OH	DETROIT	COLUMBUS	49	
37	HYDROCODONE(9193)				AL	NEW ORLEANS	MOBILE	45	
38	HYDROCODONE(9193)				MA	BOSTON	BOSTON	35	
39	HYDROCODONE(9193)				NC	ATLANTA	GREENSBORO	17	
40	HYDROCODONE(9193)				FL	MIAMI	TAMPA	11	
41	HYDROCODONE(9193)				CA	LOS ANGELES	LOS ANGELES	9	
42	HYDROCODONE(9193)				PA	PHILADELPHIA	PHILADELPHIA	8	
43	HYDROCODONE(9193)				FL	MIAMI	TALLAHASSEE	3	

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Substance	2011	c.f.	base total
Alfentanil	0.491	0.900	0.442
Amphetamine	20,153.177		21,664.666
Cocaine	48.516	0.890	43.179
Codeine	25,974.865	0.860	22,338.384
Dihydrocodeine	106.161	0.640	67.943
Diphenoxylate	455.692	0.930	423.794
[illegible]			
Fentanyl	536.229	1.000	536.229
Hydrocodone	64,813.797	0.610	39,536.416
Hydromorphone	1,669.942	0.890	1,486.248
Levorphanol	0.323	1.000	0.323
Lisdexamfetamine	12,236.523	0.580	7,097.183
Meperidine	2,296.373	0.870	1,997.844
Methadone	7,621.043	0.890	6,782.729
Methamphetamine	13.645	0.800	10.916
Methylphenidate	19,043.348	0.870	16,567.713
Morphine	30,317.864	0.750	22,738.398
Nabilone	0.058	1.000	0.058
Opium	84.217	1.000	84.217
Oxycodone	70,572.060	0.900	63,514.854
Oxymorphone	2,640.625	0.890	2,350.156
Pentazocine	832.885	1.000	832.885
Pentobarbital	79.042	0.910	71.928
[illegible]			
Remifentanil	1.044	0.910	0.950
Secobarbital	20.550	0.920	18.906
Sufentanil	0.052	0.670	0.035
Tapentadol	4,996.502	0.860	4,296.992

Dea Num	Drug Code	Quota Type	Company	Quota Request	Quota Allotment	Comm Manuf	Transfers	Prod Dev	Replacements	Packaging	
(b)(4);(b)(7)(E)	9143-B	PROCUREMENT	(b)(4)	5,925,000	1,630,000	1,200,000	0	430,000	0	0	
	9143-B	PROCUREMENT		7,560	7,560	0	0	7,560	0	0	
	9143-B	PROCUREMENT		106,920	106,920	0	0	106,920	0	0	
	9143-B	PROCUREMENT		16,400	16,400	0	0	16,400	0	0	
	9143-B	PROCUREMENT		100	100	0	0	100	0	0	
	9143-B	PROCUREMENT		5	5	0	0	5	0	0	
	9143-B	PROCUREMENT		1,129,050	1,129,050	0	0	1,129,050	0	0	
	9143-B	PROCUREMENT		1,170	1,170	0	0	1,170	0	0	
	9143-B	PROCUREMENT		15,000	14,985	0	0	14,985	0	0	
	9143-B	PROCUREMENT		81,000	72,900	0	0	72,900	0	0	
	9143-B	PROCUREMENT		37,980	37,980	0	0	37,980	0	0	
	9143-B	PROCUREMENT		6,782	6,782	0	0	6,782	0	0	
	9143-B	PROCUREMENT		270,140	561,910	0	0	561,910	0	0	
	9143-B	PROCUREMENT		157,250	157,250	0	0	157,250	0	0	
	9143-B	PROCUREMENT		155,227	137,000	0	0	137,000	0	0	
	9143-B	PROCUREMENT		1,020	1,020	0	0	1,020	0	0	
	9143-B	PROCUREMENT		4,700	1,800	0	0	1,800	0	0	
	9143-B	PROCUREMENT		45,900	45,900	0	0	45,900	0	0	
	9143-B	PROCUREMENT		26,100	20,880	0	0	20,880	0	0	
	9143-B	PROCUREMENT		485,000	455,018	0	0	455,018	0	0	
	9143-B	PROCUREMENT		1,890	1,890	0	0	1,890	0	0	
	9143-B	PROCUREMENT		96,000	96,000	0	0	96,000	0	0	
	9143-B	PROCUREMENT		9,900	9,000	0	0	9,000	0	0	
	9143-B	PROCUREMENT		117,000	117,000	0	0	117,000	0	0	
	9143-B	PROCUREMENT		13,992,103	12,484,709	12,245,433	0	239,276	0	0	
	9143-B	PROCUREMENT		5,925,000	3,030,000	0	0	430,000	0	2,600,000	
	9143-B	PROCUREMENT		322,020	225,500	0	0	225,500	0	0	
	9143-B	PROCUREMENT		278,913	148,000	0	0	148,000	0	0	
	9143-B	PROCUREMENT		1,924,100	315,328	0	0	315,328	0	0	
	9143-B	PROCUREMENT		98,392	58,500	0	0	58,500	0	0	
	9143-B	PROCUREMENT		1,710	1,710	0	0	1,710	0	0	
	9143-B	PROCUREMENT		234,000	395,700	0	0	395,700	0	0	
	9143-B	PROCUREMENT		122,085	122,000	0	0	122,000	0	0	
	9143-B	PROCUREMENT		3,364,695	714,600	98,600	0	616,000	0	0	
	9143-B	PROCUREMENT		4,068	4,068	0	0	4,068	0	0	
	9143-B	PROCUREMENT		39,710	39,710	0	0	39,710	0	0	
	9143-B	PROCUREMENT		37,000	36,568	0	0	36,568	0	0	
	9143-B	PROCUREMENT		11,340	11,340	0	0	11,340	0	0	
	9143-B	PROCUREMENT		17,683,638	17,682,198	15,932,000	0	1,750,198	0	0	
	9143-B	PROCUREMENT		195,800	195,800	0	0	195,800	0	0	
	9143-B	PROCUREMENT		81,000	70,670	0	0	70,670	0	0	
	9143-B	PROCUREMENT		58,320	58,320	0	0	58,320	0	0	
	9143-D	PROCUREMENT		5,000	5,000	0	0	5,000	0	0	
	9143-B	PROCUREMENT		492,321	492,321	133,882	0	358,439	0	0	
	9143-B	PROCUREMENT		105,000	73,000	0	0	73,000	0	0	
	9143-B	PROCUREMENT		2,275,308	1,467,471	1,449,426	0	18,045	0	0	
	9143-B	PROCUREMENT		31,417	58,479	0	0	58,479	0	0	
	9143-B	PROCUREMENT		300	300	0	0	300	0	0	
	9143-B	PROCUREMENT		450	450	0	0	261	0	189	
	9143-B	PROCUREMENT		121,830	67,600	0	0	67,600	0	0	
	9143-B	PROCUREMENT		1,000	900	0	0	900	0	0	
							PO total	8,729,232			

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Dea Num	Company	Quota Request	Quota Allotment	Comm Manuf	Transfers	Prod Dev	Replacements	Packaging
(b)(4);(b)(7)(E)	(b)(4)	109,800	54,900	0	0	54,900	0	0
		575,000	575,000	0	0	575,000	0	0
		5	5	0	0	5	0	0
		599,250	521,650	219,700	0	301,950	0	0
		80,830	80,830	0	0	80,830	0	0
		9,211	9,211	0	0	9,211	0	0
		77,928	77,928	17,080	0	60,848	0	0
		478,088	129,000	108,000	0	21,000	0	0
		101	101	0	0	101	0	0
		8,693	8,693	0	0	8,693	0	0
		257,030	228,673	94,756	0	133,917	0	0
		157,600	153,305	153,061	0	244	0	0
		49,040	49,040	0	0	1,683	0	47,357
		42,000	42,000	0	0	42,000	0	0
		1,700	800	0	0	800	0	0
		18,300	3,660	0	0	3,660	0	0
		915	443	0	0	443	0	0
		27,000	27,000	0	0	27,000	0	0
		244	231	0	0	231	0	0
		22,229	21,923	0	0	21,923	0	0
		127,185	79,605	0	0	79,605	0	0
		114,757	54,635	45,535	0	9,100	0	0
		275,113	173,000	134,000	0	39,000	0	0
		37,711	30,000	0	0	30,000	0	0
		96,080	79,498	0	0	79,498	0	0
		13,039	12,200	0	0	12,200	0	0
		2,106	2,106	0	0	2,106	0	0
		60,000	60,000	0	0	60,000	0	0
		6,161	6	0	0	6	0	0
		8,854	8,854	0	0	8,854	0	0
		9,614	9,614	0	0	9,614	0	0
		52,004	52,004	0	0	52,004	0	0
		58,953	56,368	0	0	56,368	0	0
		36,000	36,000	0	0	36,000	0	0
		2,440	484	0	0	484	0	0
		109,800	60,390	0	0	60,390	0	0
		335,942	249,622	37,250	0	212,372	0	0
		15,258	15,257	0	0	15,257	0	0
		2,149,390	714,044	698,855	0	15,189	0	0
		5,494	5,494	0	0	5,494	0	0
		38,125	38,125	0	0	38,125	0	0
		577,000	380,147	353,647	0	26,500	0	0
		80,760	80,760	0	0	80,760	0	0
		21,731	13,879,642	13,841,000	0	38,642	0	0

PD total 2,312,007

2012 Proposed Adjusted Aggregate Production Quotas

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

- The attached Federal Register notice, prepared for your signature, Proposed Revised Aggregate Production Quotas (APQ) for 2012 for schedules I and II controlled substances for which the United States has medical, scientific, industrial, export, and reserve stock requirements. Also attached is a list of the 2010 and 2011 APQs for these substances for comparison.

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

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

Schedule I substances

- The APQ for 11-[1-(2-Thienyl)cyclohexyl]piperidine, 2,5-Dimethoxyamphetamine, 2,5-Dimethoxy-4-ethylamphetamine (DOET), 2,5-Dimethoxy-4-n-propylthiophenethylamine, 3,4-Methylenedioxy-N-methylcathinone (methylone), 3,4-Methylenedioxy-N-ethylamphetamine (MDEA), 3,4-Methylenedioxypyrovalerone (MDPV), 3,4,5-Trimethoxyamphetamine, 4-Bromo-2,5-dimethoxyamphetamine (DOB), 4-Bromo-2,5-dimethoxyphenethylamine (2-CB), 4-Methoxyamphetamine, 4-Methylaminorex, 4-Methyl-2,5-dimethoxyamphetamine (DOM), 4-Methyl-N-methylcathinone (mephedrone), 5-Methoxy-3,4-methylenedioxyamphetamine, 5-Methoxy-N,N-diisopropyltryptamine, Alpha-ethyltryptamine, Alpha-methyltryptamine (AMT), Aminorex, Carfentanil, Cathinone, Diethyltryptamine, Dimethyltryptamine, Mescaline, Methcathinone, N-Benzylpiperazine, N,N-Dimethylamphetamine, N-Ethylamphetamine, N-Hydroxy-3,4-methylenedioxyamphetamine 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 alfentanil was increased due to increased exportation requirements. One DEA registrant is now the sole supplier to the European market, the registrant's European company has stopped manufacturing alfentanil products.

- The APQ for 1-Piperdinocyclohexanecarbonitrile was increased. The manufacturing of this substance will be used for analytical standards, reference, and research material. New DEA registrant(s) entering the reference standard market at the bulk manufacturing level.

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

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

- The APQ for oripavine was increased due to the increased sales of the controlled substances that utilize oripavine as the starting material. These controlled substances include: hydromorphone, oxymorphone, noroxymorphone, and the "nal" drugs.

ODQ 06-04-2012

Aggregate Production Quota Changes

(all values are in grams unless indicated otherwise)

Controlled Substance	Final Revised	Initial	Final	Established	Proposed Revised
Schedule I:	**2010**	**2011**	**2011**	**2012**	**2012**
2,5-Dimethoxyamphetamine	2	2	2	2	12
2,5-Dimethoxy-4-Ethylamphetamine (DOET)	2	2	2	2	12
2,5-Dimethoxy-4-(n)-propylthiophenethylamine	0	2	2	2	12
3,4-Methylenedioxy-N-Ethylamphetamine (MDEA)	10	15	15	15	24
3,4-Methylenedioxy-N-methylcathinone (methylone)				8	12
3,4-Methylenedioxypyrovalerone (MDPV)				8	12
3,4,5-Trimethoxyamphetamine	2	2	2	2	12
4-Bromo-2,5-Dimethoxyamphetamine (DOB)	2	2	2	2	12
4-Bromo-2,5-Dimethoxyphenethylamine (2-CB)	2	2	2	2	12
4-Methoxyamphetamine	77	77	77	77	88
4-Methylaminorex	2	2	2	2	12
4-Methyl-2,5-Dimethoxyamphetamine (DOM)	2	2	2	2	12
4-Methyl-N-methylcathinone (mephedrone)				8	12
5-Methoxy-3,4-Methylenedioxyamphetamine	2	2	2	2	12
5-Methoxy-N,N-diisopropyltryptamine	0	2	2	2	12
Alpha-ethyltryptamine	2	2	2	2	12
Alpha-methyltryptamine (AMT)	2	2	2	2	12
Aminorex	2	2	2	2	12
Cathinone	3	4	4	4	12
Diethyltryptamine	2	2	2	2	12
Dimethyltryptamine	3	7	7	7	18
Mescaline	5	5	5	5	13
Methcathinone	4	4	4	4	12
N-Benzylpiperazine	2	2	2	2	12
N,N-Dimethylamphetamine	2	2	2	2	12
N-Ethylamphetamine	2	2	2	2	12
N-Hydroxy-3,4-Methylenedioxyamphetamine	2	2	2	2	12

	Final Revised	Initial	Final	Established	Proposed
Schedule II:	**2010**	**2011**	**2011**	**2012**	**2012**
Alfentanil	8,000	8,000	11,600	15,000	19,550
Amphetamine (for sale)	18,600,000	18,600,000	25,300,000	25,300,000	33,400,000
Carfentanil	200	0	0	0	5
Hydrocodone (for sale)	55,000,000	55,000,000	59,000,000	59,000,000	63,000,000
Noroxymorphone (for sale)	41,000	401,000	401,000	401,000	1,981,000
Opium (powdered)	230,000	230,000		63,000	73,000
Oripavine	15,000,000	15,000,000		9,800,000	15,300,000
Oxycodone (for sale)	105,500,000	105,500,000		98,000,000	98,700,000

Billing Code 4410-09-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-363]

Controlled Substances:
Proposed Adjustment to the Aggregate Production Quotas for 2012

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes to adjust the 2012 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Electronic comments must be submitted and written comments must be postmarked on or before *[INSERT 30 DAYS FROM DATE OF PUBLICATION]*. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-363" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through http://www.regulations.gov using the electronic comment form provided on that site. An electronic copy of this document is also available at the http://www.regulations.gov website 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. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701

Morrissette Drive, Springfield, VA 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

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

Background

Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. 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 2012 established aggregate production quotas for controlled substances in schedules I and II were published in the Federal Register (76 FR 78044) on December 15, 2011. That notice stipulated that, as provided for in 21 CFR 1303.13, all aggregate production quotas are subject to adjustment.

Analysis for Proposed Revised 2012 Aggregate Production Quotas

DEA now proposes to adjust the established 2012 aggregate production quotas for some schedule I and II controlled substances. In proposing the adjustment, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 CFR 1303.13. DEA proposes the adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances by considering (1) changes in demand for the class, changes in the national rate of net disposal for the class, and changes in the rate of net disposal by the registrants holding individual manufacturing quotas for the class; (2) whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; (3)

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

In determining whether to propose adjustments to the 2012 aggregate production quotas, DEA considered updated information obtained from 2011 year-end inventories, 2011 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to DEA after the initial aggregate production quotas had been established. The Deputy Administrator, therefore, proposes to adjust the 2012 aggregate production quotas for some schedule I and II controlled substances, expressed in grams of anhydrous acid or base, as follows:

Basic Class – Schedule I	Previously Established 2012 Quotas	Proposed Adjusted 2012 Quotas
1-[1-(2-Thienyl)cyclohexyl]piperidine	0 g	5 g
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g	No Change
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g	No Change
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g	No Change
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g	No Change
2,5-Dimethoxyamphetamine	2 g	12 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g	12 g
3-Methylfentanyl	2 g	No Change
3-Methylthiofentanyl	2 g	No Change
3,4-Methylenedioxyamphetamine (MDA)	22 g	30 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	8 g	12 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g	24 g
3,4-Methylenedioxymethamphetamine (MDMA)	22 g	30 g
3,4-Methylenedioxypyrovalerone (MDPV)	8 g	12 g

3,4,5-Trimethoxyamphetamine	2 g	12 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g	12 g
4-Methoxyamphetamine	77 g	88 g
4-Methylaminorex	2 g	12 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g	12 g
4-Methyl-N-methylcathinone (mephedrone)	8 g	12 g
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g	No Change
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	53 g	No Change
5-Methoxy-3,4-methylenedioxyamphetamine	2 g	12 g
5-Methoxy-N,N-diisopropyltryptamine	2 g	12 g
Acetyl-alpha-methylfentanyl	2 g	No Change
Acetyldihydrocodeine	2 g	No Change
Acetylmethadol	2 g	No Change
Allylprodine	2 g	No Change
Alphacetylmethadol	2 g	No Change
Alpha-ethyltryptamine	2 g	12 g
Alphameprodine	2 g	No Change
Alphamethadol	2 g	No Change
Alpha-methylfentanyl	2 g	No Change
Alpha-methylthiofentanyl	2 g	No Change
Alpha-methyltryptamine (AMT)	2 g	12 g
Aminorex	2 g	12 g
Benzylmorphine	2 g	No Change
Betacetylmethadol	2 g	No Change
Beta-hydroxy-3-methylfentanyl	2 g	No Change
Beta-hydroxyfentanyl	2 g	No Change
Betameprodine	2 g	No Change
Betamethadol	2 g	No Change
Betaprodine	2 g	No Change
Bufotenine	3 g	No Change
Cathinone	4 g	12 g
Codeine-N-oxide	602 g	No Change
Diethyltryptamine	2 g	12 g
Difenoxin	50 g	No Change
Dihydromorphine	3,608,000 g	No Change
Dimethyltryptamine	7 g	18 g
Gamma-hydroxybutyric acid	47,000,000 g	No Change
Heroin	20 g	No Change
Hydromorphinol	54 g	No Change
Hydroxypethidine	2 g	No Change
Ibogaine	5 g	No Change
Lysergic acid diethylamide (LSD)	16 g	No Change

Marihuana	21,000 g	No Change
Mescaline	5 g	13 g
Methaqualone	10 g	No Change
Methcathinone	4 g	12 g
Methyldihydromorphine	2 g	No Change
Morphine-N-oxide	655 g	No Change
N-Benzylpiperazine	2 g	12 g
N,N-Dimethylamphetamine	2 g	12 g
N-Ethylamphetamine	2 g	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g	12 g
Noracymethadol	2 g	No Change
Norlevorphanol	52 g	No Change
Normethadone	2 g	No Change
Normorphine	18 g	No Change
Para-fluorofentanyl	2 g	No Change
Phenomorphan	2 g	No Change
Pholcodine	2 g	No Change
Properidine	2 g	No Change
Psilocybin	2 g	No Change
Psilocyn	2 g	No Change
Tetrahydrocannabinols	393,000 g	No Change
Thiofentanyl	2 g	No Change
Tilidine	10 g	No Change
Trimeperidine	2 g	No Change

Basic Class – Schedule II	Previously Established 2012 Quotas	Proposed Adjusted 2012 Quotas
1-Phenylcyclohexylamine	2 g	No Change
1-Piperdinocyclohexanecarbonitrile	2 g	27 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g	No Change
Alfentanil	15,000 g	19,550 g
Alphaprodine	2 g	No Change
Amobarbital	40,007 g	No Change
Amphetamine (for conversion)	8,500,000 g	No Change
Amphetamine (for sale)*	25,300,000 g	33,400,000 g
* DEA has determined that the revised total quantity 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 stock is 29,400,000 g. DEA has further determined that an additional 4,000,000 g is necessary to provide for future research and development needs and unexpected emergencies that could affect market availability.		
Carfentanil	0 g	5 g

Cocaine	216,000 g	No Change
Codeine (for conversion)	65,000,000 g	No Change
Codeine (for sale)	39,605,000 g	No Change
Dextropropoxyphene	7 g	No Change
Dihydrocodeine	400,000 g	No Change
Diphenoxylate	900,000 g	No Change
Ecgonine	83,000 g	No Change
Ethylmorphine	2 g	No Change
Fentanyl	1,428,000 g	No Change
Glutethimide	2 g	No Change
Hydrocodone (for sale)	59,000,000 g	63,000,000 g
Hydromorphone	3,455,000 g	3,628,000 g
Isomethadone	4 g	No Change
Levo-alphacetylmethadol (LAAM)	3 g	No Change
Levomethorphan	5 g	No Change
Levorphanol	3,600 g	No Change
Lisdexamfetamine	12,000,000 g	No Change
Meperidine	5,500,000 g	No Change
Meperidine Intermediate-A	5 g	No Change
Meperidine Intermediate-B	9 g	No Change
Meperidine Intermediate-C	5 g	No Change
Metazocine	5 g	No Change
Methadone (for sale)	20,000,000 g	No Change
Methadone Intermediate	26,000,000 g	No Change
Methamphetamine	3,130,000 g	No Change
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]		
Methylphenidate	56,000,000 g	No Change
Morphine (for conversion)	83,000,000 g	No Change
Morphine (for sale)	39,000,000 g	No Change
Nabilone	20,502 g	No Change
Noroxymorphone (for conversion)	7,200,000 g	No Change
Noroxymorphone (for sale)	401,000 g	1,981,000 g
Opium (powder)	63,000 g	73,000 g
Opium (tincture)	1,000,000 g	No Change
Oripavine	9,800,000 g	15,300,000 g
Oxycodone (for conversion)	5,600,000 g	No Change
Oxycodone (for sale)	98,000,000 g	98,700,000 g
Oxymorphone (for conversion)	12,800,000 g	No Change
Oxymorphone (for sale)	5,500,000 g	No Change
Pentobarbital	34,000,000 g	No Change
Phenazocine	5 g	No Change

Phencyclidine	24 g	No Change
Phenmetrazine	2 g	No Change
Phenylacetone	16,000,000 g	No Change
Racemethorphan	2 g	No Change
Remifentanil	2,500 g	No Change
Secobarbital	336,002 g	No Change
Sufentanil	5,000 g	No Change
Tapentadol	5,400,000 g	No Change
Thebaine	116,000,000 g	No Change

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 Part 1303, the Deputy Administrator may adjust the 2012 aggregate production quotas and individual manufacturing quotas allocated for the year.

Comments

Pursuant to 21 CFR 1303.11 and 1303.13, 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 determining any adjustment of the aggregate production quota.

Dated:

Michele M. Leonhart
Administrator

OC:_____

OD:_____

OD/D:_____

ODX:_____

ODXS:_____

ODW: _____

ODQ:_____

ODQ:(b)(6)

Webcims #

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

San Rafael, California; Canadian Solar Inc. of Kitchener, Ontario, Canada; and Canadian Solar (USA) Inc. of San Ramon, California. *Id.*

On May 25, 2012, all of the private parties filed a joint motion to terminate the investigation based on confidential settlement agreements under Commission rules 210.21(a)(2) and (b). The Commission investigative attorney supported the motion.

On June 13, 2012, the presiding ALJ issued an ID (Order No. 11) granting the joint motion. No party petitioned for review of the ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.42(h) of the Commission's Rules of Practice and Procedure, 19 CFR 210.42(h).

By order of the Commission.

Issued: June 29, 2012.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2012–16433 Filed 7–3–12; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree With Dairyland Power Cooperative Under the Clean Air Act

Pursuant to 28 CFR 50.7, notice is hereby given that on June 28, 2012, a proposed Consent Decree in *United States of America* v. *Dairyland Power Cooperative ("Dairyland")*, Civil Action No. 12-cv-462, was lodged with the United States District Court for the Western District of Wisconsin.

In this civil enforcement action under the federal Clean Air Act ("Act"), the United States alleges that Dairyland—an electric utility—failed to comply with certain requirements of the Act intended to protect air quality. The complaint alleges that Dairyland violated the Prevention of Significant Deterioration ("PSD") and Title V provisions of the Act, 42 U.S.C. 7401–7671 *et seq.*, and related state and federal implementing regulations, at the Alma/J.P. Madgett Generating Station, a coal-fired power plant in Buffalo County, Wisconsin, and the Genoa Generating Station, a coal-fired power plant in Vernon County, Wisconsin. The alleged violations arise from the construction of modifications at the power plants and operation of the plants in violation of PSD and Title V requirements. The complaint alleges that Dairyland failed to obtain appropriate permits and failed to install and apply required pollution control devices to reduce emissions of various air pollutants. The complaint seeks both injunctive relief and civil penalties.

The proposed Decree lodged with the Court requires installation and operation of certain pollution control devices at the Alma/J.P. Madgett and Genoa plants, and the permanent cessation of operations of certain units at the Alma/J.P. Madgett plant. The settlement will reduce emissions of sulfur dioxide ("SO_2"), nitrogen oxides ("NO_X"), and particular matter ("PM") through emission control requirements and limitations specified by the proposed Decree. Dairyland will also fund environmental projects at a cost of at least $5 million to mitigate the alleged adverse effects of its past violations, and will pay a civil penalty of $950,000.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either emailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Dairyland Power Cooperative*, D.J. Ref. 90–5–2–1–10163.

During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site, *http://www.usdoj.gov/enrd/Consent_Decrees.html*. A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611 or by faxing or emailing a request to "Consent Decree Copy" (*EESCDCopy.ENRD@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–5271. If requesting a copy from the Consent Decree Library by mail, please enclose a check in the amount of $24.25 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if requesting by email or fax, forward a check in that amount to the Consent Decree Library at the address given above.

Maureen Katz,

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

[FR Doc. 2012–16353 Filed 7–3–12; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–363]

Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

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

ACTION: Notice with request for comments.

SUMMARY: This notice proposes to adjust the 2012 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Electronic comments must be submitted and written comments must be postmarked on or before August 6, 2012. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–363" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to *www.regulations.gov* will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying

information (such as your name, address, etc.) voluntarily submitted by the commenter.

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

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

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

Background

Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in schedules I and II. 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 2012 established aggregate production quotas for controlled substances in schedules I and II were published in the **Federal Register** (76 FR 78044) on December 15, 2011. That notice stipulated that, as provided for in 21 CFR 1303.13, all aggregate production quotas are subject to adjustment.

Analysis for Proposed Revised 2012 Aggregate Production Quotas

DEA now proposes to adjust the established 2012 aggregate production quotas for some schedule I and II controlled substances. In proposing the adjustment, DEA has taken into account the criteria that DEA is required to consider in accordance with 21 CFR 1303.13. DEA proposes the adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances by considering (1) Changes in demand for the class, changes in the national rate of net disposal for the class, and changes in the rate of net disposal by the registrants holding individual manufacturing quotas for the class; (2) whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; (3) whether any increased demand can be met through existing inventories, increased individual manufacturing quotas, or increased importation without increasing the aggregate production quota; (4) whether any decreased demand will result in excessive inventory accumulation by all persons registered to handle the class; and (5) other factors affecting the medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Administrator finds relevant.

In determining whether to propose adjustments to the 2012 aggregate production quotas, DEA considered updated information obtained from 2011 year-end inventories, 2011 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to DEA after the initial aggregate production quotas had been established. The Deputy Administrator, therefore, proposes to adjust the 2012 aggregate production quotas for some schedule I and II controlled substances, expressed in grams of anhydrous acid or base, as follows:

Basic class	Previously established 2012 quotas	Proposed adjusted 2012 quotas
Schedule I		
1-[1-(2-Thienyl)cyclohexyl]piperidine	0 g	5 g.
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45 g	No Change.
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45 g	No Change.
1-Methyl-4-phenyl-4-propionoxypiperidine	2 g	No Change.
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g	No Change.
2,5-Dimethoxyamphetamine	2 g	12 g.
2,5-Dimethoxy-4-ethylamphetamine (DOET)	2 g	12 g.
2,5-Dimethoxy-4-n-propylthiophenethylamine	2 g	12 g.
3-Methylfentanyl	2 g	No Change.
3-Methylthiofentanyl	2 g	No Change.
3,4-Methylenedioxyamphetamine (MDA)	22 g	30 g.
3,4-Methylenedioxy-N-methylcathinone (methylone)	8 g	12 g.
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	15 g	24 g.
3,4-Methylenedioxymethamphetamine (MDMA)	22 g	30 g.
3,4-Methylenedioxypyrovalerone (MDPV)	8 g	12 g.
3,4,5-Trimethoxyamphetamine	2 g	12 g.
4-Bromo-2,5-dimethoxyamphetamine (DOB)	2 g	12 g.
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	2 g	12 g.
4-Methoxyamphetamine	77 g	88 g.
4-Methylaminorex	2 g	12 g.
4-Methyl-2,5-dimethoxyamphetamine (DOM)	2 g	12 g.
4-Methyl-N-methylcathinone (mephedrone)	8 g	12 g.
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68 g	No Change.
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	53 g	No Change.

Basic class	Previously established 2012 quotas	Proposed adjusted 2012 quotas
5-Methoxy-3,4-methylenedioxyamphetamine	2 g	12 g.
5-Methoxy-N,N-diisopropyltryptamine	2 g	12 g.
Acetyl-alpha-methylfentanyl	2 g	No Change.
Acetyldihydrocodeine	2 g	No Change.
Acetylmethadol	2 g	No Change.
Allylprodine	2 g	No Change.
Alphacetylmethadol	2 g	No Change.
Alpha-ethyltryptamine	2 g	12 g.
Alphameprodine	2 g	No Change.
Alphamethadol	2 g	No Change.
Alpha-methylfentanyl	2 g	No Change.
Alpha-methylthiofentanyl	2 g	No Change.
Alpha-methyltryptamine (AMT)	2 g	12 g.
Aminorex	2 g	12 g.
Benzylmorphine	2 g	No Change.
Betacetylmethadol	2 g	No Change.
Beta-hydroxy-3-methylfentanyl	2 g	No Change.
Beta-hydroxyfentanyl	2 g	No Change.
Betameprodine	2 g	No Change.
Betamethadol	2 g	No Change.
Betaprodine	2 g	No Change.
Bufotenine	3 g	No Change.
Cathinone	4 g	12 g.
Codeine-N-oxide	602 g	No Change.
Diethyltryptamine	2 g	12 g.
Difenoxin	50 g	No Change.
Dihydromorphine	3,608,000 g	No Change.
Dimethyltryptamine	7 g	18 g.
Gamma-hydroxybutyric acid	47,000,000 g	No Change.
Heroin	20 g	No Change.
Hydromorphinol	54 g	No Change.
Hydroxypethidine	2 g	No Change.
Ibogaine	5 g	No Change.
Lysergic acid diethylamide (LSD)	16 g	No Change.
Marihuana	21,000 g	No Change.
Mescaline	5 g	13 g.
Methaqualone	10 g	No Change.
Methcathinone	4 g	12 g.
Methyldihydromorphine	2 g	No Change.
Morphine-N-oxide	655 g	No Change.
N-Benzylpiperazine	2 g	12 g.
N,N-Dimethylamphetamine	2 g	12 g.
N-Ethylamphetamine	2 g	12 g.
N-Hydroxy-3,4-methylenedioxyamphetamine	2 g	12 g.
Noracymethadol	2 g	No Change.
Norlevorphanol	52 g	No Change.
Normethadone	2 g	No Change.
Normorphine	18 g	No Change.
Para-fluorofentanyl	2 g	No Change.
Phenomorphan	2 g	No Change.
Pholcodine	2 g	No Change.
Properidine	2 g	No Change.
Psilocybin	2 g	No Change.
Psilocyn	2 g	No Change.
Tetrahydrocannabinols	393,000 g	No Change.
Thiofentanyl	2 g	No Change.
Tilidine	10 g	No Change.
Trimeperidine	2 g	No Change.
Schedule II		
1-Phenylcyclohexylamine	2 g	No Change.
1-Piperidinocyclohexanecarbonitrile	2 g	27 g.
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g	No Change.
Alfentanil	15,000 g	19,550 g.
Alphaprodine	2 g	No Change.
Amobarbital	40,007 g	No Change.
Amphetamine (for conversion)	8,500,000 g.	
Amphetamine (for sale) *	25,300,000 g	33,400,000 g.

Basic class	Previously established 2012 quotas	Proposed adjusted 2012 quotas
*DEA has determined that the revised total quantity 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 stock is 29,400,000 g. DEA has further determined that an additional 4,000,000 g is necessary to provide for future research and development needs and unexpected emergencies that could affect market availability.		
Carfentanil	0 g	5 g.
Cocaine	216,000 g	No Change.
Codeine (for conversion)	65,000,000 g	No Change.
Codeine (for sale)	39,505,000 g	No Change.
Dextropropoxyphene	7 g	No Change.
Dihydrocodeine	400,000 g	No Change.
Diphenoxylate	900,000 g	No Change.
Ecgonine	83,000 g	No Change.
Ethylmorphine	2 g	No Change.
Fentanyl	1,428,000 g	No Change.
Glutethimide	2 g	No Change.
Hydrocodone (for sale)	59,000,000 g	63,000,000 g.
Hydromorphone	3,455,000 g	3,628,000 g.
Isomethadone	4 g	No Change.
Levo-alphacetylmethadol (LAAM)	3 g	No Change.
Levomethorphan	5 g	No Change.
Levorphanol	3,600 g	No Change.
Lisdexamfetamine	12,000,000 g	No Change.
Meperidine	5,500,000 g	No Change.
Meperidine Intermediate-A	5 g	No Change.
Meperidine Intermediate-B	9 g	No Change.
Meperidine Intermediate-C	5 g	No Change.
Metazocine	5 g	No Change.
Methadone (for sale)	20,000,000 g	No Change.
Methadone Intermediate	26,000,000 g	No Change.
Methamphetamine	3,130,000 g	No Change.
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]		
Methylphenidate	56,000,000 g	No Change.
Morphine (for conversion)	83,000,000 g	No Change.
Morphine (for sale)	39,000,000 g	No Change.
Nabilone	20,502 g	No Change.
Noroxymorphone (for conversion)	7,200,000 g	No Change.
Noroxymorphone (for sale)	401,000 g	1,981,000 g.
Opium (powder)	63,000 g	73,000 g.
Opium (tincture)	1,000,000 g	No Change.
Oripavine	9,800,000 g	15,300,000 g.
Oxycodone (for conversion)	5,600,000 g	No Change.
Oxycodone (for sale)	98,000,000 g	98,700,000 g.
Oxymorphone (for conversion)	12,800,000 g	No Change.
Oxymorphone (for sale)	5,500,000 g	No Change.
Pentobarbital	34,000,000 g	No Change.
Phenazocine	5 g	No Change.
Phencyclidine	24 g	No Change.
Phenmetrazine	2 g	No Change.
Phenylacetone	16,000,000 g	No Change.
Racemethorphan	2 g	No Change.
Remifentanil	2,500 g	No Change.
Secobarbital	336,002 g	No Change.
Sufentanil	5,000 g	No Change.
Tapentadol	5,400,000 g	No Change.
Thebaine	116,000,000 g	No Change.

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 part 1303, the Deputy Administrator may adjust the 2012 aggregate production quotas and individual manufacturing quotas allocated for the year.

Comments

Pursuant to 21 CFR 1303.11 and 1303.13, 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 determining any adjustment of the aggregate production quota.

Dated: June 28, 2012.

Michele M. Leonhart,

Administrator.

[FR Doc. 2012–16396 Filed 7–3–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application; Myoderm

Pursuant to Title 21 Code of Federal Regulations 1301.34(a), this is notice that on May 9, 2012, Myoderm, 46 East Main Street, Norristown, Pennsylvania 19401, made application to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Nabilone (7379)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone Intermediate (9254)	II
Morphine (9300)	II
Oxymorphone (9652)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form for clinical trials, and research.

The import of the above listed basic classes of controlled substances would be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule I or II, which fall under the authority of section 1002(a)(2)(B) of the Act 21 U.S.C. 952(a)(2)(B) may, in the circumstances set forth in 21 U.S.C. 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than August 6, 2012.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic class of any controlled substance in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a); 21 U.S.C. 823(a); and 21 CFR 1301.34(b), (c), (d), (e), and (f) are satisfied.

Dated: June 28, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 2012–16493 Filed 7–3–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—Curricula Review and Revision: NIC Trainer Development Series

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a Cooperative Agreement.

SUMMARY: The National Institute of Corrections' (NIC) Academy Division is soliciting proposals from organizations, groups, or individuals to enter into a cooperative agreement for the review, revision, and/or development of competency-based, blended modality training curricula with the aim of providing corrections agencies and professionals with the knowledge, skills, and abilities needed to train and develop their staff.

DATES: Application must be received by 4 p.m. (EDT) on Friday, July 20, 2012.

ADDRESSES: Mailed applications must be sent to: Director, National Institute of Corrections, 320 First Street NW., Room 5002, Washington, DC 20534.

Applicants are encouraged to use Federal Express, UPS, or similar service to ensure delivery by the due date.

Hand delivered applications should be brought to 500 First Street NW., Washington, DC 20534. At the front desk, dial 7–3106, extension 0 for pickup.

Faxed applications will not be accepted. Electronic applications can be submitted via *http://www.grants.gov.*

FOR FURTHER INFORMATION CONTACT: All technical or programmatic questions concerning this announcement should be directed to Michael Guevara, Correctional Program Specialist, National Institute of Corrections. Mr. Guevara can be reached by calling 800–995–6429, ext. 6617, or by email at *mguevar@bop.gov.* In addition to the direct reply, all questions and responses will be posted on NIC's Web site at *www.nicic.gov* for public review (the names of those submitting questions will not be posted). The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation. Only questions received by 12 p.m. (EDT) on July 13, 2012 will be posted on the NIC Web site.

SUPPLEMENTARY INFORMATION:

Overview: NIC is revitalizing its trainer development series with the goal of helping corrections agencies and trainers improve staff training and development. NIC is interested in updating some of its curricula, including "Training Design and Development," "Foundation Skills for Trainers," "Building Agency Success: Developing an Effective FTO/OJT Training Program," and "Training for Training Directors." NIC is also interested in the development of a model Training for Trainers template that could be applied broadly, enabling agencies to train trainers in existing curricula.

All curricula will follow the Instructional Theory into Practice (ITIP) model and will incorporate blended learning strategies. A copy of the "ITIP Toolkit," which may be useful in helping awardees develop acceptable curricula, is available on the NIC Web site at *http://nicic.gov/Library/024773.* An essential component of this project will be the incorporation of current research on adult learning and performance. The use of multiple delivery technologies is required.

Background: NIC has prioritized capacity building in corrections agencies for decades. While NIC frequently relied on traditional classroom-based training in the past, the emergence of new technologies and the

Substance	2012*	30-50% inventory	salt total	c.f.	base total	Notes	pd efforts	2011 exports
Alfentanil	0.487	0.243	0.730	0.900	0.657	most dispositions are exports	2.760	5.833
Amphetamine	22,211.267	8,884.507	31,095.774		33,427.957	multiple salts	337.136	509.777
Cocaine	46.054	13.816	59.870	0.890	53.285		0.005	0.228
Codeine	25,473.127	12,736.563	38,209.690	0.860	32,860.333		46.131	1,216.533
Dihydrocodeine	89.749	44.874	134.623	0.640	86.159		0.000	0.003
Diphenoxylate	411.656	205.828	617.484	0.930	574.260	made into schedule 5 preps	0.000	41.852
Fentanyl	569.110	170.733	739.843	1.000	739.843		16.375	175.328
Hydrocodone	64,786.963	19,436.089	84,223.052	0.610	51,376.062		685.180	30.306
Hydromorphone	1,896.024	568.807	2,464.831	0.890	2,193.699		209.098	550.175
Levorphanol	1.344	0.672	2.016	1.000	2.016		0.000	0.004
Lisdexamfetamine	13,925.864	6,962.932	20,888.795	0.580	12,115.501		532.500	0.195
Meperidine	2,134.683	1,067.341	3,202.024	0.870	2,785.761		73.085	583.594
Methadone	7,443.038	2,232.911	9,675.949	0.890	8,611.595		85.600	390.134
Methamphetamine	14.494	7.247	21.741	0.800	17.393			0.082
Methylphenidate	20,563.448	6,169.034	26,732.483	0.870	23,257.260		836.220	8,766.604
Morphine	31,061.877	15,530.938	46,592.815	0.750	34,944.611		6,405.397	547.128
Nabilone	0.045	0.022	0.067	1.000	0.067		0.000	
Opium	81.843	40.921	122.764	1.000	122.764		0.000	
Oxycodone	68,325.161	20,497.548	88,822.709	0.900	79,940.438		4,626.726	6,061.125
Oxymorphone	2,179.282	1,089.641	3,268.923	0.890	2,909.342		2,566.825	18.191
Pentazocine	713.667	356.834	1,070.501	1.000	1,070.501			
Pentobarbital	71.114	35.557	106.671	0.910	97.071	mostly used in vet medicince	51.999	5,247.353
Remifentanil	1.133	0.566	1.699	0.910	1.546		1.500	0.237
Secobarbital	16.680	8.340	25.020	0.920	23.018		0.000	
Sufentanil	0.067	0.034	0.101	0.670	0.068		0.873	1.502
Tapentadol	5,900.110	2,950.055	8,850.165	0.860	7,611.142	importation	0.000	

Billing Code 441009-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-363]

Controlled Substances:
Final Adjusted Aggregate Production Quotas for 2012

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

ACTION: Notice.

SUMMARY: This notice establishes final adjusted 2012 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

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

SUPPLEMENTARY INFORMATION:

Background

Section 306 of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. In accordance with 21 U.S.C. 826 and 21 CFR 1303.11, DEA published in the Federal Register on December 15, 2011, notice of the established 2012 aggregate production quotas for controlled substances in Schedules I and II (76 FR 78044). That notice stated that the Administrator would adjust, as needed, the established aggregate production quotas in 2012 as provided for in 21 CFR 1303.13. The 2012 proposed adjusted aggregate production quotas were subsequently published in the Federal Register on July 5, 2012 (77 FR 39737) in consideration of the outlined criteria.

All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas on or before August 6, 2012.

Analysis for Final Adjusted 2012 Aggregate Production Quotas

Consideration has been given to the criteria outlined in the July 5, 2012, notice of proposed adjusted aggregate production quotas in accordance with 21 CFR 1303.13. In addition, nine companies, eight DEA registered manufacturers and one non-registrant, submitted timely comments regarding a total of 23 Schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 3,4-Methylenedioxy-N-Methylcathinone (methylone), alfentanil, amphetamine (for conversion), amphetamine (for sale), codeine (for conversion), codeine (for sale), desomorphine, dihydromorphine, hydrocodone (for sale), hydromorphone, levomethorphan, lisdexamfetamine, methadone intermediate, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), noroxymorphone (for sale), oripavine, oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), sufentanil, and tapentadol 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.

DEA has taken into consideration the above comments along with the relevant 2011 year-end inventories, initial 2012 manufacturing quotas, 2012 export requirements, actual and projected 2012 sales, research and product development requirements, and additional applications received. Based on all of the above, the Administrator has determined that the proposed adjusted 2012 aggregate production quotas for 3,4-Methylenedioxypyrovalerone (MDPV), 3,4-Methylenedioxy-N-Methylcathinone (methylone), 4-Methyl-N-Methylcathinone

(mephedrone), alfentanil, amphetamine (for conversion), desomorphine, dihydromorphine, gamma hydroybutyric acid, hydrocodone (for sale), hydromorphone, levomethorphan, methadone, methadone intermediate, methylphenidate, morphine (for sale), oxycodone (for conversion), oxycodone (for sale), and sufentanil required additional consideration and hereby further adjusts the 2012 aggregate production quotas for those substances. Regarding amphetamine (for sale), codeine (for conversion), codeine (for sale), morphine (for conversion), noroxymorphone (for conversion), noroxymorphone (for sale), oripavine, oxymorphone (for conversion), oxymorphone (for sale), and tapentadol, the Administrator hereby determines that the proposed adjusted 2012 aggregate production quotas for these substances as published on July 5, 2012, at 77 FR 39737 are sufficient to meet the current 2012 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories. Pursuant to the above, the Administrator hereby establishes the 2012 final aggregate production quotas for Schedule I and II controlled substances, expressed in grans of anhydrous acid or base, as follows:

Basic Class – Schedule I	Final Adjusted 2012 Quotas
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-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
2,5-Dimethoxyamphetamine	12 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	30 g
3,4-Methylenedioxy-N-methylcathinone (methylone)	30 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxymethamphetamine (MDMA)	30 g
3,4-Methylenedioxypyrovalerone (MDPV)	20 g
3,4,5-Trimethoxyamphetamine	12 g

4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g
4-Methoxyamphetamine	88 g
4-Methylaminorex	12 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g
4-Methyl-N-methylcathinone (mephedrone)	25 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
5-Methoxy-3,4-methylenedioxyamphetamine	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	12 g
Codeine-N-oxide	602 g
Desomorphine	10 g
Diethyltryptamine	18 g
Difenoxin	50 g
Dihydromorphine	3,750,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	37,000,000 g
Heroin	20 g
Hydromorphinol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	13 g

Methaqualone	10 g
Methcathinone	12 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N-Benzylpiperazine	12 g
N,N-Dimethylamphetamine	12 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

Basic Class – Schedule II	Final Adjusted 2012 Quotas
1-Phenylcyclohexylamine	2 g
1-Piperdinocyclohexanecarbonitrile	27 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g
Alfentanil	29,002 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	13,300,000 g
Amphetamine (for sale)	33,400,000g
Carfentanil	5 g
Cocaine	216,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	7 g
Dihydrocodeine	400,000 g
Diphenoxylate	900,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	79,700,000 g

Hydromorphone	4,207,000 g
Isomethadone	4 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	10 g
Levorphanol	3,600 g
Lisdexamfetamine	12,000,000 g
Meperidine	5,500,000 g
Meperidine Intermediate-A	5 g
Meperidine Intermediate-B	9 g
Meperidine Intermediate-C	5 g
Metazocine	5 g
Methadone (for sale)	23,100,000 g
Methadone Intermediate	29,970,000 g
Methamphetamine	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]	
Methylphenidate	64,600,000 g
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	48,200,000 g
Nabilone	20,502 g
Noroxymorphone (for conversion)	7,200,000 g
Noroxymorphone (for sale)	1,981,000 g
Opium (powder)	73,000 g
Opium (tincture)	1,000,000 g
Oripavine	15,300,000 g
Oxycodone (for conversion)	5,600,000 g
Oxycodone (for sale)	105,200,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	5,500,000 g
Pentobarbital	34,000,000 g
Phenazocine	5 g
Phencyclidine	24 g
Phenmetrazine	2 g
Phenylacetone	16,000,000 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	336,002 g
Sufentanil	6,730 g
Tapentadol	5,400,000 g
Thebaine	116,000,000 g

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

Dated:

Michele M. Leonhart,
Administrator

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

copy from the Consent Decree Library by mail, please enclose a check in the amount of $3.75 ($.25 per page) payable to the U.S. Treasury or, if by email or fax, forward a check in that amount to the Consent Decree Library at the address given above.

Robert Brook,

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

[FR Doc. 2012-22121 Filed 9-7-12; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-363]

Controlled Substances: Final Adjusted Aggregate Production Quotas for 2012

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

ACTION: Notice.

SUMMARY: This notice establishes final adjusted 2012 aggregate production quotas for controlled substances in Schedules I and II of the Controlled Substances Act (CSA).

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

SUPPLEMENTARY INFORMATION:

Background

Section 306(a) of the CSA (21 U.S.C. 826) requires that the Attorney General establish aggregate production quotas for each basic class of controlled substance listed in Schedules I and II. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100. In accordance with 21 U.S.C. 826 and 21 CFR 1303.11, DEA published in the **Federal Register** on December 15, 2011, notice of the established 2012 aggregate production quotas for controlled substances in Schedules I and II (76 FR 78044). That notice stated that the Administrator would adjust, as needed, the established aggregate production quotas in 2012 as provided for in 21 CFR 1303.13. The 2012 proposed adjusted aggregate production quotas were subsequently published in the **Federal Register** on July 5, 2012 (77 FR 39737) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas on or before August 6, 2012.

Analysis for Final Adjusted 2012 Aggregate Production Quotas

Consideration has been given to the criteria outlined in the July 5, 2012, notice of proposed adjusted aggregate production quotas in accordance with 21 CFR 1303.13. In addition, nine companies, eight DEA registered manufacturers and one non-registrant, submitted timely comments regarding a total of 25 Schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 3,4-Methylenedioxy-N-Methylcathinone (methylone), alfentanil, amphetamine (for conversion), amphetamine (for sale), codeine (for conversion), codeine (for sale), desomorphine, dihydromorphine, hydrocodone (for sale), hydromorphone, levomethorphan, lisdexamfetamine, methadone intermediate, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), noroxymorphone (for sale), oripavine, oxycodone (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), sufentanil, and tapentadol 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.

DEA has taken into consideration the above comments along with the relevant 2011 year-end inventories, initial 2012 manufacturing quotas, 2012 export requirements, actual and projected 2012 sales, research and product development requirements, and additional applications received. Based on all of the above, the Administrator has determined that the proposed adjusted 2012 aggregate production quotas for 3,4-Methylenedioxypyrovalerone (MDPV), 3,4-Methylenedioxy-N-Methylcathinone (methylone), 4-Methyl-N-Methylcathinone (mephedrone), alfentanil, amphetamine (for conversion), desomorphine, diethyltryptamine, dihydromorphine, gamma hydroxybutyric acid, hydrocodone (for sale), hydromorphone, levomethorphan, methadone, methadone intermediate, methylphenidate, morphine (for sale), oxycodone (for conversion), oxycodone (for sale), and sufentanil required additional consideration and hereby further adjusts the 2012 aggregate production quotas for those substances. Regarding amphetamine (for sale), codeine (for conversion), codeine (for sale), morphine (for conversion), noroxymorphone (for conversion), noroxymorphone (for sale), oripavine, oxymorphone (for conversion), oxymorphone (for sale), and tapentadol, the Administrator hereby determines that the proposed adjusted 2012 aggregate production quotas for these substances as published on July 5, 2012, at 77 FR 39737 are sufficient to meet the current 2012 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate inventories. Pursuant to the above, the Administrator hereby establishes the 2012 final aggregate production quotas for Schedule I and II controlled substances, expressed in grams of anhydrous acid or base, as follows:

	Final adjusted 2012 quotas
Basic Class—Schedule I	
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-Methyl-4-phenyl-4-propionoxypiperidine	2 g
1-Pentyl-3-(1-naphthoyl)indole (JWH-018)	45 g
2,5-Dimethoxyamphetamine	12 g
2,5-Dimethoxy-4-ethylamphetamine (DOET)	12 g
2,5-Dimethoxy-4-n-propylthiophenethylamine	12 g
3-Methylfentanyl	2 g
3-Methylthiofentanyl	2 g
3,4-Methylenedioxyamphetamine (MDA)	30 g

	Final adjusted 2012 quotas
3,4-Methylenedioxy-N-methylcathinone (methylone)	30 g
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	24 g
3,4-Methylenedioxymethamphetamine (MDMA)	30 g
3,4-Methylenedioxypyrovalerone (MDPV)	20 g
3,4,5-Trimethoxyamphetamine	12 g
4-Bromo-2,5-dimethoxyamphetamine (DOB)	12 g
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	12 g
4-Methoxyamphetamine	88 g
4-Methylaminorex	12 g
4-Methyl-2,5-dimethoxyamphetamine (DOM)	12 g
4-Methyl-N-methylcathinone (mephedrone)	25 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
5-Methoxy-3,4-methylenedioxyamphetamine	12 g
5-Methoxy-N,N-diisopropyltryptamine	12 g
Acetyl-alpha-methylfentanyl	2 g
Acetyldihydrocodeine	2 g
Acetylmethadol	2 g
Allylprodine	2 g
Alphacetylmethadol	2 g
Alpha-ethyltryptamine	12 g
Alphameprodine	2 g
Alphamethadol	2 g
Alpha-methylfentanyl	2 g
Alpha-methylthiofentanyl	2 g
Alpha-methyltryptamine (AMT)	12 g
Aminorex	12 g
Benzylmorphine	2 g
Betacetylmethadol	2 g
Beta-hydroxy-3-methylfentanyl	2 g
Beta-hydroxyfentanyl	2 g
Betameprodine	2 g
Betamethadol	2 g
Betaprodine	2 g
Bufotenine	3 g
Cathinone	12 g
Codeine-N-oxide	602 g
Desomorphine	10 g
Diethyltryptamine	18 g
Difenoxin	50 g
Dihydromorphine	3,750,000 g
Dimethyltryptamine	18 g
Gamma-hydroxybutyric acid	37,000,000 g
Heroin	20 g
Hydromorphinol	54 g
Hydroxypethidine	2 g
Ibogaine	5 g
Lysergic acid diethylamide (LSD)	16 g
Marihuana	21,000 g
Mescaline	13 g
Methaqualone	10 g
Methcathinone	12 g
Methyldihydromorphine	2 g
Morphine-N-oxide	655 g
N-Benzylpiperazine	12 g
N,N-Dimethylamphetamine	12 g
N-Ethylamphetamine	12 g
N-Hydroxy-3,4-methylenedioxyamphetamine	12 g
Noracymethadol	2 g
Norlevorphanol	52 g
Normethadone	2 g
Normorphine	18 g
Para-fluorofentanyl	2 g
Phenomorphan	2 g
Pholcodine	2 g
Properidine	2 g
Psilocybin	2 g
Psilocyn	2 g
Tetrahydrocannabinols	393,000 g
Thiofentanyl	2 g
Tilidine	10 g
Trimeperidine	2 g

	Final adjusted 2012 quotas
Basic Class—Schedule II	
1-Phenylcyclohexylamine	2 g
1-Piperdinocyclohexanecarbonitrile	27 g
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,800,000 g
Alfentanil	29,002 g
Alphaprodine	2 g
Amobarbital	40,007 g
Amphetamine (for conversion)	13,300,000 g
Amphetamine (for sale)	33,400,000 g
Carfentanil	5 g
Cocaine	216,000 g
Codeine (for conversion)	65,000,000 g
Codeine (for sale)	39,605,000 g
Dextropropoxyphene	7 g
Dihydrocodeine	400,000 g
Diphenoxylate	900,000 g
Ecgonine	83,000 g
Ethylmorphine	2 g
Fentanyl	1,428,000 g
Glutethimide	2 g
Hydrocodone (for sale)	79,700,000 g
Hydromorphone	4,207,000 g
Isomethadone	4 g
Levo-alphacetylmethadol (LAAM)	3 g
Levomethorphan	10 g
Levorphanol	3,600 g
Lisdexamfetamine	12,000,000 g
Meperidine	5,500,000 g
Meperidine Intermediate-A	5 g
Meperidine Intermediate-B	9 g
Meperidine Intermediate-C	5 g
Metazocine	5 g
Methadone (for sale)	23,100,000 g
Methadone Intermediate	29,970,000 g
Methamphetamine	3,130,000 g
[750,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 2,331,000 grams for methamphetamine mostly for conversion to a schedule III product; and 49,000 grams for methamphetamine (for sale)]	
Methylphenidate	64,600,000 g
Morphine (for conversion)	83,000,000 g
Morphine (for sale)	48,200,000 g
Nabilone	20,502 g
Noroxymorphone (for conversion)	7,200,000 g
Noroxymorphone (for sale)	1,981,000 g
Opium (powder)	73,000 g
Opium (tincture)	1,000,000 g
Oripavine	15,300,000 g
Oxycodone (for conversion)	7,600,000 g
Oxycodone (for sale)	105,200,000 g
Oxymorphone (for conversion)	12,800,000 g
Oxymorphone (for sale)	5,500,000 g
Pentobarbital	34,000,000 g
Phenazocine	5 g
Phencyclidine	24 g
Phenmetrazine	2 g
Phenylacetone	16,000,000 g
Racemethorphan	2 g
Remifentanil	2,500 g
Secobarbital	336,002 g
Sufentanil	6,730 g
Tapentadol	5,400,000 g
Thebaine	116,000,000 g

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

Dated: August 31, 2012.

Michele M. Leonhart,

Administrator.

[FR Doc. 2012-22128 Filed 9-7-12; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA 353]

Final Adjusted Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2012

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

ACTION: Notice.

SUMMARY: This notice establishes the Final Adjusted 2012 Assessment of Annual Needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: *Effective Date:* September 10, 2012.

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

SUPPLEMENTARY INFORMATION: The 2012 Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and imported into the United States in 2012 to provide adequate supplies of each chemical for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks of such chemicals. Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires that the Attorney General establish an assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. This responsibility has been delegated to the Administrator of the DEA by 28 CFR 0.100.

On July 18, 2012, a notice entitled "Proposed Adjustment of the Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2012" was published in the **Federal Register** (77 FR 42333). That notice proposed to adjust the 2012 Assessment of Annual Needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale) and phenylpropanolamine (for conversion). All interested persons were invited to comment on or object to the proposed assessments on or before August 17, 2012.

Comments Received

DEA did not receive any comments to the proposed adjustment of the assessment of annual needs for ephedrine (for sale), ephedrine (for conversion), pseudoephedrine (for sale), phenylpropanolamine (for sale), and phenylpropanolamine (for conversion).

Conclusion

In determining the adjusted 2012 assessments, 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 considered changes in demand, changes in the national rate of net disposal, and changes in the rate of net disposal by the registrants holding individual manufacturing or import quotas for the chemical; whether any increased demand or changes in the national and/or individual rates of net disposal are temporary, short term, or long term; whether any increased demand could be met through existing inventories, increased individual manufacturing quotas, or increased importation without increasing the assessment of annual needs; whether any decreased demand would result in excessive inventory accumulation by all persons registered to handle the particular chemical; and other factors affecting the medical, scientific, research, industrial, and importation needs in the United States, lawful export requirements, and reserve stocks, as found relevant.

Other factors that DEA considered include trends as derived from information provided in applications for import, manufacturing, and procurement quotas and in import and export declarations. The inventory, acquisition (purchases), and disposition (sales) data as provided by DEA-registered manufacturers and importers reflects the most current information available to DEA at the time of publication of this Notice. The underlying data used to determine the final 2012 assessment of annual needs is the same as that used in determining the proposed 2012 assessment of annual needs, as published on September 14, 2011, at 76 FR 56809.

In accordance with 21 U.S.C. 826(a) and 21 CFR 1315.13, the Administrator hereby orders that the 2012 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in kilograms of anhydrous acid or base, is adjusted and established as follows:

List I chemical	Final 2012 assessment of annual needs (kg)
Ephedrine (for sale)	4,300
Phenylpropanolamine (for sale)	5,800
Pseudoephedrine (for sale)	278,000
Phenylpropanolamine (for conversion)	26,200
Ephedrine (for conversion)	12,000

Dated: August 31, 2012.

Michele M. Leonhart,

Administrator.

[FR Doc. 2012-22127 Filed 9-7-12; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration; Cambrex Charles City, Inc.

By Notice dated June 18, 2012, and published in the **Federal Register** on June 26, 2012, 77 FR 38085, Cambrex Charles City, Inc., 1205 11th Street, Charles City, Iowa 50616-3466, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the following basic classes of controlled substances:

Drug	Schedule
4-Anilino-N-phenethyl-4-piperidine (8333).	II
Phenylacetone (8501)	II
Opium, raw (9600)	II
Poppy Straw Concentrate (9670)	II

The company plans to import the listed controlled substances for internal use, and to manufacture bulk intermediates for sale to its customers. No comments or objections have been received. Comments and requests for hearings on applications to import narcotic raw material are not appropriate. 72 FR 3417 (2007).

DEA has considered the factors in 21 U.S.C. 823(a) and 952(a), and determined that the registration of Cambrex Charles City, Inc. to import the

2012 Revised APQ
Worksheets

Basic Class: 9050-II
PQ Total(DM+PD): 20,591,267,000

FDA Est: -2.680%
IMS Est: -1.930%

Company	DEA Reg#	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	5,000	5,000	0.000	31,229,517,699	0.000	0.000	1,636	0.000	-1,636	-1,636
		100,000	100,000	5,725	31,229,517,699	0.000	0.000	30,566	0.000	-25,759	-24,516
		445,000,000	445,000,000	200,985,000	31,229,517,699	0.006	1.539,520,004	278,063,000	0.000	-104,366,565	-60,756,745
		33,000,000,000	13,416,000,000	16,333,548,000	31,229,517,699	0.523	10,767,975,944	3,398,457,000	9,613,200,000	19,606,811,208	23,149,349,430
		24,537,000,000	15,023,900,000	13,365,010,000	31,229,517,699	0.429	8,823,442,963	9,048,389,000	8,176,000,000	14,600,686,331	17,505,656,703
		50,000,000	34,100,000	118,310	31,229,517,699	0.000	78,008	0.000	0.000	101,410	127,088
		2,550,000,000	2,444,000,000	1,319,650,000	31,229,517,699	0.042	870,246,669	1,639,449,000	0.000	-568,121,330	-281,678,164
MQ Totals:		60,582,105,000	32,865,105,000	31,229,517,035				10,422,990,302	17,789,200,000	33,534,856,229	

Final Initial APQ:	39,605,000,000
Proposed Revised:	39,605,000,000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-18,801,194,802
2011 Initial APQ:	39,605,000,000
FDA Est = 2011 APQ * FDA %:	38,498,050,000
IMS Est = 2011 APQ * IMS %:	38,840,825,500

CFR 50%: -10,411,383,522

CODEINE (FOR SALE)

2012 Revised APQ Worksheets

Basic Class: 9050-A

PQ Total(CM+PQ): 19,726,428.000

FDA Est: 000%

IMS Est: .000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	11,700,000.000	8,264,000.000	5,854,250.000	32,519,640.000	0.181	0.000	906,539.000	0.000	-906,539.000	516,925.750
		24,000,000.000	8,579,000.000	0.000	32,519,640.000	0.000	0.000	0.000	0.000	0.000	0.000
		38,000,000.000	23,045,000.000	24,765,581.000	32,519,640.000	0.809	0.000	18,665,597.000	0.000	-18,665,597.000	-5,474,201.750
		8,000,000.000	8,000,000.000	0.000	32,519,640.000	0.000	0.000	448,810.000	0.000	-448,810.000	-448,810.000
MQ Totals:		72,700,000.000	42,887,000.000	30,619,840.000				19,020,946.000	0.000	-19,020,946.000	

Final Initial APQ:	65,000,000.000
Proposed Revised:	65,000,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-32,426,218.000
2011 Initial APQ:	65,000,000.000
FDA Est = 2011 APQ * FDA %:	0.000
IMS Est = 2011 APQ * IMS %:	0.000

CFR 50%: -28,704,661.000

CODEINE (FOR CONVERSION)

2012 Revised APQ Worksheets

Basic Class: 9170-8
PQ Total(CM+PD): 1.000

FDA Est: +1.100%
IMS Est: -9.660%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 60% Invent
(b)(4)	(b)(4);(b)(7)(E)	2.000	2.000	0.000	597,950.000	0.000	0.000	0.000	0.000	0.000	0.000
		20,000.000	20,000.000	0.000	597,950.000	0.000	0.000	0.000	0.000	0.000	0.000
		48,500.000	25,000.000	0.000	597,950.000	0.000	0.000	0.000	0.000	0.000	0.000
		950,000.000	858,000.000	597,950.000	597,950.000	1.000	0.000	308,577.000	18,600.000	-289,977.000	-140,489.500
MQ Totals:			1,018,502.000	699,002.000	597,950.000			308,577.000	18,600.000	-289,977.000	

Final Initial APQ:	900,000.000
Proposed Revised:	2,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-1,207,577.500
2011 Initial APQ:	827,000.000
FDA Est = 2011 APQ * FDA %:	817,903.000
IMS Est = 2011 APQ * IMS %:	747,111.800

CFR 60%: -1,058,000.250

DIPHENOXYLATE (FOR SALE)

2012 Revised APQ
Worksheets

Basic Class: 9120-0
PQ Total(CSA+PD): 820,015.000

FDA Est: -12.900%
IMS Est: -15.460%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invest	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	5.000	5.000	0.000	90,338.076	0.000	0.000	0.000	0.000	0.000	0.000
		5.000	5.000	0.788	90,338.076	0.000	1.044	11.375	0.000	-10.018	-9.873
		280,000.000	280,000.000	90,291.000	90,338.076	0.999	119,952.458	110,786.000	0.000	45,152.197	58,727.324
		500.000	300.000	48.290	90,338.076	0.001	61.497	191.550	0.000	-111.604	-100.107
MQ Totals:		280,510.000	280,310.000	90,338.076				110,988.925	0.000	45,030.575	58,614.344

Final Initial APQ:	400,000.000
Proposed Revised:	400,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-211,276.425
2011 Initial APQ:	800,000.000
FDA Est = 2011 APQ * FDA %:	696,600.000
IMS Est = 2011 APQ * IMS %:	676,320.000

CFR 50%: -218,695.656

DIHYDROCODEINE

2012 Revised APQ
Worksheets

Basic Class: 9180-0
PQ Total(CM+PD): 6.000

FDA Est: 00%
IMS Est: 00%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	2.000	2.000	0.000	0.000	0.000	0.000	1.292	0.000	-1.292	-1.292
MQ Totals:		2.000	2.000	0.000				1.292	0.000	-1.292	

Final Initial APQ:	2.000
Proposed Revised:	2.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	5.708
2011 Initial APQ:	2.000
FDA Est = 2011 APQ * FDA %:	0.000
IMS Est = 2011 APQ * IMS %:	0.000

CFR 50%: 4.208

ETHYLMORPHINE

2012 Revised APQ Worksheets

Basis Class: 8801-0
PQ Total(CM+PQ): 1,152,580.000

FDA Est: 4.300%
IMS Est: 8.130%

Company	DEA Num	2012 MQ Request	2012 MQ	2010 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	0.000	0.000	0.000	1,112,159.038	0.000	0.000	0.001	0.000	-0.001	-0.001
		200,000.000	80,520.000	30,401.000	1,112,159.038	0.027	31,518.646	102,363.000	0.000	-61,391.100	-55,368.683
		65,000.000	65,000.000	59,830.286	1,112,159.038	0.054	62,028.312	8,598.946	90,000.000	182,035.359	173,691.515
		2.000	2.000	0.000	1,112,159.038	0.000	0.000	0.226	0.000	-0.226	-0.226
		13,500.000	7,500.000	7,595.000	1,112,159.038	0.007	7,977.439	1,400.000	0.000	6,970.871	10,455.649
		500,000.000	474,000.000	361,196.000	1,112,159.038	0.325	374,453.501	294,415.000	0.000	197,377.151	265,953.676
		1,600,000.000	779,000.000	632,756.000	1,112,159.038	0.587	676,713.581	357,329.000	95,600.000	617,999.045	747,352.102
MQ Totals:		1,858,507.000	1,396,307.000	1,414,579.286				764,138.175	185,600.000	919,990.788	

Final Initial APQ:	1,428,000.000
Proposed Revised:	1,[illegible],000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-430,943.175
2011 Initial APQ:	1,428,000.000
FDA Est = 2011 APQ * FDA %:	1,469,404.000
IMS Est = 2011 APQ * IMS %:	1,515,536.400

CFR 50%: -441,215.354

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2012 Revised APQ Worksheets

Basic Class: 9150-0
PC Total(CM+PD): 2,855,462.000

FDA Est: 4.500%
IMS Est: 13.540%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PC	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	5.000	5.000	0.000	2,704,390.290	0.000	0.000	0.000	0.000	0.000	0.000
		20.000	20.000	2.501	2,704,390.290	0.000	0.001	2.456	38.823	0.000	-39.126
		156,000.000	154,000.000	0.000	2,704,390.290	0.000	0.000	0.000	0.000	0.000	0.000
		1.200	0.000	0.000	2,704,390.290	0.000	0.000	0.000	0.000	0.000	0.000
		417,200.000	244,815.000	166,612.700	2,704,390.290	0.062	163,598.547	13,242.700	0.000	197,436.781	230,909.909
		439,700.000	410,500.000	458,364.439	2,704,390.290	0.169	450,075.021	131,336.272	80,640.000	534,401.356	625,488.616
		360,000.000	495,000.000	261,400.000	2,704,390.290	0.097	256,672.840	101,706.000	0.000	254,958.432	284,484.800
		1,230,000.000	961,000.000	942,154.000	2,704,390.290	0.348	925,115.357	356,950.000	22,250.000	867,549.964	1,057,232.696
		1,468,000.000	1,049,100.000	855,618.810	2,704,390.290	0.316	840,145.135	517,218.050	0.000	574,959.627	748,867.073
		135,000.000	75,000.000	29,320.000	2,704,390.290	0.007	19,654.326	48,514.000	0.000	-22,203.376	-16,641.033
MQ Totals:		4,425,926.200	3,338,240.000	2,734,372.450				1,171,606.845	102,890.000	2,383,986.982	2,927,306.871

Final Initial APQ:	2,455,000.000
Proposed Revised:	3,828,000.000
Final Revised APQ:	0.000
MQ Needed=PC* 1.5 - Revised MQ - Inventory:	-377,023.845
2011 Initial APQ:	3,455,000.000
FDA Est = 2011 APQ * FDA %:	3,810,475.000
IMS Est = 2011 APQ * IMS %:	3,922,807.000

CFR 30%: -514,801.235

HYDROMORPHONE

Vol. I

2012 Revised APQ
Worksheets

Basic Class: 9193-0
PQ Total(CM+PD): 58,687,824.161

FDA Est: 5.000%
IMS Est: 5.000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 60% Invent
(b)(4)	(b)(4);(b)(7)(E)	5.000	5.000	0.000	53,575,359.954	0.000	0.000	0.051	0.000	-0.051	-0.051
		20.000	20.000	2.883	53,575,359.954	0.000	3.168	97.671	0.000	-53.551	-53.886
		817,000.000	220,000.000	65,888.000	53,575,359.954	0.001	72,176.624	31,269.000	0.000	52,500.612	25,424.051
		81,600.000	37,500.000	0.000	53,575,359.954	0.000	0.000	0.000	0.000	0.000	0.000
		1,000,000.000	3,887,000.000	0.000	53,575,359.954	0.000	0.000	0.000	0.000	0.000	0.000
		8,150,000.000	9,958,000.000	4,429,364.000	53,575,359.954	0.082	4,830,128.310	331,339.000	0.000	5,847,841.325	6,808,675.369
		29,000,000.000	18,647,000.000	20,302,273.000	53,575,359.954	0.379	22,339,864.742	6,313,114.000	3,050.000	22,597,505.365	26,561,080.178
		9,910,000.000	4,498,000.000	412,332.000	53,575,359.954	0.008	452,842.072	195,459.000	0.000	393,235.864	673,041.841
		41,466,000.000	16,984,000.000	23,067,572.750	53,575,359.954	0.431	25,290,783.860	2,638,184.340	0.000	29,869,808.678	34,497,163.922
		18,000,000.000	7,291,000.000	4,957,173.000	53,575,359.954	0.093	5,430,225.789	23,667.000	0.000	6,985,673.000	7,953,405.062
MQ Totals:		101,263,625.000	58,610,725.000	53,235,658.643				8,837,080.062	3,050.000	65,976,521.979	76,369,844.283

Final Initial APQ:	50,000,000.000
Proposed Revised:	63,000,000.000
Final Revised APQ:	0.000
MQ Need=PQF 1.8 - Revised MQ - Inventory:	19,284,671.180
2011 Initial APQ:	55,000,000.000
FDA Est = 2011 APQ * FDA %:	58,650,000.000
IMS Est = 2011 APQ * IMS %:	54,978,000.000

CFR 60%: 17,924,007.300

PENDING

Company	DEA Num	Requested Increase/Decrease	Web/CMS	Created Increase/Decrease	
(b)(4)	(b)(4);(b)(7)(E)	10,531,000.000		0.000	limited by APQ, would grant 2,017kg
		22,811,800.000	12.487	0.000	

HYDROCODONE (FOR SALE)

2012 Revised APQ
Worksheets

Basic Class: 9226-I
PQ Total(CM+PD): 0.000

FDA Est: .000%
IMS Est: .000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 60% Invent
(b)(4)	(b)(4);(b)(7)(E)	2.000	2.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		2.000	2.000	0.000				0.000	0.000	0.000	

Final Initial APQ: 4.000
Proposed Revised: 4.000
Final Revised APQ: 0.000
MQ Needs=PQ* 1.5 - Revised MQ - Inventory: -2.000
2011 Initial APQ: 81.000
FDA Est = 2011 APQ * FDA %: 0.000
IMS Est = 2011 APQ * IMS %: 0.000

CFR 60%: 0.000

ISOMETHADONE

2012 Revised APO Worksheets

Basic Class: 9210-0
PQ Total(CM+PD): 0.600

FDA Est: 000%
INS Est: 000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	2.000	2.000	0.170	0.170	1.000	0.000	0.768	0.000	-0.768	-0.726
MQ Totals:		2.000	2.000	0.170				0.768	0.000	-0.768	

First Initial APQ:	5.000
Proposed Revised:	5.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-2.768
2011 Initial APQ:	5.000
FDA Est = 2011 APQ * FDA %:	0.000
INS Est = 2011 APQ * INS %:	0.000

CFR 50%: 0.043

LEVOMETHORPHAN

2012 Revised APQ
Worksheets

Basic Class: 9648-0
PQ Total (CM+PD): 1.000

FDA Est: .000%
IMS Est: .000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	2.000	2.000	0.000	0.000	0.000	0.000	0.012	0.000	-0.012	-0.012
MQ Totals:		2.000	2.000	0.000				0.012	0.000	-0.012	

Final Initial APQ:	3.000
Proposed Revised:	3.000
Final Revised APQ:	0.000
MQ Need=PQ*1.5+Revised MQ-Inventory:	-0.512
2011 Initial APQ:	3.000
FDA Est=2011 APQ*FDA %:	0.000
IMS Est=2011 APQ*IMS %:	0.000

CFR 50%: 1.250

LEVO-ALPHACETYLMETHADOL (LAAM

2013 Revised APQ Worksheets

Base Class: 9300-II
PQ Total(CIII+PD): 40,491,096.000

FDA Est: 5.200%
IMS Est: 2.450%

Company	DEA Num	2013 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2013 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	5.000	5.000	0.000	34,493,652.732	0.000	0.000	0.014	0.000	-0.014	-0.014
		100.000	900.000	2.232	34,493,652.732	0.000	0.629	120.638	0.000	116.632	-166.295
		318,500.000	0.000	44,830.000	34,493,652.732	0.001	52,634.634	86,128.000	0.000	-17,715.978	-9,139.709
		4,500,000.000	3,450,000.000	0.000	34,493,652.732	0.000	0.000	0.000	0.000	0.000	0.000
		3,500,000.000	3,500,000.000	1,567,667.000	34,493,652.732	0.045	1,640,473.484	666,165.000	0.000	1,726,430.529	2,026,373.605
		23,000,000.000	17,000,000.000	20,026,175.000	34,493,652.732	0.580	23,502,175.184	2,787,040.000	300,000.000	28,085,617.752	31,915,197.743
		1,500,000.000	1,007,000.000	277.500	34,493,652.732	0.000	325.749	0.000	0.000	423.424	476.561
		10,421,000.000	12,264,000.000	11,908,432.000	34,493,652.732	0.345	13,976,574.332	5,725,343.000	0.000	11,444,255.631	13,722,032.915
		8,250,000.000	1,250,000.000	953,069.000	34,493,652.732	0.028	1,118,770.988	0.000	0.000	1,454,413.984	8,536,742.234
MQ Totals:		50,490,605.000	38,472,005.000	34,493,652.732				10,245,716.052	300,000.000	42,692,708.748	49,291,567.131

Final Initial APQ:	39,000,000.000
Proposed Revised:	39,000,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 -Revised MQ - Inventory:	12,018,922.948
2011 Initial APQ:	39,000,000.000
FDA Est= 2011 APQ * FDA %:	41,029,000.000
IMS Est = 2011 APQ * IMS %:	39,955,500.000

CFR 50%: 6,288,856.383

PENDING

Company	DEA Num	Requested Increase/Decrease	WebCMS	Granted Increase/Decrease
(b)(4)	(b)(4);(b)(7)(E)	318,500.000		

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2012 Revised APQ
Worksheets

Basic Class: 9300-A
PQ Total(QM+PD): 3,651,335.000

FDA Est: 000%
IMS Est: 000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	305,000.000	190,880.000	0.000	61,183,660.000	0.000	0.000	0.000	0.000	0.000	0.000
		2,000,000.000	1,500,000.000	0.000	61,183,660.000	0.000	0.000	0.000	1,500,000.000	1,500,000.000	1,500,000.000
		46,000,000.000	41,508,000.000	45,231,003.000	61,183,660.000	0.739	0.000	13,237,215.000	0.000	-13,237,215.000	-1,928,464.250
		21,165,000.000	15,125,100.000	13,532,757.000	61,183,660.000	0.221	0.000	5,595,504.000	0.000	-5,595,504.000	-2,212,314.750
		3,200,000.000	2,133,300.000	2,429,900.000	61,183,660.000	0.040	0.000	0.000	0.000	0.000	607,475.000
MQ Totals:		72,690,000.000	60,457,280.000	61,183,660.000				18,832,719.000	1,500,000.000	-17,332,719.000	

Final Initial APQ:	63,000,000.000
Proposed Revised:	63,000,000.000
Final Revised APQ:	0.000
MQ Need=PQF 1.5 - Revised MQ - Inventory:	-73,512,996.500
2011 Initial APQ:	63,000,000.000
FDA Est = 2011 APQ * FDA %:	0.000
IMS Est = 2011 APQ * IMS %:	0.000

CFR 50%: -59,177,415.250

MORPHINE (FOR CONVERSION)

2012 Revised APQ
Worksheets

Basic Class: 9254-0
IPQ Total(CM+PD): 5,423,025.000

FDA Est: 0.00%
IMS Est: 0.00%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	7,550,000.000	7,414,000.000	4,825,350.000	16,899,036.000	0.286	0.000	570,580.000	0.000	-570,580.000	535,757.500
		0.001	0.000	0.000	16,899,036.000	0.000	0.000	0.000	0.000	0.000	0.000
		4.000	4.000	0.000	16,899,036.000	0.000	0.000	0.000	0.000	0.000	0.000
		791,000.000	791,000.000	209.000	16,899,036.000	0.000	0.000	0.000	0.000	0.000	52.250
		150,000.000	0.000	0.000	16,899,036.000	0.000	0.000	0.000	0.000	0.000	0.000
		12,000,000.000	8,765,000.000	9,059,811.000	16,899,036.000	0.536	0.000	1,738,970.000	0.000	-1,738,970.000	753,367.750
		8,080,000.000	3,186,129.000	2,133,568.000	16,899,036.000	0.126	0.000	209,709.000	0.000	-209,709.000	333,832.500
MQ Totals:		28,571,004.001	20,158,124.000	16,899,036.000				2,511,959.000	0.000	-2,511,959.000	

Final Initial APQ:	25,000,000.000
Proposed Revised:	25,000,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-14,543,575.500
2011 Initial APQ:	25,000,000.000
FDA Est = 2011 APQ * FDA %:	0.000
IMS Est = 2011 APQ * IMS %:	0.000

CFR 50%: -11,674,567.250

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METHADONE-INTERMEDIATE

Vol. I

2012 Revised APQ Worksheets

Basic Class: 9250.0
PQ Total(CM+PD): 44,115,764.000

FDA Est: -100%
IMS Est: +2.340%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 32% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	6,528,400.000	2,975,400.000	3,809,609.000	16,165,323.276	0.235	0.000	2,467,356.000	0.000	-2,467,356.000	-1,515,795.750
		5.000	5.000	0.276	16,165,323.276	0.000	0.000	0.468	0.000	-0.468	-0.399
		492,000.000	232,000.000	445.000	16,165,323.276	0.000	0.000	31,191.000	0.000	-31,191.000	-31,039.000
		95,000.000	0.000	0.000	16,165,323.276	0.000	0.000	0.000	0.000	0.000	0.000
		11,000,200.000	10,756,000.000	10,215,121.000	16,165,323.276	0.632	0.000	3,198,756.000	13,350.000	-3,185,406.000	-631,658.000
		5,400,000.000	3,039,604.000	2,143,165.000	16,165,323.276	0.133	0.000	390,755.000	0.000	-290,755.000	245,031.500
MQ Totals:		23,515,405.000	17,005,009.000	16,165,323.276				6,586,092.468	63,350.000	-5,974,742.468	

First Initial APQ:	20,000,000.000
Proposed Revised:	20,000,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.8 - Revised MQ - Inventory:	-1,819,455.468
2011 Initial APQ:	20,000,000.000
FDA Est = 2011 APQ * FDA %:	19,960,000.000
IMS Est = 2011 APQ * IMS %:	19,532,000.000

CFR 50%: -1,307,085.649

PENDING

Company	DEA Num	Requested Increase/Decrease	WebCIMS	Granted Increase/Decrease
(b)(4)	(b)(4);(b)(7)(E)	3,553,000.000		

METHADONE

2013 Revised APQ
Worksheets

Basic Class: 9232-0
PQ Total(CM+PD): 0.000

FDA Est: 000%
IMS Est: 000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2013 Total PQ	2011 Inventory	2013 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	3.000	3.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		3.000	3.000	0.000				0.000	0.000	0.000	

Final Initial APQ:	5.000
Proposed Revised:	5.000
Final Revised APQ:	6.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-3.000
2011 Initial APQ:	3.000
FDA Est = 2011 APQ * FDA %:	0.000
IMS Est = 2011 APQ * IMS %:	0.000

CFR 50%: -3.000

MEPERIDINE-INTERMEDIATE-A

Vol. I

2012 Revised APQ
Worksheets

Basic Class: 9233-0
PQ Total(CN+PD): 2.000

FDA Est: .000%
IMS Est: .000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	7.000	7.000	0.081	0.081	8.000	0.000	5.168	0.000	-5.168	-5.168
MQ Totals:		7.000	7.000	0.081				5.168	0.000	-5.168	

Final Initial APQ: 9.000
Proposed Revised: 9.000
Final Revised APQ: 0.000
MQ Needed*PQF 1.5 = Revised MQ - Inventory: -9.168 CFR 50%: -9.668
2011 Initial APQ: 7.000
FDA Est = 2011 APQ * FDA %: 0.000
IMS Est = 2011 APQ * IMS %: 0.000

MEPERIDINE-INTERMEDIATE-B

2012 Revised APQ
Worksheets

Basic Class: 9334-0
PD Total(CM+PD): 0.000

FDA Est: .000%
IMS Est: 000%

Company	DEA Num	2012 MQ Request	2012 MQ	2010 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	3.000	3.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		3.000	3.000	0.000				0.000	0.000	0.000	

Final Initial APQ: 5.000
Proposed Revised: 5.000
Final Revised APQ: 0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory: -3.000 CFR 50%: -3.000
2011 Initial APQ: 3.000
FDA Est = 2011 APQ * FDA %: 0.000
IMS Est = 2011 APQ * IMS %: 0.000

MEPERIDINE-INTERMEDIATE-C

2012 Revised APQ
Worksheets

Base Class: 9210-0
PQ Total(Clin+PD): 2,727,125.000

FDA Est: -14.500%
IMS Est: -7.040%

Company	DEA No.	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	5.000	5.000	0.000	3,266,312.972	0.000	0.000	0.000	0.000	0.000	0.000
		4,100,000.000	3,131,000.000	2,189,007.000	3,266,312.972	0.670	1,628,480.664	1,013,967.000	0.000	1,363,070.589	1,849,148.105
		2.000	2.000	0.173	3,266,312.972	0.000	1.046	2.142	0.000	-0.002	0.409
		121,800.000	2,000.000	0.000	3,266,312.972	0.000	0.000	0.000	0.000	0.000	0.000
		2,100,000.000	1,194,000.000	1,076,304.000	3,266,312.972	0.330	598,632.670	290,363.000	65,700.000	973,558.471	1,197,703.637
MQ Totals:		6,321,807.000	4,327,007.000	3,266,312.972				1,304,332.142	65,700.000	2,336,630.358	

Final Initial APQ:	5,500,000.000
Proposed Revised:	5,500,000.000
Final Revised APQ:	0.000
MQ Need+PQ* 1.5 - Revised MQ - Inventory:	-1,540,651.642
2011 Initial APQ:	6,500,000.000
FDA Est = 2011 APQ * FDA %:	5,643,000.000
IMS Est = 2011 APQ * IMS %:	6,135,360.000

CFR 50%: -1,405,854.649

MEPERIDINE

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2012 Revised APQ
Worksheets

Basis Class: 9652-II
PQ Total(C&I+PD): 2,905,285.000

FDA Est: 26.000%
IMS Est: -13.470%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 35% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	5.000	5.000	0.000	2,730,638.372	0.000	0.000	0.007	0.000	-0.007	-0.007
		60.000	60.000	8.467	2,730,638.372	0.000	0.000	210.849	0.000	-210.849	-210.734
		843,000.000	50,000.000	0.000	2,730,638.372	0.000	0.000	0.000	0.000	0.000	0.000
		1,780,000.000	389,000.000	170,920.000	2,730,638.372	0.063	0.000	131,681.000	0.000	-131,681.000	-89,151.000
		4,000,000.000	1,897,000.000	2,358,244.000	2,730,638.372	0.864	0.000	377,233.000	0.000	-377,233.000	212,328.000
		1,833,000.000	697,653.000	188,014.000	2,730,638.372	0.069	0.000	143,425.000	16,000.000	-159,425.000	-76,425.500
		5,000.000	5,000.000	501.810	2,730,638.372	0.000	0.000	9,361.760	0.000	-9,361.760	-9,236.233
		600,000.000	43,000.000	13,156.000	2,730,638.372	0.005	0.000	12,623.000	0.000	-12,623.000	-9,333.500
MQ Totals:		9,166,065.000	3,288,718.000	2,730,638.372				874,738.565	16,000.000	-856,738.568	

Final Initial APQ:	5,500,000.000
Proposed Revised:	5,500,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	401,470.934
2011 Initial APQ:	3,070,000.000
FDA Est = 2011 APQ * FDA %:	3,858,200.000
IMS Est = 2011 APQ * IMS %:	2,533,671.000

CFR 50%: 257,859.217

PENDING

Company	DEA Num	Requested Increase/Decrease	WebCMS	Granted Increase/Decrease
(b)(4)	(b)(4);(b)(7)(E)	2,103,000.000	12-447	1,541,253.000
		557,000.000	12-513	480.000

OXYMORPHONE (FOR SALE)

Vol. 1

2012 Revised APQ Worksheets

Basic Class: 9652-A
PQ Total(CM+PO): 255,400.000

FDA Est: .000%
INS Est: .000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 32% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	9,400,000.000	4,710,000.000	5,967,399.000	5,975,827.000	0.998	0.000	819,564.000	0.000	-819,564.000	672,265.000
		4,230,000.000	1,501,500.000	8,431.000	5,975,827.000	0.001	0.000	205,700.000	0.000	-205,700.000	-203,592.250
		2,425,000.000	1,000,000.000	0.000	5,975,827.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		16,055,000.000	7,211,500.000	5,975,827.000				1,025,264.000	0.000	-1,025,264.000	

Final Initial APQ: 12,800,000.000
Proposed Revised: 12,800,000.000
Final Revised APQ: 0.000
MQ Need=PQ*1.3 - Revised MQ - Inventory: -7,853,684.000 CFR 50%: -6,423,577.250
2013 Initial APQ: 12,800,000.000
FDA Est = 2013 APQ * FDA %: 0.000
INS Est = 2013 APQ * INS %: 0.000

PENDING

Company	DEA Num	Requested Increase/Decrease	WebCIMS	Granted Increase/Decrease
(b)(4)	(b)(4);(b)(7)(E)	4,690,000.000	12-495	3,056,000.000

OXYMORPHONE (FOR CONVERSION)

Vol. 1

2012 Revised APQ
Worksheets

Basic Class: 9143-B
PQ Total(CM+PD): 85,936,100.000

FDA Est: 7.100%
IMS Est: 3.160%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Shares of 2012 Total PQ	2011 Inventory	2013 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	5.000	5.000	0.000	60,012,088.034	0.000	0.000	0.000	0.000	-0.030	-0.030
		60.000	60.000	0.054	60,012,088.034	0.000	7.461	923.615	0.000	-913.615	-912.595
		913,000.000	118,000.000	67,625.000	60,012,088.034	0.001	55,734.487	22,235.000	0.000	50,195.833	64,316.868
		122,400.000	0.000	0.000	60,012,088.034	0.000	0.000	0.000	0.000	0.000	0.000
		5,400,000.000	800,000.000	440,149.000	60,012,088.034	0.006	367,681.018	852,485.000	0.000	-474,525.675	-361,371.476
		742,000.000	0.000	0.000	60,012,088.034	0.000	0.000	0.000	0.000	0.000	0.000
		28,000,000.000	23,000,000.000	18,821,894.000	60,012,088.034	0.233	15,545,882.026	14,832,717.000	8,100.000	5,325,613.007	9,215,703.618
		3,000.000	3,000.000	758,083.000	60,012,088.034	0.010	650,274.004	32,387.000	0.000	813,886.308	877,748.180
		45,000,000.000	45,000,000.000	38,268,520.000	60,012,088.034	0.481	33,363,274.427	8,508,165.000	2,183,000.000	34,663,191.256	42,882,308.034
		22,000,000.000	20,672,700.000	20,843,147.000	60,012,088.034	0.258	17,011,837.338	14,948,992.000	7,000,000.000	14,149,006.797	18,498,218.870
		844,000.000	322,000.000	175,644.000	60,012,088.034	0.002	144,744.137	248,198.000	0.000	60,030.822	-23,356.828
MQ Totals:		112,824,485.000	87,918,765.000	60,012,088.034				40,455,103.535	9,201,700.000	54,455,526.465	71,871,742.974

Final Initial APQ:	86,000,000.000
Proposed Revised:	68,700,000.000
Final Revised APQ:	0.000
MQ Need "PQ" 1.0 - Revised MQ - Inventory:	-29,305,718.535
2011 Initial APQ:	105,500,000.000
FDA Est = 2010 APQ * FDA %:	112,960,500.000
IMS Est = 2011 APQ * IMS %:	102,145,100.000

CFR 50%: -35,848,722.027

PENDING

Company	DEA Num	Requested Increase/Decrease	WebCSS	Granted Increase/Decrease
(b)(4)	(b)(4);(b)(7)(E)	322,000.000		183,000.000 APQ as asked, justified for total 640kg

OXYCODONE (FOR SALE)

2012 Revised APQ
Worksheets

Basic Class: 9143-A
PQ Total(CM+PQ): 5,000.000

FDA Est: 000%
DEA Est: 000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	7,300,000.000	4,230,000.000	4,452,292.000	4,452,299.600	1.000	5,004.995	1,871,751.000	0.000	-1,865,244.507	-752,421.757
MQ Totals:		7,300,000.000	4,230,000.000	4,452,292.000				1,871,751.000	0.000	-1,865,244.507	

Final Initial APQ:	5,600,000.000
Proposed Revised:	0.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.3 - Revised MQ - Inventory:	-6,094,243.500
2011 Initial APQ:	5,600,000.000
FDA Est = 2011 APQ * FDA %:	0.000
DEA Est = 2011 APQ * DEA %:	0.000

CFR 50%: -4,882,421.750

PENDING

Company	DEA Num	Requested Increase/Decrease	WebCINS	Granted Increase/Decrease
(b)(4)	(b)(4);(b)(7)(E)	3,070,000.000	12-447	775,000.000

OXYCODONE (FOR CONVERSION)

2012 Revised APQ
Worksheets

Basic Class: 9330-0
PQ Total(CM+PQ): 2,264,905.000

FDA Est: 000%
DIS Est: 000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	5.000	5.000	0.000	10,092,742.410	0.000	0.000	0.000	0.000	0.000	0.000
		750,000.000	0.000	0.000	10,092,742.410	0.000	0.000	0.000	0.000	0.000	0.000
		2,674,000.000	1,830,000.000	1,577,657.000	10,092,742.410	0.156	443,804.572	326,052.000	0.000	250,893.944	723,117.065
		9,900,000.000	3,866,000.000	6,783,759.000	10,092,742.410	0.670	1,518,299.067	980,957.000	0.000	992,631.788	2,808,356.584
		4,575,000.000	2,312,000.000	1,143,250.440	10,092,742.410	0.113	256,355.965	484,215.850	0.000	-150,092.857	122,291.845
		615,000.000	120,000.000	208,078.000	10,092,742.410	0.020	46,245.366	1,955.000	0.000	58,153.875	167,375.703
MQ Totals:		18,514,005.000	7,648,005.000	10,092,742.440				1,793,179.850	0.000	1,151,186.850	3,961,137.203

Final Initial APQ: 9,800,000.000
Proposed Revised: 15,300,000.000
Final Revised APQ: 0.000
MQ based=PQF 1.5 - Revised MQ - Inventory: -5,343,817.150
2011 Initial APQ: 15,000,000.000
FDA Est = 2011 APQ * FDA %: 0.000
DIS Est = 2011 APQ * DIS %: 0.000

CFR 50%: -4,388,857.796

PENDING

Company	DEA Num	Requested Increase/Decrease	WebCMS	Granted Increase/Decrease	
(b)(4)	(b)(4);(b)(7)(E)	750,000.000	62-350	750,000.000	
		6,014,000.000	62-496	1,350,000.000	limited by APQ; eligible for 6014aq
		2,293,000.000	62-487	0.000	
		495,000.000	62-493	495,000.000	

ORIPAVINE

2012 Revised APQ
Worksheets

Basic Class: 9639-0
PQ Total(C14+PD): 55,000.000

FDA Est: 500%
IMS Est: -2.820%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	60,000.000	23,000.000	0.000	55,230.000	0.000	0.000	0.000	0.000	0.000	0.000
		50,000.000	40,000.000	55,230.000	55,230.000	1.000	55,000.000	31,146.000	0.000	40,354.000	51,411.500
MQ Totals:		110,000.000	63,000.000	55,230.000				31,146.000	0.000	40,354.000	51,411.500

Final Initial APQ: 63,000.000
Proposed Revised: 73,000.000 *Based on (b)(4) Initial 2012
Final Revised APQ: 0.000
MQ Needed*PQ* 1.5 - Revised MQ - Inventory: -11,646.000 CFR 50%: -41,588.500
2011 Initial APQ: 230,000.000
FDA Est = 2011 APQ * FDA %: 231,840.000
IMS Est = 2011 APQ * IMS %: 223,514.000

OPIUM, POWDERED

2012 Revised APQ Worksheets

Basic Class: 9640-II
PQ Total(Cat+PQ): 0.000

FDA Est: .000%
IMS Est: .000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	20,000.000	10,000.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		20,000.000	10,000.000	0.000				0.000	0.000	0.000	

Final Initial APQ: 0.000
Proposed Revised: 0.000
Final Revised APQ: 0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory: -10,000.000 CFR 50%: 0.000
2011 Initial APQ: 0.000
FDA Est = 2011 APQ * FDA %: 0.000
IMS Est = 2011 APQ * IMS %: 0.000

OPIUM, GRANULATED

2012 Revised APQ
Worksheets

Basic Class: 9650-0
PQ Total(CM+PD): 944,451.000

FDA Est: .830%
IMS Est: -2.920%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 32% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	8,000.000	0.000	0.000	509,400.000	0.000	0.000	0.000	0.000	0.000	0.000
		100,000.000	10,000.000	0.000	509,400.000	0.000	0.000	0.000	0.000	0.000	0.000
		1,000,000.000	881,000.000	509,400.000	509,400.000	1.000	944,451.000	457,739.000	0.000	770,047.300	850,174.750
MQ Totals:		1,108,000.000	891,000.000	509,400.000				457,739.000	0.000	770,047.300	850,174.750

Final Initial APQ: 1,000,000.000
Proposed Revised: 1,000,000.000
Final Revised APQ: 0.000
MQ Needed*Q* 1.5 + Revised MQ - Inventory: 267,837.500
2011 Initial APQ: 1,500,000.000
FDA Est = 2011 APQ * FDA %: 1,512,000.000
IMS Est = 2011 APQ * IMS %: 1,457,700.000

CFR 50%: 159,174.750

OPIUM TINCTURE

2012 Revised APQ Worksheets

Basic Class: 9650-B
PQ Total(CM+PD): 140.000

FDA Est: .000%
IMS Est: .000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	1,691,360.000	369,995.000	169,200.000	169,501.260	0.998	139.751	69,483.000	1,337,600.000	1,266,298.877	1,310,591.889
		5.000	5.000	0.000	169,501.260	0.000	0.000	835.434	0.000	-135.434	-135.434
		3,500.000	3,000.000	301.000	169,501.260	0.002	0.249	491.000	5.000	-465.677	-418.439
		1,000.000	1,000.000	0.260	169,501.260	0.000	0.000	0.000	0.000	0.000	0.065
MQ Totals:		1,695,865.000	401,000.000	169,501.260				70,109.434	1,337,605.000	1,267,677.566	

Final Initial APQ: 401,000.000
Proposed Revised: 1,961,000.000
Final Revised APQ: 0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory: -470,699.434
2011 Initial APQ: 401,000.000
FDA Est = 2011 APQ * FDA %: 0.000
IMS Est = 2011 APQ * IMS %: 0.000

(b)(4) is supporting (b)(4) exports

CFR 50%: -426,559.119

NOROXYMORPHONE (FOR SALE)

2012 Revised APQ
Worksheets

Basic Class: 9739-0
PQ Total(CM+PQ): 2,492.000

FDA Est: 14.700%
IMS Est: 8.450%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	1,820.000	1,820.000	448.000	448.000	1.000	2,492.000	1,168.000	0.000	2,073.600	2,061.000
MQ Totals:		1,820.000	1,820.000	448.000				1,168.000	0.000	2,073.600	2,061.000

Final Initial APQ:	2,500.000
Proposed Revised:	2,500.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	752.000
2011 Initial APQ:	2,500.000
FDA Est = 2011 APQ * FDA %:	2,867.500
IMS Est = 2011 APQ * IMS %:	2,711.250

CFR 50%: 241.000

REMIFENTANIL

2012 Revised APQ
Worksheets

Basic Class: 9740-0
PQ Total(QM+PD): 1,167.000

FDA Est: .000%
IMS Est: .000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	2,500.000	1,800.000	3.000	1,699.000	0.002	1.844	997.100	0.000	-994.703	-994.045
		2.000	2.000	0.000	1,699.000	0.000	0.000	0.000	0.000	0.000	0.000
		750.000	500.000	339.000	1,699.000	0.179	208.327	629.000	581.000	222.825	297.159
		2,100.000	2,100.000	1,557.000	1,699.000	0.820	956.829	1,008.000	1,536.000	1,771.878	2,113.287
MQ Totals:		5,352.000	4,502.000	1,899.000				2,634.100	2,117.000	1,000.000	1,416.400

Final Initial APQ:	5,000.000
Proposed Revised:	5,000.000
Final Revised APQ:	0.000
MQ Need=PQ* 1.5 - Revised MQ - Inventory:	-5,385.500
2011 Initial APQ:	7,000.000
FDA Est = 2011 APQ * FDA %:	0.000
IMS Est = 2011 APQ * IMS %:	0.000

CFR 50%: -5,202.600

SUFENTANIL

Vol. I

2012 Revised APQ
Worksheets

Basic Class: 6333-0
PQ Total(CM+PDI): 11,138,185.000

FDA Est: 000%
IMS Est: 000%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2011 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2011 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	5.000	5.000	0.000	83,802,122.204	0.000	0.000	0.000	0.000	-0.008	-0.008
		670,000.000	670,000.000	0.000	83,802,122.204	0.000	0.000	0.000	0.000	0.000	0.000
		25.000	25.000	0.664	83,802,122.204	0.000	0.000	55.631	0.000	-55.506	-55.345
		1,749,000.000	623,000.000	138,585.000	83,802,122.204	0.002	16,418.540	132,618.000	0.000	-100,672.599	-74,947.076
		2.000	2.000	0.000	83,802,122.204	0.000	0.000	0.000	0.000	0.000	0.000
		500,000.000	500,000.000	0.000	83,802,122.204	0.000	0.000	46,650.000	0.000	-46,650.000	-46,650.000
		2,000,000.000	1,687,000.000	0.000	83,802,122.204	0.000	0.000	0.000	0.000	0.000	0.000
		40,000,000.000	36,432,000.000	35,991,639.000	83,802,122.204	0.429	4,783,588.293	14,305,195.000	0.000	-7,987,490.219	721,050.117
		3,000.000	3,000.000	104.540	83,802,122.204	0.000	13.894	2,555.370	0.000	-2,537.397	-2,511.867
		16,000,000.000	13,843,100.000	11,334,634.000	83,802,122.204	0.135	1,506,492.263	836,500.000	0.000	1,121,959.868	3,660,273.654
		64,000,000.000	6,868,400.000	12,327,258.000	83,802,122.204	0.147	1,639,751.576	74,650.000	0.000	2,956,727.049	5,959,953.671
		20,000,000.000	20,000,000.000	24,000,509.000	83,802,122.204	0.286	3,189,919.325	9,081,546.000	0.000	-4,914,652.678	825,978.156
MQ Totals:		103,142,032.000	83,168,532.000	83,802,122.204				24,381,931.939	0.000	-9,851,391.499	10,512,029.882

Final Initial APQ:	116,000,000.000
Proposed Revised:	116,000,000.000
Final Revised APQ:	0.000
MQ Need=PQF 1.5 - Revised MQ - Inventory:	-50,822,486.499
2011 Initial APQ:	126,000,000.000
FDA Est = 2011 APQ * FDA %:	0.000
IMS Est = 2011 APQ * IMS %:	0.000

CFR 50%: -72,656,502.195

THEBAINE

Vol. I

2012 Revised APQ
Worksheets

Basic Class: 4780
PC Total(C+P): 25,774,565,000

FDA Est: 27.700%
IMS Est: 18.650%

Company	DEA Num	2012 MQ Request	2012 MQ	2011 Sales	2001 Total Sales	% of 2011 Sales	Share of 2012 Total PQ	2012 Inventory	2012 Projected Exports	Calc Using CFR 30% Invent	Calc Using CFR 50% Invent
(b)(4)	(b)(4);(b)(7)(E)	1,400,180,000	622,935,000	128,155,000	6,325,122,696	0.020	596,299,050	672,795,000	0.000	511,333,726	517,367,563
		10,000	10,000	0.126	6,325,122,696	0.000	0.513	4,579	0.000	-3,912	-3,906
		500,000,000	304,000,000	0.000	6,325,122,696	0.000	0.000	0.000	0.000	0.000	0.000
		72,000,000	72,000,000	6,195,967,770	6,325,122,696	0.980	25,248,205,433	3,378,914,608	0.000	29,243,752,483	29,530,334,134
		3,000,000,000	3,000,000,000	0.000	6,325,122,696	0.000	0.000	0.000	0.000	0.000	0.000
MQ Totals:		4,781,190,000	3,998,945,000	6,325,122,696				3,351,714,179	0.000	29,755,142,321	30,047,897,795

Final Initial APQ:	5,400,000,000
Proposed Revised:	5,400,000,000
Final Revised APQ:	0.000
MQ Needs*PQ* 1.5 - Revised MQ - Inventory:	30,911,065,331
2011 Initial APQ:	1,000,000,000
FDA Est = 2011 APQ * FDA %:	1,277,000,000
IMS Est = 2011 APQ * IMS %:	1,180,800,000

CFR 50%: 26,048,352,795

TAPENTADOL

2012 Final Revi[illegible] Comments

Drug	Company	Comment	Amount	Response	Proposed APQ	Final APQ	Change
3,4-Methylenedioxy-N-Methylcathinone (methylone)	(b)(4)	increase APQ	10	justified, increase APQ	12	20	8
alfentanil		increase APQ	14,002	justified, increase APQ	19,550	29,002	9,452
amphetamine (for conversion)		increase APQ	13,000,000	justified, increase APQ	8,500,000	13,300,000	4,800,000
amphetamine (for sale)		increase APQ	7,800,000	APQ adequate, no change	33,400,000	33,400,000	-
		increase APQ	2,000,000				
		increase APQ	N/A				
		increase APQ	240,000				
codeine (for conversion)		increase APQ	6,955,000	APQ adequate, no change	65,000,000	65,000,000	-
		increase APQ	12,601,282				
codeine (for sale)		increase APQ	4,584,000	APQ adequate, no change	39,605,000	39,605,000	-
desomorphine		increase APQ	10	justified, increase APQ	-	10	10
dihydromorphine		increase APQ	446,000	justified, increase APQ	3,608,000	3,750,000	142,000
hydrocodone (for sale)		increase APQ	2,574,000	justified, increase APQ	63,000,000	86,600,000	23,600,000
		increase APQ	21,603,000				
		increase APQ	9,153,000				
hydromorphone		increase APQ	297,000	justified, increase APQ	3,628,000	4,207,000	579,000
		increase APQ	233,000				
		increase APQ	39,000				
levomethorphan		increase APQ	1	justified, increase APQ	5	10	5
lisdexamfetamine		increase APQ	1,000,000	APQ adequate, no change	12,000,000	12,000,000	-
methadone intermediate		increase APQ	3,035,000	justified, increase APQ	26,000,000	29,970,000	3,970,000
methylphenidate		increase APQ	7,256,000	justified, increase APQ	56,000,000	64,600,000	8,600,000
morphine (for conversion)		increase APQ	700,000	APQ adequate, no change	83,000,000	83,000,000	-
		increase APQ	13,492,000				
morphine (for sale)		increase APQ	500,000	justified, increase APQ	39,000,000	48,200,000	9,200,000
		increase APQ	6,285,000				
		increase APQ	10,000,000				
noroxymorphone (for conversion)		increase APQ	1,994,000	APQ adequate, no change	7,200,000	7,200,000	-
noroxymorphone (for sale)		increase APQ	1,981,000	APQ adequate, no change	1,981,000	1,981,000	-
oripavine		increase APQ	1,064,000	APQ adequate, no change	15,300,000	15,300,000	-
		increase APQ	2,920,000				
oxycodone (for conversion)		increase APQ	2,995,000	justified, increase APQ	5,600,000	7,600,000	2,000,000
oxycodone (for sale)		increase APQ	45,000	justified, increase APQ	98,700,000	105,200,000	6,500,000
		increase APQ	139,000				
		increase APQ	15,000,000				
oxymorphone (for conversion)		increase APQ	8,049,000	APQ adequate, no change	12,800,000	12,800,000	-
oxymorphone (for sale)		increase APQ	361,737	APQ adequate, no change	5,500,000	5,500,000	-
sufentanil		increase APQ	2,000	justified, increase APQ	5,000	6,730	1,730
tapentadol		increase APQ	150,000	APQ adequate, no change	5,400,000	5,400,000	-

(b)(4)

Number of Companies commenting: 9 (one non-registrant)

Number of drugs commented on: 25

(b)(4)

25 25

Additional Considerations:

Drug	Consideration	Proposed	Revised	Change
3,4-Methylenedioxypyrovalerone (MDPV)	(b)(4) request 8g, but no comment	12	20	8
3,4-Methylenedioxy-N-Methylcathinone (methylone)	request 10g, but no comment (b)(4) commented for 10g + total 20g			see above
4-Methyl-N-Methylcathinone (mephedrone)	request of 10g but no comment	12	25	13
amphetamine (for conversion)	did not comment, but was eligible for 4,200,000g - commented for company			see above
amphetamine (for sale)	additional request 1100,000g but no comment			see above
gamma hydroxybutyric acid	No requests for change, but all requests have been granted	47,000,000	37,000,000	(10,000,000)
hydrocodone (for sale)	requests 4400kg, but no comment			see above
hydromophone	requests 111,600g, but no comment			see above
methadone	requested 3,553kg no comment - granted 2,985kg requests 2,000,396g , but no comments	20,000,000	23,100,000	3,100,000
methylphenidate	did not comment, but was eligible for 3,081,000g. request 504kg			see above

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

Controlled Substance	Justification
4-Methylenedioxy-N-Methylcathinone (methylone)	just received drug code on bulk manufacturer registration - ref stds. increase APQ
amphetamine (for conversion)	converts to lisdexamphetamine, increased for correct conversion ratio, increase APQ
amphetamine (for sale)	requests 1100kg - analysis grants same; (b)(4) requests 2000kg - analysis grants - 1875kg; (b)(4) requests 7800kg - analysis grants 1750; (b)(4) requests 240kg - analysis grants 0, increase APQ
codeine (for conversion)	request for 12,601kg - analysis grants 10,602kg; (b)(4) request for 6,955kg - analysis grants same; available in APQ
codeine (for sale)	request for 4504kg - analysis would grant 1095kg - available in APQ
[illegible]	just received drug code on bulk manufacturer registration - ref stds, increase APQ
dihydromorphine	request for 446kg - analysis grants 395kg; (b)(4) requested 112kg - analysis grants same
hydrocodone	requests 2754kg - analysis grants 2216kg; (b)(4) request 9153kg - analysis grants same; (b)(4) requests 21,603kg - analysis grants 14,623kg (b)(4) request 4400kg - analysis grants 3782kg, increase APQ
hydromorphone	requests 114kg - analysis grants same; (b)(4) request 297kg - analysis grants 115kg; (b)(4) requests 39kg - analysis grants same (b)(4) request 233kg - analysis grants 190kg, increase APQ
levomethorphan	just received drug code on bulk manufacturer registration - ref stds, increase APQ
lisdexamfetamine	(b)(4) - analysis grants 0 - available in APQ
methadone intermediate	request 3836kg - analysis grants 1190kg; (b)(4) requests 3500kg - analysis grants 0kg and (b)(4) his pending requests - available in APQ
methylphenidate	requests 7265kg - analysis grants 5048; (b)(4) requests 3081kg - analysis grants same; increase APQ
morphine (for sale)	requests 3500 - analysis grants 0; (b)(4) request 10,000kg - analysis grants 7571kg; (b)(4) request 6285kg - analysis grants 1806kg, increase APQ
morphine (for conversion)	request 13,492kg - analysis grants 11,748kg, available in APQ
noroxymorphone (for sale)	request 1981kg for clinical trials - already considered in proposed revised APQ
noroxymorphone (for conversion)	request 1994kgs; available in APQ
oripavine	request 1064kg - analysis grants same; (b)(4) request 2920kg - analysis grants 1372kg; already considered in proposed revised APQ
oxycodone (for conversion)	request 2995kg - analysis grants 2537kg increase APQ
oxycodone (for sale)	request 15,000kg - analysis grants for 3171kg; (b)(4) request 139kg - no application (b)(4) requests 4500kg - analysis grants 3684kg increase APQ
oxymorphone (for conversion)	request 1900kgs; available in APQ
oxymorphone (for sale)	request for 561kg - analysis grants 110kg - available in APQ
sufentanil	request 2.9kg - analysis grants 2.250kg for pd and commercial efforts; increase APQ
tapentadol	requests 150kg - analysis grants same, available in APQ

Drug	Proposed APQ	Final APQ	Change
3,4-Methylenedioxy-N-Methylcathinone (methylone)	12	30	18
3,4-Methylenedioxypyrovalerone (MDPV)	12	20	8
4-Methyl-N-methylcathinone (mephedrone)	12	25	13
alfentanil	19,550	29,002	9,452
amphetamine (for conversion)	8,500,000	13,300,000	4,800,000
desomorphine	-	10	10
dihydromorphine	3,608,000	3,750,000	142,000
gamma hydroxybutyric acid	47,000,000	37,000,000	(10,000,000)
hydrocodone (for sale)	63,000,000	79,700,000	16,700,000
hydromorphone	3,628,000	4,207,000	579,000
levomethorphan	5	10	5
methadone	20,000,000	23,100,000	3,100,000
methadone intermediate	26,000,000	29,970,000	3,970,000
methylphenidate	56,000,000	64,600,000	8,600,000
morphine (for sale)	39,000,000	48,200,000	9,200,000
oxycodone (for conversion)	5,600,000	7,600,000	2,000,000
oxycodone (for sale)	98,700,000	105,200,000	6,500,000
sufentanil	5,000	6,730	1,730

Proposed Adjustment to the Aggregate Production Quotas for 2012 – Comments

Document DEA-2012-0003-DRAFT-0002

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

Increase Amphetamine (1100) – insure adequate year-end inventory to allow delivery of API to dosage form manufacturers in January 2013.

Document DEA-2012-00003-DRAFT-0003

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

Amphetamine (1100) – recently denied MQ based on insufficient available APQ – (b)(4) needs additional 7200kg – believe increase of 8100kg is insufficient; scheduled a 600kg validation campaign in 4Q 2012 – expect material to be unavailable for distribution and sale until stability data customer qualification work is completed sometime in 2013

Noroxymorphone (9668) – believe they are the only firm to require any substantial amount of quota – proposed adjustment from 401kg to 1981kg is more than sufficient; lowered volume for 2012, increased volume in 2013 because manufacturing activities will begin in 4Q 2012 and continue into 2013

Document DEA-2012-0003-DRAFT-0004

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

Desomorphine (9055) – newly registered – no initial quota – need 10g

3,4-Methylenedioxy-N-methylcathinone [Methylone] (7540) – newly registered – no initial quota – increase to 12g; may need up to 10g

Document DEA-2012-0003-DRAFT-0005

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

Hydrocodone for sale (9193)

Hydromorphone (9150)

Morphine for sale (9300)

Methylphenidate (1724)

Oxycodone for sale (9143)

Oxymorphone for converions (9652)

General comment for each substance – an aggregate increase based on (b)(4) customer demand.

Document DEA-2012-0003-DRAFT-0006

(b)(6)

(b)(4)

Levomethorphan (9210) – increase an additional 3g to cover possible increased yields on a production batch that is planned for 2012, as well as for crude, non-specification product that will come out of the synthesis batch.

Document DEA-2012-0003-DRAFT-0007

(b)(6)

(b)(4)

Amphetamine (for sale) (1100) – requested 240kg

Codeine (for conversion) (9050) – requested 32,000kg

Codeine (for sale) (9050) – requested 18,000kg

Dihydromorphine (9145) – requested 2,200kg

Hydrocodone (9193) – requested 28,000kg

Hydromorphone (9150) – requested 1,000kg

Methadone Intermediate (9254) – requested 11,800kg

Morphine (for conversion) (9300) – requested 54,000kg

Morphine (for sale) (9300) – requested 27,000kg

Noroxymorphone (for conversion) (9668) – 5,600kg

Oripavine (9330) – requested 6,300kg

Oxycodone (for conversion) (9143) – requested 8,000kg

Oxymorphone (for sale) (9652) – requested 4,000kg

Sufentanil (9740) – requested 5,000kg

Document DEA-2012-0003-DRAFT-0008

(b)(6)

(b)(4)

Amphetamine (for conversion) – increase commensurate with lisdexamfetamine increase

Lisdexamfetamine – increase to 13,000kg to provide an adequate and uninterrupted supply of Vyvanse for commercial distribution, exports to growing existing markets, and exports for launch into 9 new markets. (b)(4) supplies bulk manufacturers (b)(4) and (b)(4) and dosage form manufacturers (b)(4) to manufacture Vyvanse.

FedEx Comments

(b)(6)

(b)(4)

Oxycodone – previously requested +322kg but were granted only +183kg due to limitations of the currently established APQ; 30% perceived manufacturing loss between the point the DEA now requires (b)(4) to count quota as consumed and the final saleable product; +322kg of quota will only yield approx. 250kg (225kg as base) of saleable product; request increase of at least 139kg

(b)(6)

(b)(4)

Alfentanil – increase by 14,002g

Hydrocodone – increase by 2,574,000g

Morphine (for sale) – increase by 500,000g

Oxycodone – increase by 4,500,000g

Tapentadol – increase by 150,000g

(b)(6)

(b)(4)

Hydromorphone - increase by 297,000g

PUBLIC SUBMISSION

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Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Comment On: DEA-2012-0003-0001
Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Document: DEA-2012-0003-DRAFT-0003
Comment on FR Doc # 2012-16396

Submitter Information

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

General Comment

Comment included as attached file.

Attachments

Docket DEA-363

(b)(4)

July 12, 2012

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

via e-mail: www.regulations.gov

Re: **Docket No. DEA-363**

To Whom It May Concern:

This letter is in response to the Proposed Adjustments to the Aggregate Production Quotas for 2012, published in the Federal Register on July 5, 2012 under Docket No. DEA-363.

(b)(4) is registered with the Drug Enforcement Administration as a (Bulk) Manufacturer. We also hold registrations as an Importer, Exporter, Researcher, Chemical Importer, Analytical Laboratory, and as a Schedule 1 Researcher. Our principal business with regard to controlled substances is as a bulk manufacturer of Active Pharmaceutical Ingredients (API). (b)(4) manufactures approximately 30% of the bulk amphetamine (Drug Code 1100) produced in the United States, and was recently denied a Manufacturing Quota increase due to insufficient available Aggregate Quota. The proposed increase from 25,300 kilograms to 33,400 kilograms of aggregate amphetamine (for sale) is of critical interest to our firm. While supportive of the proposed increase, we are concerned whether the increase will be sufficient to meet industry and subsequently consumer needs.

(b)(4) currently needs a 7,200 kg Manufacturing Quota increase of Drug Code 1100 by the end of August 2012 to meet known customer demand and allow for year end inventory to better mitigate continued drug shortages to the consumer. We believe the proposed aggregate increase of 8,100 kg is likely insufficient to support our needs and those of other manufacturers. We encourage the Administration to critically review overall needs and requests of the API manufacturing community to assess whether a larger increase should be finalized for Drug Code 1100.

As (b)(4) noted during our verbal comments at DEA offices on May 30, 2012, the lack of timely issuance of sufficient quota in 2011 resulted in a shortage in year end inventory. As a result we have had to ration material between our customer base further exacerbating the drug shortage situation in the consumer marketplace. This rationing still continues for (b)(4) and its customer base. Our concern is the Manufacturing Quota increase as proposed is too limiting and will extend this rationing of the supply chain into 2013. (b)(4) has already received metric ton forecasts from customers for January 2013 that we can not support with the proposed level of an aggregate adjustment. We recognize the balance that DEA strives to maintain between inventory buildup and the prevention of diversion, but the drug shortages of 2011/2012 are unfortunately the outcome of too tight of

(b)(4)

(b)(4)

a restriction on manufacturing quotas at the API level. A second subsequent increase to the aggregate quota later in the year will likely be of no value to API manufacturers as it will be too late to utilize any quota grants considering the lengthy lead times of our processes.

Finally for Drug Code 1100, (b)(4) has scheduled a 600 kg validation campaign in fourth quarter 2012 to qualify a new source of a key starting material. As you know with validation materials, that material will not be available for distribution and sale until stability data and customer qualification work is completed, likely sometime in 2013, so it does not add to the distribution channels for the consumer in 2012.

(b)(4) would also like to comment on the proposed increase to noroxymorphone (for sale), Drug Code 9668. We believe, (b)(4) is the only firm to require any substantial amount of quota for this product. If that is accurate, then the proposed adjustment from 401 kilograms to 1,981 kilograms is more than sufficient for our purposes. Due to various factors, (b)(4) has had to revise our production schedule such that our Drug Code 9668 manufacturing activities will begin in fourth quarter 2012 upon receipt of an adjustment in manufacturing quota but then will continue into 2013. This lowers the volume of our manufacturing quota need for 2012, but results in a corresponding increase in 2013 for Drug Code 9668.

(b)(4) appreciates the opportunity to comment on the above proposed adjustments and understands the challenges facing DEA in preventing diversion while still ensuring adequate drug supply to the marketplace. We look forward to your finalization of the aggregate quota adjustments and are available for any follow-up questions at (b)(6) for (b)(6) Regulatory Specialist or (b)(6) Vice President Operations at (b)(6)

Sincerely,

(b)(6)

Regulatory Specialist

(b)(4)

√√ 2 Comments

PUBLIC SUBMISSION

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Docket: DEA-2012-0003
Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Comment On: DEA-2012-0003-0001
Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Document: DEA-2012-0003-DRAFT-0004
Comment on FR Doc # 2012-16396

Submitter Information

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

General Comment

See attached document with comment.

Attachments

(b)(4) fedreg comment 07242012

(b)(4)

CONFIDENTIAL

24 July 2012

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

Subject: Comment on Proposed Adjustment to 2012 Aggregate Production Quotas
Docket No. DEA-363

Dear Sir or Madam:

(b)(4) is submitting this comment in reference to the Proposed Adjustment to the 2012 Aggregate Production Quotas published in the Federal Register under citation Vol. 77, No. 129, pages 39737-39741, dated 05 July 2012. This is Docket No. DEA-363. This comment is CONFIDENTIAL BUSINESS INFORMATION and relates to two controlled substances.

(b)(4) is currently registered as a bulk manufacturer for Desomorphine (9055) and 3,4-Methylenedioxy-N-methylcathinone [Methylone] (7540). These two substances were recently approved additions to the company's bulk manufacturing registration and, therefore, no 2012 manufacturing quota has been assigned at this point. For Desomorphine, there was no initial aggregate production quota assigned. Therefore, (b)(4) is submitting this comment to request that an aggregate quota be assigned to allow for (b)(4) to obtain an initial manufacturing quota for the substance in 2012.

For Methylone, an initial aggregate quota of 8 g was assigned. As part of this publication, DEA is proposing that the aggregate quota for this substance be increased to 12 g. At the end of 2011, (b)(4) provided a comment to DEA that indicated the company was in the process of adding the substance as a new bulk manufactured drug code to its registration and that it would require a 5 g manufacturing quota in 2012. It is unclear whether the assigned quota for 2012 (or the proposed increase) actually covers (b)(4) previously indicated need. Therefore, at this time, (b)(4) is submitting this comment. As part of this comment, the company would like to re-iterate the need for a quota and indicates that it may need up to 10 g in 2012. Since the company previously submitted a comment indicating a need for 2012, it will go ahead and submit a request for an initial quota in the near future.

Based on this information, (b)(4) requests that the initial 2012 aggregate production quota for the following two substances be adjusted as needed to ensure that (b)(4) anticipated requirement in the amounts listed below are covered:

(b)(4)

(b)(4)

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Desomorphine (9055)	10 g
3,4-Methylenedioxy-N-methylcathinone [Methylone] (7540)	10 g

Should you have any questions regarding this comment, please contact me at (b)(6)
(b)(6)

Sincerely,

(b)(6)

Vice President
Regulatory Affairs

(b)(4)

PUBLIC SUBMISSION

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Tracking No. 810be104
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Docket: DEA-2012-0003
Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Comment On: DEA-2012-0003-0001
Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Document: DEA-2012-0003-DRAFT-0006
Comment on FR Doc # 2012-16396

Submitter Information

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

General Comment

See attached comment.

Attachments

(b)(4) fedreg comment 08012012

(b)(4)

CONFIDENTIAL

01 August 2012

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

Subject: Comment on Proposed Adjustment to 2012 Aggregate Production Quotas
Docket No. DEA-363

Dear Sir or Madam:

(b)(4) is submitting this comment in reference to the Proposed Adjustment to the 2012 Aggregate Production Quotas published in the Federal Register under citation Vol. 77, No. 129, pages 39737-39741, dated 05 July 2012. This is Docket No. DEA-363. This comment is CONFIDENTIAL BUSINESS INFORMATION and relates to one controlled substance.

(b)(4) is currently registered as a bulk manufacturer for Levomethorphan [9210]. The proposed revised aggregate production quota for this drug code is 5 g. (b)(4) would like to request an increase of 3 g for this drug code to accommodate a request that the company will submit for an increase in its 2012 manufacturing quota. That request will intended to cover possible increased yields on a production batch is that is planned for 2012, as well as for crude, non-specification product that will come out of the synthesis batch.

Should you have any questions regarding this comment, please contact me at (b)(6)
(b)(6)

Sincerely,

(b)(6)

Vice President
Regulatory Affairs

(b)(4)

received
8-6-12

(b)(4)

July 3, 2012

Attn; John Partridge
Chief Liaison and Policy Section
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

Re: Reference Docket No. DEA-363

Comments on "Controlled Substances: Proposed Revised Aggregate Production Quotas for 2012, "Federal Register Volume 77, Number 129 (Thursday July 5, 2012); Docket No. DEA-363"

Dear John:

(b)(4) herewith comments on a portion of the above referenced Federal Register proposal, specifically, the 2012 Proposed Revised Aggregate Production Quota for Hydromorphone (drug code 9150). During 2012 (b)(4) (b)(4) submitted a manufacturing allocation request dated June 1, 2012. DEA was unable to process due to insufficient quantity remaining in the aggregate.

(b)(4) received Hydromorphone quota for 410500 grams base for 2012. will require an additional 297,000grams of hydromorphone base to satisfy the demands of our customers for 2012 (192000 grams) along with a yearend inventory allowance of 18% for 2012 (105000 grams). Manufacturers' must have a yearend inventory allowance to provide for 1st quarter demand for 2013.

The proposed adjusted 2012 quota for Hydromorphone displays a proposed increase of 173000 grams base. The proposed adjustable quota should be increased by at least another 297000 grams base to provide for (b)(4) customer requirements. The proposed aggregate should be 3925000 grams base.

Attached find the supporting documentation for the increase.

Thank you for your time and consideration in this important matter.

Respectfully submitted,

(b)(6)

Director DEA Compliance & Security

Attachments

(b)(4)

(b)(4)

FED EX

June 1, 2012

Drug Enforcement Administration Headquarters
Drug and Chemical Evaluation Section (ODE)
8701 Morrissette Drive
Springfield, VA 22152

2012 Hydromorphone (9150) and Morphine (9300) Quota
Manufacturer DEA # (b)(4);(b)(7)(E)

Hydromorphone 297000 grams base
Morphine 700000 grams base

Ladies and Gentlemen:

(b)(4) is requesting an increase of 297000 gms base of bulk manufacturing quota of Hydromorphone and 700000 gms base Morphine.

Attached find the following supporting documents:

Hydromorphone sales thru May 31, 2012	247494 gms base
Current API inventory on hand May 31, 2012	87711 gms base
Purchase Order requirements for June – Dec 20112	354160 gms base

Quota for 2012	410500 gms base
Sales and Purchase Orders for 2012	601654 gms base
Quantity required to meet Purchase Orders for 2012	191154 gms base

(b)(4)

Based upon the above figures and attached documents, (b)(4) cannot fulfill their Hydromorphone orders for 2012. (b)(4) will be short 191154 gms base just to meet the purchase orders for the remainder of 2012 and will run out of Hydromorphone API by the end of September.

Manufacturers of an API are allowed to have carryover inventory up to 50% of quota at the end of each year. (b)(4) is requesting 105000 gms which represents approximately 18 % of quota for 2012.

Therefore, (b)(4) requires an additional 297000 grams base of Hydromorphone and 700000 grams base of Morphine. The synthesis process uses 18750 gms base of Morphine to produce 1 batch of 11000 gms of Hydromorphone base. (b)(4) needs to produce 27 batches of Hydromorphone in 2012, which consumes 27 x 18750 gms (506250 gms) of Morphine base.

The additional Morphine requested (193750gms) is required to be on hand at the end of 2012 to allow for production start up in January 2013.

In 2010, (b)(4) had to wait for the aggregate to be adjusted and had a difficult time trying to produce enough Hydromorphone to get production done in the beginning of 2011.

If you have any additional questions, please contact me at (b)(6) or email (b)(4);(b)(6)

Sincerely,

(b)(6)

Director DEA Compliance & Security

2012 Quota Increase Hydromorphone

2012 Quota	410500 gms

Sales thru 5/30/12

Hydromorphone tablets	158325 gms
Dilaudid tablets/liquids	15711 gms
Exports	35900 gms
Hydromorphone API	37558 gms
Total	247494 gms

Purchase Orders for June – Dec

Hydromorphone tablets	226094 gms
Dilaudid tablets/liquids	24255 gms
Exports	81311 gms
Hydromorphone API	22500 gms
Total	354160 gms

Total Requirements for 2012

Sales	247494 gms
Purchase Orders	354160 gms
Total	601654 gms

Hydromorphone Sales

Customers	Sales 1/1/2012 thru 5/30/2012
	grams base
(b)(4)	
Export (b)(4);(b)(7)(E)	
Dilaudid FG	35900.00
(b)(4)	
DEA Reg # (b)(4);(b)(7)(E)	
Dilaudid Finished Goods Sales	15711.00
Hydromorphone Finished Goods Sales	158325.00
Hydromorphone API	10858
(b)(4);(b)(7)(E)	
Hydromorphone API	26700.00
TOTAL SALES	247494.00

2012 Sales

		Sales		gms base
Sales from 1/1/12 to 5/31/12				
HYDROMORPHONE HCL 2MG HUD 100'S	2mg HUD DAG002	40,874	7,276	
HYDROMORPHONE HCL 2MG 100'S	2mg 100's DAG102	177,481	31,592	
HYDROMORPHONE HCL 4MG HUD'S 100'S	4mg HUD DAG004	8,738	3,111	
HYDROMORPHONE HCL 4MG 100'S	4mg 100's DAG104	115,356	41,067	
HYDROMORPHONE HCL 4MG 500'S	4mg 500's DAG504	2,341	4,167	
HYDROMORPHONE HCL 8MG 100'S	8mg 100's DAG108	99,878	71,113	
		total		158,325
Dilaudid oral liquid 1mg/ml 473ml		7,766	3,269	
Dilaudid 2mg HUD 100		5,854	1,042	
Dilaudid 2mg 100s		5,920	1,054	
Dilaudid 4mg 500s		2,360	4,201	
Dilaudid 4mg 100s		11,841	4,215	
Dilaudid 8mg 100's		2,710	1,930	
		total		15,711

(b)(4)

2012 Purchase Orders . Hydromorphone tablets

Purchase Orders for Hydromorphone Tablets

		Jun 12	Jul 12	Aug 12	Sep-12	Oct-12	Nov-12	Dec-12	Totals 2012	Gms Base
HYDROMORPHONE HCL 2MG HUD 100'S	2mg HUD DAG002	5,880	5,880	11,760	5,880	5,880	5,880	5,880	47,040	8,373
HYDROMORPHONE HCL 2MG 100'S	2mg 100's DAG102	23,520	29,400	41,160	17,640	23,520	23,520	23,520	182,280	32,446
HYDROMORPHONE HCL 4MG HUD'S 100'S	4mg HUD DAG004	0	0	0	0	3,000	0	0	3,000	1,068
HYDROMORPHONE HCL 4MG 100'S	4mg 100's DAG104	0	17,640	17,640.	23,520	23,520	23,520	17,640	123,480	43,959
HYDROMORPHONE HCL 4MG 500'S	4mg 500's DAG504	0	1,175	0	0	0	0	0	1,175	2,092
HYDROMORPHONE HCL 8MG 100'S	8mg 100's DAG108	53,900	53,900	21,560	16,170	16,170	16,170	16,170	194,040	138,156
									total	226,094

(b)(4) DILAUDID Purchase Orders - US

Country	SKU	Description	MOQ	Jan-12	Jul-12	Aug-12	Sep-12	Oct-12	Nov-12	Dec-12	total	same base
USA	(b)(4)	DILAUDID 2 MG TABLETS 100S	5,880	5,880	-	-	-	-	-	5,880	11,760	2,090
				4500065416								
USA		DILAUDID 2 MG TABLETS HUD 100S	5,880	-	-	5,880	-	-	5,880	-	11,760	2,090
						4500066235						
USA		DILAUDID 4 MG TABLETS 100S	5,880	5,880	2,660	-	-	5,880	5,880	-	20,520	7,305
				4500065415	4500065726							
USA		DILAUDID 4 MG TABLETS 500S	1,175	-	-	-	-	1,175	-	-	1,175	2,092
								**New MPS #				
USA		DILAUDID 4 MG TABLETS HUD 100S	6,000	-	3,000	-	-	-	-	3,000	6,000	2,135
					4500065727							
USA		DILAUDID 8 MG TABLETS 100S	2,695	-	-	2,695	-	2,695	-	-	5,390	3,838
						4500066236						
USA		DILAUDID 1 MG/ML ORAL LIQUID 473ml	3,720	-	-	3,720	-	3,720	3,720	-	11,160	4,638
						4500066237						
											total	24,255

(b)(4) Purchase Orders Dilaudid - Canada / Australia

as at May 16, 2012

Country	SKU	Description	MOQ	Jun-12	Jul-12	Aug-12	Sep-12	Oct-12	Nov-12	Dec-12	total	gms base	
	(b)(4)	Batch Size(Tablets)											
CAN		Dilaudid Tablets 1mg 100's - Bottles	588,000			24,000					24,000	2,136,000	
AUS		2MG x 20 TABS	588,000	14400							14,400	512,640	
CAN		Dilaudid Tablets 2mg 100's - Bottles		27,120		24,000		24,000			75,120	13,371,360	
AUS		4MG x 20 TABS	588,000	14,400							14,400	1,025,280	
CAN		Dilaudid Tablets 4mg 100's - Bottles		21,120			30,000				51,120	18,788,760	
AUS		8MG x 20 TABS	269,500	17,350							17,350	2,470,640	
CAN		Dilaudid Tablets 8mg 100's - Bottles		16,830		16,500			16,500		51,830	36,902,960	
AUS		ORAL LIQUID 1MG/ML 473ML	6,000	6,000				6,000			12,000	5,051,640	
CAN		Dilaudid Oral Liquid 1mg/mL, 450mL	2,000		2,100				2,000		4,100	1,642,050	

total 81,341

5/30/2012 (b)(4) KANSAS

ITEM #	Description			Apr-12	May-12	Jun-12	Jul-12	Aug-12	Sep-12	Oct-12	Nov-12	Dec-12	Jan-13	Feb-13	Mar-13
(b)(4)	HYDROMORPHONE HCL USP	(b)(4)	KG	0.000	0.000	5.000	0.000	10.000	5.000	0.000	5.000	0.000	10.000	10.000	5.000
			PO #												

	2012 25 kgs	2013 25 kgs
Total	25 kgs	25 kgs
Grams Base	22.25	22.25

(b)(4)

5/1/2012

Hospira 2012 forecast for 5/30/12

8-6-12

CONFIDENTIAL

August 2, 2012

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

Subject: Docket No. DEA-363

Dear Sirs:

I, (b)(4);(b)(6), manufacturing registration (b)(4);(b)(7)(E) am submitting this comment on the 2012 Proposed Aggregate Production Quota for various products as published in the July 5, 2012 Federal Register. We consider the information in this first paragraph to be "PERSONAL IDENTIFYING INFORMATION" and this information should not be released under the Freedom of Information Act per 5 USC Sec. 552(b)(4). In addition, the following information is "CONFIDENTIAL BUSINESS INFORMATION". The following items' manufacturing quota should be increased by the identified quantity: (i) Alfentanil by 14,002 grams as base; (ii) Hydrocodone by 2,574,000 grams as base; (iii) Morphine (for Sale) by 500,000 grams as base; (iv) Oxycodone by 4,500,000 grams as base; and (v) Tapentadol by 150,000 grams as base. As noted herein, this first paragraph of this letter contains personal identifying and confidential business information and should be redacted in its entirety from any public docket.

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

Very truly yours

received
8-6-12

CONFIDENTIAL

August 2, 2012

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

Subject: Docket No. DEA-363

Dear Sirs:

I, (b)(4) , manufacturing registration (b)(4);(b)(7)(E) am submitting this comment on the 2012 Proposed Aggregate Production Quota for various products as published in the July 5, 2012 Federal Register. We consider the information in this first paragraph to be "PERSONAL IDENTIFYING INFORMATION" and this information should not be released under the Freedom of Information Act per 5 USC Sec. 552(b)(4). In addition, the following information is "CONFIDENTIAL BUSINESS INFORMATION". The following items' manufacturing quota should be increased by the identified quantity: (i) D,L-Amphetamine (for sale) by 1,080,000 grams as base; (ii) D-Amphetamine (for sale) by 920,000 grams as base; and (iii) Codeine (for conversion) by 12,601,282 grams as base. As noted herein, this first paragraph of this letter contains personal identifying and confidential business information and should be redacted in its entirety from any public docket.

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

Very truly yours

PUBLIC SUBMISSION

As of: August 10, 2012
Received: August 06, 2012
Status: Pending_Post
Tracking No. 810c37e4
Comments Due: August 06, 2012
Submission Type: Web

Docket: DEA-2012-0003
Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Comment On: DEA-2012-0003-0001
Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Document: DEA-2012-0003-DRAFT-0007
Comment on FR Doc # 2012-16396

Submitter Information

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

General Comment

See attached file(s)

The attached letter constitutes (b)(4) comment on the Proposed Revised Aggregate Production Quotas for 2012.

Attachments

(b)(4);(b)(7)(E) Docket No. DEA-363

(b)(4)

(b)(4)

August 6, 2012

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

Attn: DEA Federal Register Representative [Docket No. DEA-363]

This letter constitutes (b)(4) comments on the Proposed Revised Aggregate Production Quotas for 2012, as published in Federal Register on July 5, 2012, FR Volume 77, No. 129, pages 39737-39741.

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 Amphetamine (for Sale)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 240,000 grams AA of Amphetamine (for sale) manufacturing quota for 2012, reference DEA online submission number 113164.

9050 Codeine (for conversion)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 32,000,000 grams AA of Codeine (for conversion) manufacturing quota for 2012, reference DEA online submission number 113135.

9050 Codeine (for sale)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 18,000,000 grams AA of Codeine (for sale) manufacturing quota for 2012, reference DEA online submission number 113134.

9145 Dihydromorphine

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 2,200,000 grams AA of Dihydromorphine manufacturing quota for 2012, reference DEA online submission number 113123.

9193 Hydrocodone

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 28,000,000 grams AA of Hydrocodone manufacturing quota for 2012, reference DEA online submission number 113136.

9150 Hydromorphone

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 1,000,000 grams AA of Hydromorphone manufacturing quota for 2012, reference DEA online submission number 113124.

9254 Methadone Intermediate

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 11,800,000 grams AA of Methadone Intermediate manufacturing quota for 2012, reference DEA online submission 113021.

9300 Morphine (for Conversion)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 54,000,000 grams AA of Morphine (for Conversion) manufacturing quota for 2012, reference DEA online submission 113132.

9300 Morphine (for Sale)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 27,000,000 grams AA of Morphine (for Sale) manufacturing quota for 2012, reference DEA online submission 113074.

9668 Noroxymorphone (for Conversion)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 5,600,000 grams AA of Noroxymorphone (for Conversion) manufacturing quota for 2012, reference DEA online submission 113133.

9330 Oripavine

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 6,300,000 grams AA of Oripavine manufacturing quota for 2012, reference DEA online submission 113138.

9143 Oxycodone (for Conversion)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 8,000,000 grams AA of Oxycodone (For Conversion) manufacturing quota for 2012, reference DEA online submission 113140.

9652 Oxymorphone (for Sale)

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 4,000,000 grams AA of Oxymorphone (For Sale) manufacturing quota for 2012, reference DEA online submission 113141.

9740 Sufentanil

(b)(4) requests that the revised aggregate be sufficient to include (b)(4) request for 5,000,000 grams AA of Sufentanil manufacturing quota for 2012, reference DEA online submission 113022.

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

Sincerely,

(b)(6)

Supervisor, Controlled Substance Compliance

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

PUBLIC SUBMISSION

As of: August 06, 2012
Received: July 27, 2012
Status: Pending_Post
Tracking No. 810b3f6e
Comments Due: August 06, 2012
Submission Type: Web

Docket: DEA-2012-0003
Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Comment On: DEA-2012-0003-0001
Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012

Document: DEA-2012-0003-DRAFT-0005
Comment on FR Doc # 2012-16396

Submitter Information

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

General Comment

See attached file(s)

Attachments

(b)(4) 2012 APQ Comment

(b)(4)

(b)(4)

July 27, 2012

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

RE: Docket No. DEA-363
FR Doc No: 2012-16396 (b)(4) **Comments to Controlled Substances: Proposed Adjustment to the Aggregate Production Quotas for 2012**

(b)(4);(b)(7)(E) and (b)(4);(b)(7)(E) have previously submitted quota correspondence as set forth in the table below for the following manufacturing categories. (b)(4) requests that the correspondence provided to the Quota Unit, which constitutes "CONFIDENTIAL BUSINESS INFORMATION", be considered during the 2012 Aggregate Production Quota review.

Quota Category	Quota Application Ref. #	Material Name	Date of Correspondence	Action Needed
Manufacturing	113090 113091	Hydrocodone for Sale – 9193	July 26, 2012	An aggregate increase based on (b)(4) customer demand
Manufacturing	113092 113093 113094	Hydromorphone - 9150	July 26, 2012	An aggregate increase based on (b)(4) customer demand
Manufacturing	113102 113103	Morphine for Sale – 9300	July 26, 2012	An aggregate increase based on (b)(4) customer demand
Manufacturing	113084	Methylphenidate – 1724	July 25, 2012	An aggregate increase based on (b)(4) customer demand
Manufacturing	113098 113101	Oxycodone for Sale – 9143	July 26, 2012	An aggregate increase based on (b)(4) customer demand
Manufacturing	113099 113100	Oxymorphone for Conversion – 9652	July 26, 2012	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)(6).

Best regards,

(b)(6)

Director, Process Engineering and Controlled Substance Compliance

2012 Final Adjusted Aggregate Production Quotas

- Section 306(a) of the Controlled Substances Act (CSA) requires the Attorney General to establish the production amount of each schedule I and II controlled substance. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA).

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

- The attached Federal Register seeks to establish the final revised APQ for 2012. A table summarizing the APQ and the changes made to the proposed revised values are attached for reference.

- OD is recommending an increase in the APQ for **3,4-Methylenedioxypyrovalerone (MDPV), 3,4-Methylenedioxy-N-Methylcathinone (methylone), 4-Methyl-N-Methylcathinone (mephedrone), desomorphine, and levomethorphan.** The increase is based on newly registered bulk manufacturers for reference standards and exempt preparations.

- OD is recommending an increase in the APQ for **amphetamine (for conversion).** This increase is based on the conversion to lisdexamfetamine which was increased in the 2012 established APQ.

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

- OD is recommending a decrease in the APQ for **gamma-hydroxybutyric acid (GHB).** This decrease is a result of all manufacturers requesting material for validation efforts being granted the necessary quotas.

- OD is recommending an increase in the APQ for **hydrocodone (for sale).** This increase is due to an increase in sales; manufacturers requesting material for validation efforts per FDA's directive to lower acetaminophen concentrations in previously marketed products; as well, as new product development efforts for a single entity hydrocodone tablet.

- OD is recommending an increase in the APQ for **methadone and methadone intermediate.** The increase is based on increased sales of methadone based on registrant and ARCOS data and the conversion of methadone intermediate to methadone.

- OD is recommending an increase in the APQ for **methylphenidate.** The increase is due to increased domestic sales and export requirements as reported by registrants and verified by IMS data; validation efforts for new suppliers; new dosage form manufacturers product development efforts.

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

- OD is recommending an increase in the APQ for **oxycodone (for conversion).** This increase is based on the conversion to oxymorphone which was increased in the 2012 established APQ.

- OD is recommending an increase in the APQ for **oxycodone (for sale).** The increase is due to increased domestic sales and export requirements as reported by registrants and verified by IMS data; new dosage form manufacturers entering the market; validation efforts for new synthesis methodology.

- OD is recommending an increase in the APQ for **sufentanil.** The increase is due to validation efforts with large batch sizes relative to the initial APQ. All validation material will be saleable in 2013 and the 2013 APQ will be adjusted accordingly.