Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-378]

Established Aggregate Production Quotas for Schedule I and II Controlled Substances and Established Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2014

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

ACTION: Notice.

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

DATES: Effective: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

SUPPLEMENTARY INFORMATION:

Background

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

The 2014 aggregate production quotas and assessment of annual needs represent those quantities of Schedules I and II controlled substances and the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in the United States in 2014 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. These quotas include imports of ephedrine, pseudoephedrine, and phenylpropanolamine but do not include imports of controlled substances for use in industrial processes.

On July 3, 2013, a notice titled, "Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Proposed Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2014," was published in the Federal Register (78 FR 40186). That notice proposed the 2014 aggregate production quotas for each basic class of controlled substance listed in Schedules I and II and the 2014 assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before August 2, 2013.

Comments Received

DEA received seven comments from DEA-registered manufacturers within the published comment period on a total of 23 Schedule I and II controlled substances and one List I chemical. Commenters stated that the proposed aggregate production quotas for (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11), N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48), cathinone, amphetamine (for sale), codeine (for conversion), codeine (for sale), fentanyl, hydrocodone (for sale), hydromorphone, levomethorphan, methylphenidate, morphine (for conversion), morphine (for sale), noroxymorphone (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), phenylacetone, tapentadol, tetrahydrocannabinol, and thebaine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. One commenter stated that the proposed assessment of annual needs quota for phenylpropanolamine (for conversion) was insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

Determination of 2014 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2014 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors

set forth at 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the consideration of 2013 manufacturing quotas, current 2013 sales and inventories, 2014 export requirements, industrial use, additional applications for quotas, as well as information on research and product development requirements. Based on this information, the DEA has determined that adjustments to the proposed aggregate production quotas and assessment of annual needs for 1-[1-(2-Thienyl)cyclohexyl]piperidine, carfentanil, cathinone, dihydromorphine, dimethyltryptamine, ecgonine, hydromorphone, levomethorphan, lysergic acid diethylamide, metazocine, methamphetamine, d-methamphetamine (for conversion), methyldesorphine, noroxymorphone (for conversion), oxymorphone (for conversion), phencyclidine, phenylacetone, ephedrine (for conversion), ephedrine (for sale), phenylpropanolamine (for conversion), and pseudoephedrine (for sale) are warranted. This notice reflects those adjustments.

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

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

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

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

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

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

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

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

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

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

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

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

Dated: August 30, 2013.

Thomas M. Harrigan,
Deputy Administrator.

[FR Doc. 2013-21797 Filed 09/06/2013 at 8:45 am; Publication Date: 09/09/2013]