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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-393]

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

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

ACTION: Notice.

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

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

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

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the

"Controlled Substances Act" or the "CSA" for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

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

Background

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

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

Comments Received

Five comments were received from DEA-registered manufacturers within the published comment period, offering comments on a total of 32 schedule I and II controlled substances. None of the respondents commented on the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Commenters stated that the proposed aggregate production quotas for 1-(1,3-Benzodioxol-5-yl)-2-(methylamino) butan-1-one (butylone), 1-(1,3-Benzodioxol-5-yl)-2-(methylamino) pentan-1-one (pentylone), 2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe), 2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe), 2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe), 2-(Methylamino)-1-phenylpentan-1-one (pentedrone), 3-Fluoro-*N*-methylcathinone (3-FMC), 4-Fluoro-*N*-methylcathinone (4-FMC), 4-Anilino-*N*-phenethyl-4-piperidine (ANPP), 4-Methyl-*N*-ethylcathinone (4-MEC), 4-Methyl-*α*-pyrrolidinopropiophenone (4-MePPP), *alpha*-Pyrrolidinobutiophenone (α-PBP), *alpha*-

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

Determination of 2015 Aggregate Production Quotas and Assessment of Annual Needs

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

sale) are warranted. This notice reflects those adjustments.

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

As described in the previously published notice proposing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered

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

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

Basic Class	Established 2015 Quotas (g)
Schedule I	
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45
1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	15
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30

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

alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	15
alpha-Pyrrolidinopentiophenone (α-PVP)	15
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-*N*-oxide	305
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	125,000
Mescaline	25
Methaqualone	10
Methcathinone	25

Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-*N*-oxide	350
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	15
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	15
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	15
N,*N*-Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	15
N-Benzylpiperazine	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	18
Phenomorphan	2
Psilocybin	30
Psilocyn	30
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	15
Tetrahydrocannabinols	497,500
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
Schedule II	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	21,875,000
Amphetamine (for sale)	37,500,000

Carfentanil	19
Cocaine	275,000
Codeine (for conversion)	50,000,000
Codeine (for sale)	49,500,000
Dextropropoxyphene	19
Dihydrocodeine	226,375
Diphenoxylate	1,337,500
Ecgonine	174,375
Ethylmorphine	3
Fentanyl	2,150,000
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphacetylmethadol (LAAM)	4
Levomethorphan	5
Levorphanol	7,125
Lisdexamfetamine	29,750,000
Meperidine	6,250,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	83,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,750
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,475,000
Opium (powder)	112,500
Opium (tincture)	687,500
Oripavine	35,000,000
Oxycodone (for conversion)	8,350,000
Oxycodone (for sale)	137,500,000

Oxymorphone (for conversion)	29,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	9,375,000
Racemethorphan	3
Remifentanil	3,750
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	12,500,000
Thebaine	125,000,000
List I Chemicals	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	7,000
Pseudoephedrine (for sale)	224,500,000

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

Dated: September 2, 2014.

Thomas M. Harrigan,
Deputy Administrator.

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