Dated: July 1, 2015.

Robert W. Middleton,

Deputy Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2015–16675 Filed 7–7–15; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–418P]

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2015 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before August 7, 2015. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–418P'' on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority and Background

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

The DEA established the 2015 aggregate production quotas for substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on September 8, 2014 (79 FR 53216). That notice stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Analysis for Proposed Adjusted 2015 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2015 aggregate production quotas for certain schedule I and II controlled substances 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 do not include imports of controlled substances for use in industrial processes. The DEA is not proposing to adjust the established 2015 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported into 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.

In proposing the adjustment, the DEA has taken into account the criteria that the DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and assessment of annual needs for ephedrine, pseudoephedrine,

and phenylpropanolamine by considering: (1) Changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, and changes in the rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for the class; (2) whether any increased demand for that class or chemical, the national and/or individual rates of net disposal of that class or chemical are temporary, short term, or long term; (3) whether any increased demand for that class or chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota; (4) whether any decreased demand for that class or chemical will result in excessive inventory accumulation by all persons registered to handle that class or chemical; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Acting Administrator finds relevant.

The DEA also considered updated information obtained from 2014 year-end inventories, 2014 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to the DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed adjusted 2015 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 established assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

As previously described in the published notice establishing the 2015 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers, 21 CFR 1303.24, 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. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA has included in all proposed adjusted schedule II controlled substance aggregate production quotas, and certain proposed adjusted schedule I controlled substance aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting adjusted established aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

The Acting Administrator, therefore, proposes to adjust the 2015 aggregate production quotas for certain schedule I and II controlled substances expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Schedule I		
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR–144)	15	25
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15	25
[1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ–2201)	15	no change
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15	25
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15	25
1-(1-Phenylcyclohexyl)pyrrolidine	10	no change
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	no change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	no change
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200)	45	no change
1-Butyl-3-(1-naphthoyl)indole (JWH–073)	45	no change
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8)	45	no change
1-Hexyl-3-(1-naphthoyl)indole (JWH–019)	45	no change
1-Methyl-4-phenyl-4-propionoxypiperidine	2	no change
1-Pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678)	45	no change
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH–203)	45	no change
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250)	45	no change
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398)	45	no change
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122)	45	no change
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19, RCS–4)	45	no change
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081)	45	no change
2-(2,5-Dimethoxy-4-*n*-propylphenyl)ethanamine (2C–P)	30	no change
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30	no change
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30	no change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30	no change
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H)	30	no change
2-(4-Bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B–NBOMe; 2C–B–NBOMe; 25B; Cimbi-36).	15	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C)	30	no change

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C–NBOMe; 2C–C–NBOMe; 25C; Cimbi-82).	15	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I)	30	no change
2-(4-Iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I–NBOMe; 2C–I–NBOMe; 25I; Cimbi-5).	15	no change
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15	no change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change
2,5-Dimethoxy-4-*n*-propylthiophenethylamine	25	no change
2,5-Dimethoxyamphetamine	25	no change
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2)	30	no change
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4)	30	no change
3,4,5-Trimethoxyamphetamine	25	no change
3,4-Methylenedioxyamphetamine (MDA)	55	no change
3,4-Methylenedioxymethamphetamine (MDMA)	50	no change
3,4-Methylenedioxy-*N*-ethylamphetamine (MDEA)	40	no change
3,4-Methylenedioxy-*N*-methylcathinone (methylone)	50	no change
3,4-Methylenedioxypyrovalerone (MDPV)	35	no change
3-Fluoro-*N*-methylcathinone (3–FMC)	15	25
3-Methylfentanyl	2	no change
3-Methylthiofentanyl	2	no change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	no change
4-Bromo-2,5-dimethoxyphenethylamine (2–CB)	25	no change
4-Fluoro-*N*-methylcathinone (4–FMC)	15	25
4-Methoxyamphetamine	100	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-Methyl-*N*-ethylcathinone (4–MEC)	15	25
4-Methyl-*N*-methylcathinone (mephedrone)	45	no change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15	25
5-(1,1-Dimethylheptyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol	68	no change
5-(1,1-Dimethyloctyl)-2-[(1*R*,3*S*)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog).	53	no change
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change
5-Methoxy-*N,N*-diisopropyltryptamine	25	no change
5-Methoxy-*N,N*-dimethyltryptamine	25	no change
Acetyl-*alpha*-methylfentanyl	2	no change
Acetyldihydrocodeine	2	no change
Acetylmethadol	2	no change
Allylprodine	2	no change
Alphacetylmethadol	2	no change
alpha-Ethyltryptamine	25	no change
Alphameprodine	2	no change
Alphamethadol	2	no change
alpha-Methylfentanyl	2	no change
alpha-Methylthiofentanyl	2	no change
alpha-Methyltryptamine (AMT)	25	no change
alpha-Pyrrolidinobutiophenone (α-PBP)	15	25
alpha-Pyrrolidinopentiophenone (α-PVP)	15	25
Aminorex	25	no change
Benzylmorphine	2	no change
Betacetylmethadol	2	no change
beta-Hydroxy-3-methylfentanyl	2	no change
beta-Hydroxyfentanyl	2	no change
Betameprodine	2	no change
Betamethadol	4	no change
Betaprodine	2	no change
Bufotenine	3	no change
Cathinone	70	no change
Codeine methylbromide	5	no change
Codeine-*N*-oxide	305	no change
Desomorphine	5	25
Diethyltryptamine	25	no change
Difenoxin	11,000	no change
Dihydromorphine	3,990,000	no change
Dimethyltryptamine	35	no change
Dipipanone	5	no change
Fenethylline	5	no change
gamma-Hydroxybutyric acid	70,250,000	no change
Heroin	25	50
Hydromorphinol	2	no change

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Hydroxypethidine	2	no change
Ibogaine	5	no change
Lysergic acid diethylamide (LSD)	35	no change
Marihuana	658,000	no change
Mescaline	25	no change
Methaqualone	10	no change
Methcathinone	25	no change
Methyldesorphine	5	no change
Methyldihydromorphine	2	no change
Morphine methylbromide	5	no change
Morphine methylsulfonate	5	no change
Morphine-*N*-oxide	350	no change
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	15	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB–PINACA)	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB–FUBINACA).	15	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB–CHMINACA).	15	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB–PINACA)	15	no change
N,N-Dimethylamphetamine	25	no change
Naphthylpyrovalerone (naphyrone)	15	25
N-Benzylpiperazine	25	no change
N-Ethyl-1-phenylcyclohexylamine	5	no change
N-Ethylamphetamine	24	no change
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Noracymethadol	2	no change
Norlevorphanol	52	no change
Normethadone	2	no change
Normorphine	18	40
Para-fluorofentanyl	zero	5
Parahexyl	zero	5
Phenomorphan	2	no change
Pholcodine	zero	5
Psilocybin	30	no change
Psilocyn	30	no change
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB–22; 5F–PB–22)	15	25
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB–22; QUPIC)	15	25
Tetrahydrocannabinols	497,500	511,250
Thiofentanyl	2	no change
Tilidine	10	25
Trimeperidine	2	no change
Schedule II		
1-Phenylcyclohexylamine	5	no change
1-Piperidinocyclohexanecarbonitrile	5	no change
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500	no change
Alfentanil	17,750	no change
Alphaprodine	3	no change
Amobarbital	25,125	no change
Amphetamine (for conversion)	21,875,000	no change
Amphetamine (for sale)	37,500,000	no change
Carfentanil	19	no change
Cocaine	275,000	no change
Codeine (for conversion)	50,000,000	no change
Codeine (for sale)	49,500,000	63,900,000
Dextropropoxyphene	19	45
Dihydrocodeine	226,375	no change
Diphenoxylate (for conversion)	75,000	no change
Diphenoxylate (for sale)	1,337,500	no change
Ecgonine	174,375	no change
Ethylmorphine	3	no change
Fentanyl	2,150,000	2,300,000
Glutethimide	3	no change
Hydrocodone (for conversion)	137,500	no change
Hydrocodone (for sale)	99,625,000	no change
Hydromorphone	7,000,000	no change
Isomethadone	5	no change
Levo-alphacetylmethadol (LAAM)	4	no change
Levomethorphan	5	30
Levorphanol	7,125	no change

Basic class	Established 2015 Quotas (g)	Proposed Adjusted 2015 Quotas (g)
Lisdexamfetamine	29,750,000	no change
Meperidine	6,250,000	no change
Meperidine Intermediate-A	6	no change
Meperidine Intermediate-B	11	32
Meperidine Intermediate-C	6	no change
Metazocine	19	no change
Methadone (for sale)	31,875,000	no change
Methadone Intermediate	34,375,000	no change
Methamphetamine	2,061,375	no change
[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	87,500,000
Morphine (for conversion)	91,250,000	no change
Morphine (for sale)	62,500,000	no change
Nabilone	18,750	no change
Noroxymorphone (for conversion)	17,500,000	no change
Noroxymorphone (for sale)	1,475,000	no change
Opium (powder)	112,500	no change
Opium (tincture)	687,500	no change
Oripavine	35,000,000	no change
Oxycodone (for conversion)	8,350,000	no change
Oxycodone (for sale)	137,500,000	139,150,000
Oxymorphone (for conversion)	29,000,000	no change
Oxymorphone (for sale)	7,750,000	no change
Pentobarbital	35,000,000	no change
Phenazocine	6	no change
Phencyclidine	19	38
Phenmetrazine	3	no change
Phenylacetone	9,375,000	no change
Racemethorphan	3	no change
Remifentanil	3,750	4,200
Secobarbital	215,003	no change
Sufentanil	6,255	no change
Tapentadol	12,500,000	no change
Thebaine	125,000,000	no change
List I Chemicals		
Ephedrine (for conversion)	1,000,000	no change
Ephedrine (for sale)	4,000,000	no change
Phenylpropanolamine (for conversion)	44,800,000	no change
Phenylpropanolamine (for sale)	8,500,000	no change
Pseudoephedrine (for conversion)	7,000	no change
Pseudoephedrine (for sale)	224,500,000	no change

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

Comments

In accordance with 21 CFR 1303.13(c) and 1315.13(d), any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this notice, the Acting Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.13(c) and 1315.13(e). In the event the Acting Administrator decides to hold such a hearing, the Acting Administrator will publish a notice of the hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Acting Administrator will issue and publish in the **Federal Register** a final order establishing any adjustment of the 2015 aggregate production quota for each basic class of controlled substance and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.13(c) and 1315.13(f).

Dated: July 1, 2015.

Chuck Rosenberg,

Acting Administrator.

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