DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-378]

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

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

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2014 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-378" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov*. Paper comments that duplicate electronic submissions are

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

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

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

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

Legal Authority

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

The DEA published the established aggregate production quotas for schedule I and II controlled substances and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine for 2014 in the *Federal Register* (78 FR 55099) on September 9, 2013. That notice stipulated that, in accordance with 21

CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Analysis for Proposed Adjusted 2014 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2014 aggregate production quotas for certain schedule I and II controlled substances to be manufactured in the United States in 2014 to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes. The DEA also proposes to adjust the established 2014 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in and imported to the United States in 2014 to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks.

In proposing the adjustment, the DEA has taken into account the criteria that the DEA is required to consider in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The DEA determines whether to propose an adjustment of the aggregate production quotas for basic classes of schedule I and II controlled substances and assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine by considering: (1) changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, and changes in the rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for the class; (2) whether any

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

The DEA also considered updated information obtained from 2013 year-end inventories, 2013 disposition data submitted by quota applicants, estimates of the medical needs of the United States, product development, and other information made available to the DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the DEA considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information. In determining the proposed adjusted 2014 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 established assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

As described in the previously published notice establishing the 2014 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in

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

The Deputy Administrator, therefore, proposes to adjust the 2014 aggregate production quotas for certain schedule I and II controlled substances and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic Class	Previously Established 2014 Quotas (g)	Proposed Adjusted 2014 Quotas (g)
Schedule I		
(1-Pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15	No change
[1-(5-Fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15	No change
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15	No change
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15	No change
1-(1-Phenylcyclohexyl)pyrrolidine	10	No change
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45	No change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45	No change
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	No change
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45	No change
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45	No change
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45	No change
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45	No change
1-Methyl-4-phenyl-4-propionoxypiperidine	2	No change
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45	No change
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45	No change
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45	No change
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45	No change
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45	No change
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45	No change
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45	No change
2-(2,5-Dimethoxy-4-*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	No change

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	No change
2-(4-Chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15	No change
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30	No change
2-(4-Iodo-2,5-dimethoxyphenyl)-*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	No change
3-Methylfentanyl	2	No change
3-Methylthiofentanyl	2	No change
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25	No change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	No change
4-Fluoro-*N*-methylcathinone (4-FMC)	15	No change
4-Methoxyamphetamine	100	No change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	No change
4-Methylaminorex	25	No change
4-Methyl-*N*-ethylcathinone (4-MEC)	15	No change
4-Methyl-*N*-methylcathinone (mephedrone)	45	No change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	15	No change
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	No change
alpha-Pyrrolidinopentiophenone (α-PVP)	15	No change
Aminorex	25	No change
Benzylmorphine	2	No change
Betacetylmethadol	2	No change
beta-Hydroxy-3-methylfentanyl	2	No change
beta-Hydroxyfentanyl	2	No change
Betameprodine	2	No change
Betaprodine	2	No change
Bufotenine	3	No change
Cathinone	70	No change
Codeine methylbromide	5	No change
Codeine-*N*-oxide	200	No change
Desomorphine	5	No change
Diethyltryptamine	25	No change
Difenoxin	50	No change
Dihydromorphine	3,990,000	No change
Dimethyltryptamine	35	No change
Dipipanone	5	No change
Fenethylline	5	No change
gamma-Hydroxybutyric acid	70,250,000	No change
Heroin	25	No change
Hydromorphinol	2	No change
Hydroxypethidine	2	No change
Ibogaine	5	No change

Lysergic acid diethylamide (LSD)	35	No change
Marihuana	650,000	No change
Mescaline	25	No change
Methaqualone	10	No change
Methcathinone	25	No change
Methyldesorphine	2	No change
Methyldihydromorphine	2	No change
Morphine methylbromide	5	No change
Morphine methylsulfonate	5	No change
Morphine-*N*-oxide	175	No change
N-(1-Adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (AKB48)	15	No change
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA)	15	No change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA)	15	No change
N,*N*-Dimethylamphetamine	25	No change
Naphthylpyrovalerone (naphyrone)	15	No change
N-Benzylpiperazine	25	No change
N-Ethyl-1-phenylcyclohexylamine	5	No change
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	No change
para-Fluorofentanyl	2	No change
Parahexyl	5	No change
Phenomorphan	2	No change
Pholcodine	2	No change
Properidine	2	No change
Psilocybin	30	40
Psilocyn	30	50
Quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15	No change
Quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC)	15	No change
Tetrahydrocannabinols	491,000	No change

Thiofentanyl	2	No change
Tilidine	10	No change
Trimeperidine	2	No change
Schedule II		
1-Phenylcyclohexylamine	3	No change
1-Piperidinocyclohexanecarbonitrile	3	No change
4-Anilino-*N*-phenethyl-4-piperidine (ANPP)	2,687,500	No change
Alfentanil	17,625	No change
Alphaprodine	3	No change
Amobarbital	9	No change
Amphetamine (for conversion)	18,375,000	No change
Amphetamine (for sale)	49,000,000	No change
Carfentanil	19	No change
Cocaine	240,000	No change
Codeine (for conversion)	68,750,000	No change
Codeine (for sale)	46,125,000	No change
Dextropropoxyphene	19	No change
Dihydrocodeine	100,750	No change
Diphenoxylate	750,000	1,288,750
Ecgonine	144,000	174,375
Ethylmorphine	3	No change
Fentanyl	2,108,750	No change
Glutethimide	3	No change
Hydrocodone (for conversion)	0	137,500
Hydrocodone (for sale)	99,625,000	No change
Hydromorphone	6,750,000	No change
Isomethadone	5	No change
Levo-alphacetylmethadol (LAAM)	4	No change
Levomethorphan	195	No change
Levorphanol	2,000	4,625
Lisdexamfetamine	23,750,000	No change
Meperidine	6,250,000	No change
Meperidine Intermediate-A	6	No change
Meperidine Intermediate-B	11	No change
Meperidine Intermediate-C	6	No change
Metazocine	19	No change
Methadone (for sale)	31,875,000	No change
Methadone Intermediate	38,875,000	No change
Methamphetamine	2,811,375	No change

[1,250,000 grams of *levo*-desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]		
Methylphenidate	96,750,000	No change
Morphine (for conversion)	91,250,000	No change
Morphine (for sale)	62,500,000	No change
Nabilone	30,375	No change
Noroxymorphone (for conversion)	17,500,000	No change
Noroxymorphone (for sale)	1,262,500	No change
Opium (powder)	112,500	No change
Opium (tincture)	625,000	No change
Oripavine	22,750,000	27,625,000
Oxycodone (for conversion)	9,250,000	No change
Oxycodone (for sale)	149,375,000	No change
Oxymorphone (for conversion)	25,000,000	No change
Oxymorphone (for sale)	7,750,000	No change
Pentobarbital	35,000,000	No change
Phenazocine	6	No change
Phencyclidine	19	No change
Phenmetrazine	3	No change
Phenylacetone	67,000,000	45,750,000
Racemethorphan	3	No change
Remifentanil	3,750	5,875
Secobarbital	215,003	No change
Sufentanil	6,255	No change
Tapentadol	17,500,000	No change
Thebaine	145,000,000	No change
List I Chemicals		
Ephedrine (for conversion)	1,000,000	No change
Ephedrine (for sale)	3,000,000	No change
Phenylpropanolamine (for conversion)	44,800,000	No change
Phenylpropanolamine (for sale)	5,300,000	No change
Pseudoephedrine (for conversion)	5,000	No change
Pseudoephedrine (for sale)	192,000,000	224,500,000

The Deputy Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12

remain at zero. Pursuant to 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Deputy Administrator may adjust the 2014 aggregate production quotas and assessment of annual needs as needed**.**

Comments

Pursuant to 21 CFR 1303.11(c) and 1315.11(d), any interested person may submit written comments on or objections to these proposed determinations. Based on comments received in response to this notice, the Deputy Administrator may hold a public hearing on one or more issues raised. 21 CFR 1303.11(c) and 1515.11(e). In the event the Deputy Administrator decides to hold such a hearing, the Deputy Administrator will publish a notice of the hearing in the *Federal Register*. After consideration of any comments or objections, or after a hearing, if one is held, the Deputy Administrator will issue and publish in the *Federal Register* a final order establishing any adjustment of 2014 aggregate production quota for each basic class of controlled substance and established assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.11(c) and 1315.11(f).

Dated: June 4, 2014.

Thomas M. Harrigan,
Deputy Administrator.

BILLING CODE 4410-09-P

[FR Doc. 2014-13804 Filed 06/11/2014 at 8:45 am; Publication Date: 06/12/2014]