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 July 14, 2014. 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.

Basic class	Previously established 2014 quotas (g)	Proposed adjusted 2014 quotas (g)
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.

Basic class	Previously established 2014 quotas (g)	Proposed adjusted 2014 quotas (g)
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.

Basic class	Previously established 2014 quotas (g)	Proposed adjusted 2014 quotas (g)
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.

[FR Doc. 2014–13804 Filed 6–11–14; 8:45 am]

BILLING CODE 4410–09–P

OFFICE OF MANAGEMENT AND BUDGET

Fiscal Year 2014 Cost of Hospital and Medical Care Treatment Furnished by the Department of Defense Medical Treatment Facilities; Certain Rates Regarding Recovery From Tortiously Liable Third Persons

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice.

SUMMARY: By virtue of the authority vested in the President by Section 2(a) of Pub. B. 87–603 (76 Stat. 593; 42 U.S.C. 2652), and delegated to the Director of the Office of Management and Budget by the President through Executive Order No. 11541 of July 1, 1970, the rates referenced below are hereby established. These rates are for use in connection with the recovery from tortiously liable third persons for the cost of inpatient medical services furnished by military treatment facilities through the Department of Defense (DoD). The rates have been established in accordance with the requirements of OMB Circular A–25, requiring reimbursement of the full cost of all services provided. The *FY14 inpatient medical rates* referenced are effective upon publication of this notice in the **Federal Register** and will remain in effect until further notice. Previously published outpatient medical and dental, and cosmetic surgery rates remain in effect until further notice. Pharmacy rates are updated periodically. A full disclosure of the rates is posted on DoD's Uniform Business Office Web site: *http://www.tricare.mil/ocfo/mcfs/ubo/mhs_rates.cfm.*

Brian C. Deese,

Deputy Director.

[FR Doc. 2014–13687 Filed 6–11–14; 8:45 am]

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