Billing Code 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-443N]

Proposed 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 2017

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2017 aggregate production quotas for 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 DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in his sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the *Federal Register*. After consideration of any comments or objections, or

after a hearing, if one is held, the Administrator will publish in the *Federal Register* a final order establishing the 2017 aggregate production quotas for schedule I and II controlled substances, and an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-443N" 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/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 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. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) 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 confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that

comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

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

Legal Authority

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 the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

Analysis for Proposed 2017 Aggregate Production Quotas and Assessment of Annual Needs

The proposed year 2017 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 2017 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.

In determining the proposed 2017 aggregate production quotas and assessment of

annual needs, the Acting Administrator has taken into account the criteria pursuant to 21 U.S.C. 826(a) and in accordance with 21 CFR 1303.11 (aggregate production quotas for controlled substances) and 21 CFR 1315.11 (assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The DEA proposes the aggregate production quotas and assessment of annual needs for 2017 by considering: (1) total net disposal of each class or chemical by all manufacturers and chemical importers during the current and two preceding years; (2) trends in the national rate of net disposal of the class or chemical; (3) total actual (or estimated) inventories of the class or chemical and of all substances manufactured from the class or chemical, and trends in inventory accumulation; (4) projected demand for each class or chemical as indicated by procurement and import quotas requested in accordance with 21 CFR 1303.12, 1315.32, and 1315.34; and (5) other factors affecting medical, scientific, research, and industrial needs of the United States and lawful export requirements, as the Acting Administrator finds relevant. These quotas do not include imports of controlled substances for use in industrial processes.

Other factors the Acting Administrator 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 2017 assessment of annual needs, the DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

During the calendar years 2013–2016, the DEA included an additional 25% of the estimated medical, scientific, and research needs for the United States as part of the amount necessary to ensure the establishment and maintenance of reserve stocks for all schedule II aggregate production quotas, and certain schedule I aggregate production quotas (difenoxin, gamma-hydroxybutyric acid, and tetrahydrocannabinols). Based on interagency discussions beginning in November 2015, and after reviewing all relevant quota applications received, published FDA drug shortage lists, and subsequent reports required under 21 U.S.C. 826a for those calendar years, the Acting Administrator has determined that inclusion of the additional 25% of the estimated medical, scientific, and research needs for the United States is unnecessary. Instead, the Acting Administrator determined that 21 U.S.C. 826(c) and 21 U.S.C. 952(a)(2)(A) provide sufficient ability for the DEA to mitigate adverse public effects should a natural disaster or other unforeseen event result in substantial disruption to the amount of controlled substances available for legitimate public need. As such, DEA proposes to remove the additional 25% from the aggregate production quotas. The resulting proposed established aggregate production quotas reflect these reduced amounts.

The Acting Administrator, therefore, proposes to establish the 2017 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	Proposed 2017 Quotas (g)
Schedule I	
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	35
1-Benzylpiperazine	25
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)	35
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	30
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	30
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	30
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	30
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	30
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	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-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	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)	25
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)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine	5

(25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	
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)	40
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-FMC; Flephedrone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40
5-Fluoro-UR144, XLR11	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
AB-PINACA	15
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2

AH-7921	30
Allylprodine	2
alpha-Ethyltryptamine	25
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Alphacetylmethadol	2
Alphameprodine	2
Alphamethadol	2
Aminorex	25
APINCA, AKB48	25
Benzylmorphine	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
beta-Hydroxythiofentanyl	30
Betacetylmethadol	2
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Butylone	25
Butyryl fentanyl	30
Cathinone	24
Codeine methylbromide	5
Codeine-N-oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	8,750
Dihydromorphine	1,566,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylline	5
gamma-Hydroxybutyric acid	56,200,000

Heroin	25
Hydromorphinol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	10
Marihuana	472,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
N,N-Dimethylamphetamine	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Naphyrone	25
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Pentedrone	25
Pentylone	25
Phenomorphan	2
Pholcodine	5

Psilocybin	30
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	20
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	20
Tetrahydrocannabinols	409,000
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
UR-144	25
Schedule II	
1-Phenylcyclohexylamine	4
1-Piperidinocyclohexanecarbonitrile	4
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,000,000
Alfentanil	4,200
Alphaprodine	2
Amobarbital	20,100
Amphetamine (for conversion)	9,000,000
Amphetamine (for sale)	37,500,000
Carfentanil	10
Cocaine	94,000
Codeine (for conversion)	40,000,000
Codeine (for sale)	45,000,000
Dextropropoxyphene	15
Dihydrocodeine	81,100
Dihydroetorphine	2
Diphenoxylate (for conversion)	15,000
Diphenoxylate (for sale)	820,000
Ecgonine	90,000
Ethylmorphine	2
Etorphine hydrochloride	2
Fentanyl	1,750,000
Glutethimide	2
Hydrocodone (for conversion)	122,000
Hydrocodone (for sale)	58,410,000

Hydromorphone	4,300,000
Isomethadone	4
Levo-alphacetylmethadol (LAAM)	3
Levomethorphan	10
Levorphanol	4,900
Lisdexamfetamine	19,000,000
Meperidine	3,706,000
Meperidine Intermediate-A	5
Meperidine Intermediate-B	9
Meperidine Intermediate-C	5
Metazocine	15
Methadone (for sale)	23,700,000
Methadone Intermediate	25,600,000
Methamphetamine	1,539,100
[900,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 600,000 grams for methamphetamine mostly for conversion to a schedule III product; and 39,100 grams for methamphetamine (for sale)]	
Methylphenidate	73,000,000
Morphine (for conversion)	27,300,000
Morphine (for sale)	41,000,000
Nabilone	15,000
Noroxymorphone (for conversion)	17,700,000
Noroxymorphone (for sale)	400,000
Opium (powder)	90,000
Opium (tincture)	300,000
Oripavine	20,000,000
Oxycodone (for conversion)	2,610,000
Oxycodone (for sale)	108,510,000
Oxymorphone (for conversion)	22,300,000
Oxymorphone (for sale)	4,200,000
Pentobarbital	27,500,000
Phenazocine	5
Phencyclidine	20
Phenmetrazine	2
Phenylacetone	20
Racemethorphan	2

Racemorphan	2
Remifentanil	3,000
Secobarbital	172,002
Sufentanil	4,000
Tapentadol	21,000,000
Thebaine	100,000,000
List I Chemicals	
Ephedrine (for conversion)	50,000
Ephedrine (for sale)	4,100,000
Phenylpropanolamine (for conversion)	15,000,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for sale)	200,000,000

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 adjust the 2017 aggregate production quotas and assessment of annual needs as needed.

Conclusion

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 the 2017 aggregate production quota for controlled substances in schedules I and II and establishing an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, 21 CFR 1303.11(c) and 1315.11(f).

Dated: July 14, 2016.

Chuck Rosenberg,
Acting Administrator.
[FR Doc. 2016-17370 Filed: 7/21/2016 8:45 am; Publication Date: 7/22/2016]