



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-420P]

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 2016

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to adjust the 2016 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 1303.13(c) and 1315.13(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 2016 adjusted 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-420P” 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 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette 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 and Background

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.

The DEA established the 2016 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 October 6, 2015 (80 FR 60400). 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 2016 Aggregate Production Quotas and Assessment of Annual Needs

The DEA proposes to adjust the established 2016 aggregate production quotas and assessment of annual needs for certain schedule I and II controlled substances, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured in the United States in 2016 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.

In determining the proposed adjustment, the Acting Administrator has taken into account the criteria in accordance with 21 CFR 1303.13 (adjustment of aggregate production quotas for controlled substances) and 21 CFR 1315.13 (adjustment of the assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The DEA determined whether to propose an adjustment of the aggregate production quotas and assessment of annual needs for 2016 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. These quotas do not include imports of controlled substances for use in industrial processes.

The Acting Administrator also considered updated information obtained from 2015 year-end inventories, 2015 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 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 adjusted 2016 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 2016 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 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 Acting Administrator, therefore, proposes that the year 2016 aggregate production quotas for the two temporarily scheduled substances be established, and to adjust the 2016 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	Established 2016 Quotas	Proposed Revised 2016 Quotas
	(g)	(g)
Temporarily Scheduled Substances		
<i>beta</i> -Hydroxythiofentanyl	N/A	30
Butyryl fentanyl	N/A	30
Schedule I		
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	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-	45	no change

200)		
1-Benzylpiperazine	25	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-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-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	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)	25	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)	25	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
2,5-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-Methylenedioxyamphetamine (MDMA)	50	no change
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	no change
3,4-Methylenedioxy-N-methylcathinone (methylone)	50	no change
3,4-Methylenedioxypropylone (MDPV)	35	no change

3-FMC; 3-Fluoro-N-methylcathinone	25	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-FMC; Flephedrone	25	no change
4-Methoxyamphetamine	150	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-MEC; 4-Methyl-N-ethylcathinone	25	no change
4-Methyl-N-methylcathinone (mephedrone)	45	no change
4-Methyl- α -pyrrolidinopropiophenone (4-MePPP)	25	no change
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53	40
5-Fluoro-UR144, XLR11	25	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
AB-PINACA	15	no change
Acetyl- α -methylfentanyl	2	no change
Acetyldihydrocodeine	2	no change
Acetylmethadol	2	no change
AH-7921	N/A	30
Allylprodine	2	no change
α -Ethyltryptamine	25	no change
α -Methylfentanyl	2	no change
α -Methylthiofentanyl	2	no change
α -Methyltryptamine (AMT)	25	no change
α -Pyrrolidinobutiophenone (α -PBP)	25	no change
α -Pyrrolidinopentiophenone (α -PVP)	25	no change
Alphacetylmethadol	2	no change
Alphameprodine	2	no change
Alphamethadol	2	no change
Aminorex	25	no change
APINCA, AKB48	25	no change
Benzylmorphine	2	no change
β -Hydroxy-3-methylfentanyl	2	no change
β -Hydroxyfentanyl	2	no change
Betacetylmethadol	2	no change
Betameprodine	2	no change

Betamethadol	4	no change
Betaprodine	2	no change
Bufotenine	3	no change
Butylone	25	no change
Cathinone	70	30
Codeine methylbromide	5	no change
Codeine-N-oxide	305	no change
Desomorphine	25	no change
Diethyltryptamine	25	no change
Difenoxin	11,000	no change
Dihydromorphine	3,000,000	2,000,000
Dimethyltryptamine	35	no change
Dipipanone	5	no change
Fenethylamine	5	no change
<i>gamma</i> -Hydroxybutyric acid	70,250,000	no change
Heroin	50	no change
Hydromorphanol	2	no change
Hydroxypethidine	2	no change
Ibogaine	5	no change
Lysergic acid diethylamide (LSD)	40	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,N-Dimethylamphetamine	25	no change
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	50	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	50	no change
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15	no change
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100	no change
N-Ethyl-1-phenylcyclohexylamine	5	no change
N-Ethylamphetamine	24	no change

N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Naphyrone	25	no change
Noracymethadol	2	no change
Norlevorphanol	52	no change
Normethadone	2	no change
Normorphine	40	no change
Para-fluorofentanyl	5	no change
Parahexyl	5	no change
Pentedrone	25	no change
Pentylone	25	no change
Phenomorphan	2	no change
Pholcodine	5	no change
Psilocybin	30	no change
Psilocyn	50	no change
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	50	25
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	50	25
Tetrahydrocannabinols	511,250	no change
Thiofentanyl	2	no change
Tilidine	25	no change
Trimeperidine	2	no change
UR-144	25	no change
Schedule II		
1-Phenylcyclohexylamine	5	no change
1-Piperidinocyclohexanecarbonitrile	5	no change
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,950,000	2,250,000
Alfentanil	17,750	no change
Alphaprodine	3	no change
Amobarbital	25,125	no change
Amphetamine (for conversion)	15,000,000	no change
Amphetamine (for sale)	39,705,000	45,000,000
Carfentanil	19	no change
Cocaine	200,000	no change
Codeine (for conversion)	50,000,000	no change
Codeine (for sale)	63,900,000	no change
Dextropropoxyphene	19	no change
Dihydrocodeine	226,375	no change
Dihydroetorphine	3	no change
Diphenoxylate (for conversion)	31,250	18,750
Diphenoxylate (for sale)	1,337,500	no change
Ecgonine	125,000	no change

Ethylmorphine	3	5
Etorphine hydrochloride	3	no change
Fentanyl	2,300,000	no change
Glutethimide	3	no change
Hydrocodone (for conversion)	235,000	177,500
Hydrocodone (for sale)	88,500,000	86,000,000
Hydromorphone	8,250,000	7,000,000
Isomethadone	5	no change
Levo-alphaacetylmethadol (LAAM)	4	no change
Levomethorphan	30	33
Levorphanol	7,125	no change
Lisdexamfetamine	29,750,000	23,750,000
Meperidine	5,450,000	4,632,500
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	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	96,750,000	84,375,000
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	625,000
Opium (powder)	112,500	no change
Opium (tincture)	687,500	375,000
Oripavine	30,000,000	no change
Oxycodone (for conversion)	6,250,000	5,000,000
Oxycodone (for sale)	139,150,000	no change
Oxymorphone (for conversion)	29,000,000	25,000,000
Oxymorphone (for sale)	7,750,000	6,250,000
Pentobarbital	38,125,000	no change
Phenazocine	6	no change
Phencyclidine	50	no change
Phenmetrazine	3	no change
Phenylacetone	50	no change
Racemethorphan	3	5

Racemorphan	3	no change
Remifentanil	3,750	no change
Secobarbital	215,003	no change
Sufentanil	6,255	no change
Tapentadol	25,500,000	no change
Thebaine	125,000,000	no change
List I Chemicals		
Ephedrine (for conversion)	100,000	50,000
Ephedrine (for sale)	4,000,000	no change
Phenylpropanolamine (for conversion)	22,400,000	15,000,000
Phenylpropanolamine (for sale)	8,500,000	no change
Pseudoephedrine (for conversion)	7,000	40
Pseudoephedrine (for sale)	224,500,000	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 2016 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 any adjustment of 2016 aggregate production quota for each basic class of controlled substances in schedules I and II 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 14, 2016.

Chuck Rosenberg,
Acting Administrator.

[FR Doc. 2016-17371 Filed: 7/21/2016 8:45 am; Publication Date: 7/22/2016]