

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-488P]

**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 2019**

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2019 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 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 2019 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-488P” 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/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Thomas D. Sonnen, Diversion Control Division, 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

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 2019 Aggregate Production Quotas and Assessment of Annual Needs

The proposed year 2019 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 2019 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 2019 aggregate production quotas and assessment of

annual needs, the Acting Administrator has taken into account the criteria in 21 U.S.C. 826(a) and factors set forth in 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 2019 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 2019 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).

On July 16, 2018, DEA published a final rule regarding controlled substances quotas

with an effective date of August 15, 2018 (“Controlled Substances Quotas Final Rule”). 83 FR 32784. The Controlled Substances Quotas Final Rule added two factors for DEA to consider when setting aggregate production quotas and assessments of annual needs. These additional factors are: (1) the extent of any diversion of the controlled substance in the class; and (2) relevant information obtained from the Department of Health and Human Services, including from the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Centers for Medicare and Medicaid Services, and relevant information obtained from the states. The proposed aggregate quotas for 2019 in this notice were determined with consideration of the factors in effect prior to the effective date of the Controlled Substances Quotas Final Rule.

The Acting Administrator, therefore, proposes to establish the 2019 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 2019 Quotas
	(g)
Schedule I	
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	15
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
1-[1-(2-Thienyl)cyclohexyl]piperidine	15

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)	30
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 (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30
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	30
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-Methylenedioxypropylvalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboximide	25
4-Fluoroisobutyryl fentanyl	30
4-FMC; Flephedrone	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	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
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboximide	25
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	30
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	30
5-Fluoro-PB-22; 5F-PB-22	20
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetyl Fentanyl	100
Acetyl- <i>alpha</i> -methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	2
Acryl Fentanyl	25
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH-7921	30
Allylprodine	2
Alphacetylmethadol	2
<i>alpha</i> -Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
<i>alpha</i> -Methylfentanyl	30
<i>alpha</i> -Methylthiofentanyl	30
<i>alpha</i> -Methyltryptamine (AMT)	25
<i>alpha</i> -Pyrrolidinobutiophenone (α -PBP)	25
<i>alpha</i> -Pyrrolidinopentiophenone (α -PVP)	25
Aminorex	25
Anileridine	20
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-	25

carboxamide)	
Benzylmorphine	30
Betacetylmethadol	2
<i>beta</i> -Hydroxy-3-methylfentanyl	30
<i>beta</i> -Hydroxyfentanyl	30
<i>beta</i> -Hydroxythiofentanyl	30
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Butylone	25
Butyryl fentanyl	30
Cathinone	24
Codeine methylbromide	30
Codeine-N-oxide	192
Cyclopropyl Fentanyl	20
Desomorphine	25
Diapromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	8,225
Dihydromorphine	753,500
Dimethyltryptamine	50
Dipipanone	5
Etorphine	30
Fenethylline	30
Fentanyl related substances	25
Furanyl fentanyl	30
<i>gamma</i> -Hydroxybutyric acid	33,417,000
Heroin	45
Hydromorphenol	40
Hydroxypethidine	2
Ibogaine	30
Isobutyryl Fentanyl	25
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30

JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Lysergic acid diethylamide (LSD)	40
MAB-CHMINACA; ADB-CHMINACA (<i>N</i> -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1 <i>H</i> -indazole-3-carboxamide)	30
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
Methyl-2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3-methylbutanoate	25
Marihuana	2,450,000
Mecloqualone	30
Mescaline	25
Methaqualone	60
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
Naphthalen-1-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate	25
<i>N,N</i> -Dimethylamphetamine	25
Naphyrone	25
<i>N</i> -Ethyl-1-phenylcyclohexylamine	5
<i>N</i> -Ethyl-3-piperidyl benzilate	10
<i>N</i> -Ethylamphetamine	24
<i>N</i> -Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	55
Normethadone	2
Normorphine	40
Ocfentanil	25
Para-fluorofentanyl	25
Para-flourobutyryl fentanyl	25
Parahexyl	5
PB-22; QUPIC	20
Pentdrone	25
Pentylone	25
Phenomorphan	2
Pholcodine	5

Psilocybin	30
Psilocyn	50
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30
Tetrahydrocannabinols	384,460
Tetrahydrofuranlyl fentanyl	5
Thiofentanyl	25
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	2
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
U-47700	30
Valeryl fentanyl	25
Schedule II	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,185,000
Alfentanil	6,200
Alphaprodine	2
Amobarbital	20,100
Amphetamine (for conversion)	12,000,000
Amphetamine (for sale)	42,400,000
Carfentanil	20
Cocaine	92,120
Codeine (for conversion)	13,536,000
Codeine (for sale)	40,015,800
Dextropropoxyphene	35
Dihydrocodeine	238,466
Dihydroetorphine	2
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	88,134
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	1,185,000
Glutethimide	2
Hydrocodone (for conversion)	5,000
Hydrocodone (for sale)	44,710,000
Hydromorphone	4,071,000

Isomethadone	30
Levo-alphaacetylmethadol (LAAM)	5
Levomethorphan	4,000
Levorphanol	34,000
Lisdexamfetamine	19,000,000
Meperidine	1,580,000
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	22,278,000
Methadone Intermediate	24,064,000
Methamphetamine	1,446,754
[846,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 564,000 grams for methamphetamine mostly for conversion to a schedule III product; and 36,754 grams for methamphetamine (for sale)]	
Methylphenidate	64,600,000
Morphine (for conversion)	4,089,000
Morphine (for sale)	31,456,000
Nabilone	62,000
Noroxymorphone (for conversion)	19,169,340
Noroxymorphone (for sale)	376,000
Opium (powder)	84,600
Opium (tincture)	530,837
Oripavine	28,705,000
Oxycodone (for conversion)	2,081,000
Oxycodone (for sale)	85,578,000
Oxymorphone (for conversion)	24,525,540
Oxymorphone (for sale)	2,880,000
Pentobarbital	25,850,000
Phenazocine	5
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	1,880
Tapentadol	18,388,280
Thebaine	84,600,000
List I Chemicals	

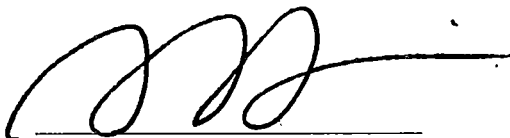
Ephedrine (for conversion)	25
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,100,000
Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	174,246,000

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 2019 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 2019 aggregate production quotas 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: August 14, 2018



Uttam Dhillon,
Acting Administrator.