



**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-471P]**

**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 2018**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice with request for comments.

**SUMMARY:** The Drug Enforcement Administration (DEA) proposes to adjust the 2018 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 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 2018 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-471P” 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 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 2018 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 November 8, 2017 (82 FR 51873). 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 2018 Aggregate Production Quotas and Assessment of Annual Needs**

The DEA proposes to adjust the established 2018 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 2018 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 2018 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 2017 year-end inventories, 2017 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 2018 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).

The Acting Administrator, therefore, proposes to adjust the 2018 aggregate production quotas for certain schedule I and II controlled substances and the 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 2018 Quotas	Proposed Revised 2018 Quotas
	(g)	(g)
<b>Temporarily Scheduled Substances</b>		
1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboximide	N/A	25
1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3carboximide	N/A	25
Cyclopropyl Fentanyl	N/A	20
Fentanyl related substances	N/A	25
Isobutyryl Fentanyl	N/A	25
Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	N/A	25
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	N/A	25
Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate	N/A	25
Ocfentanil	N/A	25
Para-flourobutyryl fentanyl	N/A	25

Tetrahydrofuranyl fentanyl	N/A	5
Valeryl fentanyl	N/A	25
<b>Schedule I</b>		
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	Zero	20
1-(1-Phenylcyclohexyl)pyrrolidine	10	15
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	zero	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30	no change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30	no change
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change
1-Benzylpiperazine	25	no change
1-Methyl-4-phenyl-4-propionoxypiperidine	2	10
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)	30	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)	30	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	30	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)	40	no change
3,4-Methylenedioxypropyrovaleone (MDPV)	35	no change
3-FMC; 3-Fluoro-N-methylcathinone	25	no change
3-Methylfentanyl	30	no change
3-Methylthiofentanyl	30	no change

4-Bromo-2,5-dimethoxyamphetamine (DOB)	30	no change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	no change
4-Fluoroisobutyryl fentanyl	30	no change
4-FMC; Flephedrone	25	no change
4-MEC; 4-Methyl-N-ethylcathinone	25	no change
4-Methoxyamphetamine	150	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-Methyl-N-methylcathinone (mephedrone)	45	no change
4-Methyl- $\alpha$ -pyrrolidinopropiophenone (4-MePPP)	25	no change
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50	no change
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40	no change
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	30	no change
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	30	no change
5-Fluoro-PB-22; 5F-PB-22	20	no change
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	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-CHMINACA	30	no change
AB-FUBINACA	50	no change
AB-PINACA	30	no change
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30	no change
Acetyl Fentanyl	100	no change
Acetyl- $\alpha$ -methylfentanyl	30	no change
Acetyldihydrocodeine	30	no change
Acetylmethadol	2	no change
Acryl Fentanyl	25	no change
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50	no change
AH-7921	30	no change
Allylprodine	2	no change
Alphacetylmethadol	2	no change



<i>alpha</i> -Ethyltryptamine	25	no change
Alphameprodine	2	no change
Alphamethadol	2	no change
<i>alpha</i> -Methylfentanyl	30	no change
<i>alpha</i> -Methylthiofentanyl	30	no change
<i>alpha</i> -Methyltryptamine (AMT)	25	no change
<i>alpha</i> -Pyrrolidinobutiophenone ( $\alpha$ -PBP)	25	no change
<i>alpha</i> -Pyrrolidinopentiophenone ( $\alpha$ -PVP)	25	no change
Aminorex	25	no change
APINCA, AKB48 ( <i>N</i> -(1-adamantyl)-1-pentyl-1 <i>H</i> -indazole-3-carboxamide)	25	no change
Benzylmorphine	30	no change
Betacetylmethadol	2	no change
<i>beta</i> -Hydroxy-3-methylfentanyl	30	no change
<i>beta</i> -Hydroxyfentanyl	30	no change
<i>beta</i> -Hydroxythiofentanyl	30	no change
Betameprodine	2	no change
Betamethadol	4	no change
Betaprodine	2	no change
Bufotenine	3	no change
Butylone	25	no change
Butyryl fentanyl	30	no change
Cathinone	24	no change
Codeine methylbromide	30	no change
Codeine-N-oxide	192	no change
Desomorphine	25	no change
Diapromide	Zero	20
Diethylthiambutene	Zero	20
Diethyltryptamine	25	no change
Difenoxin	8,225	no change
Dihydromorphine	1,000,160	no change
Dimethyltryptamine	35	50
Dipipanone	5	no change
Etorphine	30	no change
Fenethylline	30	no change
Furanyl fentanyl	30	no change
<i>gamma</i> -Hydroxybutyric acid	37,130,000	no change
Heroin	45	no change
Hydromorphanol	40	no change
Hydroxypethidine	2	no change
Ibogaine	30	no change

JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35	no change
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45	no change
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45	no change
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30	no change
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30	no change
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35	no change
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30	no change
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30	no change
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30	no change
Lysergic acid diethylamide (LSD)	40	no change
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	no change
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1 <i>H</i> -indole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1 <i>H</i> -indazole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change
Marihuana	443,680	1,140,216
Mecloqualone	30	no change
Mescaline	25	no change
Methaqualone	60	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- <i>N</i> -oxide	150	no change
<i>N,N</i> -Dimethylamphetamine	25	no change
Naphyrone	25	no change
<i>N</i> -Ethyl-1-phenylcyclohexylamine	5	no change
<i>N</i> -Ethyl-3-piperidyl benzilate	Zero	10
<i>N</i> -Ethylamphetamine	24	no change
<i>N</i> -Hydroxy-3,4-methylenedioxyamphetamine	24	no change
Noracymethadol	2	no change
Norlevorphanol	55	no change
Normethadone	2	no change
Normorphine	40	no change
Para-fluorofentanyl	25	no change
Parahexyl	5	no change
PB-22; QUPIC	20	no change

Pentadrone	25	no change
Pentylone	25	no change
Phenomorphin	2	no change
Pholcodine	5	no change
Psilocybin	30	no change
Psilocyn	50	no change
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45	no change
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30	no change
Tetrahydrocannabinols	384,460	no change
Thiofentanyl	25	no change
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30	no change
Tilidine	25	no change
Trimeperidine	2	no change
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25	no change
U-47700	30	no change
<b>Schedule II</b>		
1-Phenylcyclohexylamine	4	15
1-Piperidinocyclohexanecarbonitrile	4	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,342,320	no change
Alfentanil	6,200	no change
Alphaprodine	2	no change
Amobarbital	20,100	no change
Amphetamine (for conversion)	11,280,000	12,700,000
Amphetamine (for sale)	39,856,000	no change
Anileridine	Zero	20
Carfentanil	20	no change
Cocaine	92,120	no change
Codeine (for conversion)	15,040,000	12,900,000
Codeine (for sale)	40,015,000	no change
Dextropropoxyphene	35	no change
Dihydrocodeine	264,140	no change
Dihydroetorphine	2	no change
Diphenoxylate (for conversion)	14,100	no change
Diphenoxylate (for sale)	770,800	no change
Ecgonine	88,134	no change
Ethylmorphine	30	no change
Etorphine hydrochloride	32	no change
Fentanyl	1,342,320	no change

Glutethimide	2	no change
Hydrocodone (for conversion)	114,680	no change
Hydrocodone (for sale)	50,348,280	44,710,000
Hydromorphone	4,547,720	no change
Isomethadone	30	no change
Levo-alphaacetylmethadol (LAAM)	5	no change
Levomethorphan	30	2,200
Levorphanol	12,126	38,000
Lisdexamfetamine	17,869,000	19,000,000
Meperidine	2,717,540	1,913,148
Meperidine Intermediate-A	5	30
Meperidine Intermediate-B	30	no change
Meperidine Intermediate-C	5	30
Metazocine	15	no change
Methadone (for sale)	22,278,000	no change
Methadone Intermediate	24,064,000	no change
Methamphetamine	1,446,754	no change
[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	no change
Morphine (for conversion)	4,089,000	no change
Morphine (for sale)	33,958,440	31,456,000
Nabilone	31,000	62,000
Noroxymorphone (for conversion)	14,044,540	16,440,000
Noroxymorphone (for sale)	376,000	no change
Opium (powder)	84,600	no change
Opium (tincture)	564,000	no change
Oripavine	24,534,000	no change
Oxycodone (for conversion)	2,453,400	no change
Oxycodone (for sale)	95,692,000	85,578,000
Oxymorphone (for conversion)	20,962,000	no change
Oxymorphone (for sale)	3,395,280	3,137,240
Pentobarbital	25,850,000	no change
Phenazocine	5	no change
Phencyclidine	35	no change
Phenmetrazine	25	no change
Phenylacetone	40	no change
Racemethorphan	5	no change
Racemorphan	5	no change
Remifentanyl	2,820	3,000
Secobarbital	161,682	172,100

Sufentanil	1,880	no change
Tapentadol	18,388,280	no change
Thebaine	94,000,000	86,200,000
<b>List I Chemicals</b>		
Ephedrine (for conversion)	47,000	no change
Ephedrine (for sale)	4,136,000	no change
Phenylpropanolamine (for conversion)	14,100,000	no change
Phenylpropanolamine (for sale)	7,990,000	no change
Pseudoephedrine (for conversion)	40	1,000
Pseudoephedrine (for sale)	180,000,000	no change

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 2018 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 2018 aggregate production quotas 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: August 17, 2018

Uttam Dhillon,  
*Acting Administrator.*

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