



**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-443F]**

**Established 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:** Final order.

**SUMMARY:** This final order establishes the initial 2017 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**DATES:** Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:**

**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.

## **Background**

The 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 that may 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.

On July 22, 2016, a notice titled “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” was published in the *Federal Register*. 81 FR 47821. This notice proposed the 2017 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2017 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before August 22, 2016.

## **Comments Received**

Thirteen comments were received from five DEA-registered manufacturers and four non-DEA registered entities within the published comment period regarding 22 different

schedule I and II controlled substances. The DEA received two comments from two non-DEA registered entities within the published comment period regarding the proposed assessment of annual needs for the list I chemical ephedrine (for sale). Commenters stated that the proposed aggregate production quotas for acetyl fentanyl, AH-7921, amphetamine (for conversion), amphetamine (for sale), beta-hydroxythiofentanyl, butyryl fentanyl, cocaine, codeine (for conversion), codeine (for sale), dihydrocodeine, ecgonine, hydrocodone (for sale), hydromorphone, levorphanol, lisdexamfetamine, marihuana, meperidine, methylphenidate, nabilone, opium tincture, oxycodone (for sale), and sufentanil, as well as, the proposed assessment of annual needs for ephedrine (for sale) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

The DEA received one comment from a DEA-registrant and three comments by non-DEA registered entities regarding the proposed removal of the additional 25% of the estimated medical, scientific, and research needs for the United States. Two of the commenters requested that the DEA continue to include the additional 25%, one commenter requested transparency in the process of setting aggregate production quotas, and the last commenter agreed with the DEA that the additional 25% should not be included in aggregate production quotas values. The DEA has considered these comments, as well as the ones for specific controlled substances and ephedrine (for sale), in establishing the 2017 aggregate production quotas and assessment of annual needs.

## **Determination of 2017 Aggregate Production Quotas and Assessment of Annual Needs**

In determining the 2017 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors set forth in 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the 2016 manufacturing quotas, current 2016 sales and inventories, anticipated 2017 export requirements, industrial use, and additional applications for 2017 quotas, as well as information on research and product development requirements. Based on this information, the DEA has removed the additional 25% from the aggregate production quotas before determining that adjustments to the proposed aggregate production quotas for 4-anilino-n-phenethyl-piperidine, amphetamine (for conversion), amphetamine (for sale), cocaine, dihydrocodeine, ecgonine, etorphine hydrochloride, hydromorphone, levorphanol, lysergic acid dimethylamide, nabilone, opium tincture, and oripavine are warranted. Adjustment to the proposed annual assessment of needs for ephedrine (for sale) was also determined to be warranted. This final order reflects those adjustments.

Regarding acetyl fentanyl, AH-7921, beta-hydroxythiofentanyl, butyryl fentanyl, codeine (for conversion), codeine (for sale), hydrocodone (for sale), lisdexamfetamine, marihuana, meperidine, methylphenidate, oxycodone (for sale), and sufentanil, the DEA has determined that the proposed aggregate production quotas are sufficient to provide for the 2017 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks.

This final order establishes these aggregate production quotas at the same amounts as proposed.

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2017 aggregate production quotas for the following schedule I and II controlled substances and the 2017 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	2017 Established Quotas
	(g)
<b>Schedule I</b>	
[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 (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	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-Methylenedioxypropylvalerone (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- $\alpha$ -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 ( $\alpha$ -PBP)	25
alpha-Pyrrolidinopentiophenone ( $\alpha$ -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
Fenethylamine	5
<i>gamma</i> -Hydroxybutyric acid	56,200,000
Heroin	25
Hydromorphanol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	15
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
<b>Schedule II</b>	
1-Phenylcyclohexylamine	4
1-Piperidinocyclohexanecarbonitrile	4
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,750,000
Alfentanil	4,200
Alphaprodine	2
Amobarbital	20,100
Amphetamine (for conversion)	12,000,000
Amphetamine (for sale)	42,400,000
Carfentanil	10
Cocaine	103,400
Codeine (for conversion)	40,000,000
Codeine (for sale)	45,000,000
Dextropropoxyphene	15
Dihydrocodeine	281,100
Dihydroetorphine	2
Diphenoxylate (for conversion)	15,000
Diphenoxylate (for sale)	820,000

Ecgonine	99,000
Ethylmorphine	2
Etorphine hydrochloride	32
Fentanyl	1,750,000
Glutethimide	2
Hydrocodone (for conversion)	122,000
Hydrocodone (for sale)	58,410,000
Hydromorphone	5,140,800
Isomethadone	4
Levo-alphaacetylmethadol (LAAM)	3
Levomethorphan	10
Levorphanol	8,300
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	19,000
Noroxymorphone (for conversion)	17,700,000
Noroxymorphone (for sale)	400,000
Opium (powder)	90,000
Opium (tincture)	907,200
Oripavine	22,000,000
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
<b>List I Chemicals</b>	
Ephedrine (for conversion)	50,000
Ephedrine (for sale)	5,360,000
Phenylpropanolamine (for conversion)	15,000,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	40
Pseudoephedrine (for sale)	200,000,000

The Administrator also establishes aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 at zero. In accordance with 21 CFR 1303.13 and 21 CFR 1315.13, upon consideration of the relevant factors, the Administrator may adjust the 2017 aggregate production quotas and assessment of annual needs as needed.

Dated: September 26, 2016

Chuck Rosenberg,  
*Acting Administrator.*

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