



**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-378]**

**Final Adjusted 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 2014**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice (DOJ).

**ACTION:** Notice.

**SUMMARY:** This notice establishes the final adjusted 2014 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, as well as the 2014 aggregate production quotas for three recently temporarily controlled substances.

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

**FOR FURTHER INFORMATION CONTACT:** Imelda Paredes, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:**

**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 ephedrine, pseudoephedrine, and

phenylpropanolamine. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration (DEA) through 28 CFR 0.100(b). The Administrator, in turn, has redelegated this function to the Deputy Administrator, pursuant to 28 CFR pt. 0 subpt. R, App.

The DEA published the 2014 established aggregate production quotas for controlled substances in schedules I and II and for the assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the Federal Register (78 FR 55099) on September 9, 2013. That notice stated that the Deputy Administrator would adjust, as needed, the established aggregate production quotas in 2014 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The 2014 proposed adjusted aggregate production quotas for controlled substances in schedules I and II and assessment of annual needs for the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the Federal Register on June 12, 2014 (79 FR 33780) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before July 14, 2014.

#### **Analysis for Final Adjusted 2014 Aggregate Production Quotas and Assessment of Annual Needs**

Consideration has been given to the criteria outlined in the June 12, 2014, notice of proposed adjusted aggregate production quotas and assessment of annual needs, in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. Five companies submitted timely comments regarding a total of 11 schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 4-anilino-

phenethyl-4-piperidine (ANPP), codeine (for sale), diphenoxylate, hydromorphone, levorphanol, morphine (for conversion), oripavine, oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), and tetrahydrocannabinols were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks. The DEA did not receive any comments for the proposed adjustments to the 2014 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

The DEA has taken into consideration the above comments along with the relevant 2013 year-end inventories, initial 2014 manufacturing and import quotas, 2014 export requirements, actual and projected 2014 sales, research and product development requirements, and the additional applications received. Based on all of the above, the Deputy Administrator has determined that the proposed adjusted 2014 aggregate production quotas and assessment of annual needs for opium tincture, oripavine, and ephedrine (for sale) required additional consideration and hereby further adjusts the 2014 aggregate production quota and assessment of annual needs for these substances. Regarding 4-anilino-phenethyl-4-piperidine (ANPP), codeine (for sale), diphenoxylate, hydromorphone, levorphanol, morphine (for conversion), oxycodone (for sale), oxymorphone (for conversion), oxymorphone (for sale), and tetrahydrocannabinols the Deputy Administrator hereby determines that the proposed adjusted 2014 aggregate production quotas and assessment of annual needs for these substances and List I chemicals as published on June 12, 2014 (79 FR 33780) are sufficient to meet the current 2014 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock.

As described in the previously published notice establishing the 2014 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers 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. *See* 21 CFR 1303.24. 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 revised schedule II aggregate production quotas, and certain schedule I 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 revised established aggregate production quota 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 results in the 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.

Pursuant to the above, the Deputy Administrator hereby finalizes the 2014 aggregate production quotas for the following schedule I and II controlled substances and the 2014 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	Final adjusted 2014 quotas (g)
<b>Schedule I</b>	
(1-Pentyl-1 <i>H</i> -indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	15
[1-(5-Fluoro-pentyl)-1 <i>H</i> -indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (XLR11)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone)	15
1-(1,3-Benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
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)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4- <i>n</i> -propylphenyl)ethanamine (2C-P)	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-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	15
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	15
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2-(Methylamino)-1-phenylpentan-1-one (pentedrone)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4- <i>n</i> -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)	50
3,4-Methylenedioxyprovalerone (MDPV)	35
3-Fluoro-N-methylcathinone (3-FMC)	15
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Fluoro-N-methylcathinone (4-FMC)	15
4-Methoxyamphetamine	100
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-ethylcathinone (4-MEC)	15
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl- $\alpha$ -pyrrolidinopropiophenone (4-MePPP)	15
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
Acetyl- $\alpha$ -methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
Allylprodine	2
Alphacetylmethadol	2
$\alpha$ -Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
$\alpha$ -Methylfentanyl	2
$\alpha$ -Methylthiofentanyl	2
$\alpha$ -Methyltryptamine (AMT)	25
$\alpha$ -Pyrrolidinobutiophenone ( $\alpha$ -PBP)	15
$\alpha$ -Pyrrolidinopentiophenone ( $\alpha$ -PVP)	15
Aminorex	25
Benzylmorphine	2
Betacetylmethadol	2
$\beta$ -Hydroxy-3-methylfentanyl	2
$\beta$ -Hydroxyfentanyl	2
Betameprodine	2

Betaprodine	2
Bufotenine	3
Cathinone	70
Codeine methylbromide	5
Codeine-N-oxide	200
Desomorphine	5
Diethyltryptamine	25
Difenoxin	50
Dihydromorphine	3,990,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylamine	5
<i>gamma</i> -Hydroxybutyric acid	70,250,000
Heroin	25
Hydromorphanol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	35
Marihuana	650,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	2
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	175
<i>N</i> -(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide (AKB48)	15
<i>N</i> -(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	15
<i>N</i> -(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	15
<i>N,N</i> -Dimethylamphetamine	25
Naphthylpyrovalerone (naphyrone)	15
<i>N</i> -Benzylpiperazine	25
<i>N</i> -Ethyl-1-phenylcyclohexylamine	5
<i>N</i> -Ethylamphetamine	24
<i>N</i> -Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	18
<i>para</i> -Fluorofentanyl	2
Parahexyl	5
Phenomorphane	2

Pholcodine	2
Properidine	2
Psilocybin	40
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1 <i>H</i> -indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	15
Quinolin-8-yl 1-pentyl-1 <i>H</i> -indole-3-carboxylate (PB-22; QUPIC)	15
Tetrahydrocannabinols	491,000
Thiofentanyl	2
Tilidine	10
Trimeperidine	2
<b>Schedule II</b>	
1-Phenylcyclohexylamine	3
1-Piperidinocyclohexanecarbonitrile	3
4-Anilino- <i>N</i> -phenethyl-4-piperidine (ANPP)	2,687,500
Alfentanil	17,625
Alphaprodine	3
Amobarbital	9
Amphetamine (for conversion)	18,375,000
Amphetamine (for sale)	49,000,000
Carfentanil	19
Cocaine	240,000
Codeine (for conversion)	68,750,000
Codeine (for sale)	46,125,000
Dextropropoxyphene	19
Dihydrocodeine	100,750
Diphenoxylate	1,288,750
Ecgonine	174,375
Ethylmorphine	3
Fentanyl	2,108,750
Glutethimide	3
Hydrocodone (for conversion)	137,500
Hydrocodone (for sale)	99,625,000
Hydromorphone	6,750,000
Isomethadone	5
Levo-alphaacetylmethadol (LAAM)	4
Levomethorphan	195
Levorphanol	4,625
Lisdexamfetamine	23,750,000
Meperidine	6,250,000
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000

Methadone Intermediate	38,875,000
Methamphetamine	2,811,375
[1,250,000 grams of <i>levo</i> -desoxyephedrine for use in a non-controlled, non-prescription product; 1,500,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	96,750,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	30,375
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	1,262,500
Opium (powder)	112,500
Opium (tincture)	780,000
Oripavine	30,625,000
Oxycodone (for conversion)	9,250,000
Oxycodone (for sale)	149,375,000
Oxymorphone (for conversion)	25,000,000
Oxymorphone (for sale)	7,750,000
Pentobarbital	35,000,000
Phenazocine	6
Phencyclidine	19
Phenmetrazine	3
Phenylacetone	45,750,000
Racemethorphan	3
Remifentanil	5,875
Secobarbital	215,003
Sufentanil	6,255
Tapentadol	17,500,000
Thebaine	145,000,000
<b>List I Chemicals</b>	
Ephedrine (for conversion)	1,000,000
Ephedrine (for sale)	4,200,000
Phenylpropanolamine (for conversion)	44,800,000
Phenylpropanolamine (for sale)	5,300,000
Pseudoephedrine (for conversion)	5,000
Pseudoephedrine (for sale)	224,500,000

Aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Dated: August 15, 2014.

Thomas M. Harrigan,  
*Deputy Administrator.*

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