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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-471F]

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 2018

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2018 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

APPLICABLE DATE: Applicable [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 2018 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 2018 to provide for the estimated medical, scientific, research, 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 August 7, 2017, 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 2018" was published in the *Federal Register*. 82 FR 36830. This notice proposed the 2018 aggregate production quotas for each basic class of controlled substance listed in schedules I and II and the 2018 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 September 6, 2017.

Comments Received

Within the public comment period, the DEA received seventeen comments from three DEA-registered manufacturers regarding sixteen different schedule I and II controlled

substances and one comment from a DEA-registered manufacturer regarding the proposed assessment of annual needs for the list I chemical phenylpropanolamine (for conversion). Commenters stated the proposed aggregate production quotas for 4-anilino-n-phenethyl-4-piperadine (ANPP), amphetamine (for conversion), codeine (for sale), diphenoxylate, fentanyl, gamma hydroxybutyric acid, hydrocodone (for sale), lisdexamfetamine, methadone, methadone-intermediate, methylphenidate, morphine (for conversion), morphine (for sale), oxycodone (for sale), oxymorphone (for sale), sufentanil, as well as the proposed assessment of annual needs for phenylpropanolamine (for conversion), 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. These comments were considered in setting the final 2018 Aggregate Production Quotas as discussed below.

In addition to these seventeen comments, the DEA received one comment from a DEA-registered manufacturer seeking clarification on whether DEA considers manufacturing at outsourcing facilities when determining the Aggregate Production Quotas. The DEA notes that it is the responsibility of all DEA-registered dosage form manufacturers to submit quota applications by April 1, in order for their individual business practices to be considered when the DEA proposes the Aggregate Production Quota for the following year. 21 CFR 1303.12(b). These quota applications and comments with discrete data regarding the quantities of the basic classes of schedule I or II controlled substances received during the comment period for the proposed Aggregate Production Quotas are taken into consideration before establishing the values presented in this Final Order. This DEA-registered manufacturer provided no quantitative data

supporting the position that the proposed quota for 2018 will adversely impact outsourcing facilities for DEA to consider. The DEA also received one hundred five comments that expressed concern that DEA's proposed reduction of opioids by twenty percent would adversely impact the availability of pain relieving prescription drugs for people with chronic pain. These comments were general in nature, and raised issues of specific medical illnesses and medical treatment, and therefore are outside of the scope of this Final Order for 2018. As a result, these one hundred and six comments did not provide new discrete data for consideration, and do not impact the original analysis involved in establishing the 2018 aggregate production quotas.

Determination of 2018 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2018 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 2017 manufacturing quotas, current 2017 sales and inventories, anticipated 2018 export requirements, industrial use, additional applications for 2018 quotas, as well as information on research and product development requirements. Based on all of the above, the Administrator is adjusting the 2018 aggregate production quotas for 2-(4-bromo-2,5-dimethoxyphenyl)-n-(2-methoxybenzyl) ethanamine, 3,4,5-trimethoxy amphetamine, 4-bromo-2,5-dimethoxy-amphetamine, acryl fentanyl, alfentanil, amobarbital, methylphenidate, and nabilone, are warranted. Adjustment to the proposed assessment of annual needs for pseudoephedrine (for sale) was also determined to be warranted. This final order reflects those adjustments.

Regarding 4-anilino-n-phenethyl-4-piperadine (ANPP), amphetamine (for conversion), codeine (for sale), diphenoxylate, fentanyl, gamma hydroxybutyric acid, hydrocodone (for sale), lisdexamfetamine, methadone, methadone-intermediate, morphine (for conversion), morphine (for sale), oxycodone (for sale), oxymorphone (for sale), sufentanil, and phenylpropanolamine (for conversion), the DEA has determined the proposed aggregate production quotas and assessment of annual needs are sufficient to provide for the 2018 estimated medical, scientific, research, industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these aggregate production quotas and assessment of annual needs 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 2018 aggregate production quotas for the following schedule I and II controlled substances and the 2018 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	**2018 Established Quotas**
	(g)
Temporarily Scheduled Substances	
Acryl fentanyl	25
Schedule I	
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-Benzylpiperazine	25

1-Methyl-4-phenyl-4-propionoxypiperidine	2
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-Methylenedioxypyrovalerone (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
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
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)-1*H*-indazole-3-carboxamido)-3-methylbutanoate)	30
5F-APINACA; 5F-AKB48 (*N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide)	30
5-Fluoro-PB-22; 5F-PB-22	20
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1*H*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)-1*H*-indazole-3-carboxamide)	30
Acetyl Fentanyl	100
Acetyl-*alpha*-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	2
Acryl Fentanyl	25
ADB-PINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide)	50
AH-7921	30
Allylprodine	2
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
alpha-Methylfentanyl	30
alpha-Methylthiofentanyl	30
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
APINCA, AKB48 (*N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide)	25
Benzylmorphine	30
Betacetylmethadol	2
beta-Hydroxy-3-methylfentanyl	30

beta-Hydroxyfentanyl	30
beta-Hydroxythiofentanyl	30
Betameprodine	2
Betamethadol	4
Betaprodine	2
Bufotenine	3
Butylone	25
Butyryl fentanyl	30
Cathinone	24
Codeine methylbromide	30
Codeine-N-oxide	192
Desomorphine	25
Diethyltryptamine	25
Difenoxin	8,225
Dihydromorphine	1,000,160
Dimethyltryptamine	35
Dipipanone	5
Etorphine	30
Fenethylline	30
Furanyl fentanyl	30
gamma-Hydroxybutyric acid	37,130,000
Heroin	45
Hydromorphinol	40
Hydroxypethidine	2
Ibogaine	30
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 (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide)	30
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30

Marihuana	443,680
Mecloqualone	30
Mescaline	25
Methaqualone	60
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
N,*N*-Dimethylamphetamine	25
Naphyrone	25
N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Noracymethadol	2
Norlevorphanol	55
Normethadone	2
Normorphine	40
Para-fluorofentanyl	25
Parahexyl	5
PB-22; QUPIC	20
Pentedrone	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
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
Schedule II	
1-Phenylcyclohexylamine	4

1-Piperidinocyclohexanecarbonitrile	4
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,342,320
Alfentanil	6,200
Alphaprodine	2
Amobarbital	20,100
Amphetamine (for conversion)	11,280,000
Amphetamine (for sale)	39,856,000
Carfentanil	20
Cocaine	92,120
Codeine (for conversion)	15,040,000
Codeine (for sale)	40,015,800
Dextropropoxyphene	35
Dihydrocodeine	264,140
Dihydroetorphine	2
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	88,134
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	1,342,320
Glutethimide	2
Hydrocodone (for conversion)	114,680
Hydrocodone (for sale)	50,348,280
Hydromorphone	4,547,720
Isomethadone	30
Levo-alphacetylmethadol (LAAM)	5
Levomethorphan	30
Levorphanol	12,126
Lisdexamfetamine	17,869,000
Meperidine	2,717,540
Meperidine Intermediate-A	5
Meperidine Intermediate-B	30
Meperidine Intermediate-C	5
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)	33,958,440
Nabilone	31,000

Noroxymorphone (for conversion)	14,044,540
Noroxymorphone (for sale)	376,000
Opium (powder)	84,600
Opium (tincture)	564,000
Oripavine	24,534,000
Oxycodone (for conversion)	2,453,400
Oxycodone (for sale)	95,692,000
Oxymorphone (for conversion)	20,962,000
Oxymorphone (for sale)	3,395,280
Pentobarbital	25,850,000
Phenazocine	5
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Racemethorphan	5
Racemorphan	5
Remifentanil	2,820
Secobarbital	161,682
Sufentanil	1,880
Tapentadol	18,388,280
Thebaine	94,000,000
List I Chemicals	
Ephedrine (for conversion)	47,000
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,100,000
Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	40
Pseudoephedrine (for sale)	180,000,000

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 2018 aggregate production quotas and assessment of annual needs as needed.

Dated: November 1, 2017.

Robert W. Patterson,
Acting Administrator.

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