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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-470F]

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 2017

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

ACTION: Final order.

SUMMARY: This final order establishes the final adjusted 2017 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.

DATES: This order is 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 substances 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 Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100.

Background

The DEA published the 2017 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* on October 5, 2016. 81 FR 69079. This notice stated that the Administrator would adjust, as needed, the established aggregate production quotas in 2017 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The 2017 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 August 4, 2017, (82 FR 36449) 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 September 5, 2017.

Comments Received

Three DEA-registered entities submitted timely comments regarding a total of eleven schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for amphetamine (for conversion), dihydrocodeine, diphenoxylate (for sale), heroin, levorphanol, lisdexamfetmine, methadone intermediate, noroxymorphone (for conversion), oripavine, oxycodone (for sale), and oxymorphone (for conversion) 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 received 43 comments from non-DEA registered entities in response to the DEA's August 4, 2017, press release for the proposed 2018 aggregate production quotas. The majority of these commenters expressed concerns about the 20 percent decrease to the production quotas of controlled substances. The DEA also received two comments from non-DEA registered entities suggesting that the rescheduling of marihuana would drastically reduce opioid use, misuse, and addiction. These 45 comments addressed issues that were outside the scope of this final order, and therefore are not relevant to the analysis involved in finalizing the 2017 aggregate production quotas.

The DEA received no comments from DEA-registered or non-DEA registered entities for previously established values of the 2017 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

Analysis for Final Adjusted 2017 Aggregate Production Quotas and Assessment of Annual Needs

In determining the final adjusted 2017 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments that are specifically relevant to this Final Order for calendar year 2017 along with the factors set forth in 21 CFR 1303.13 and 21 CFR 1315.13 in accordance with 21 U.S.C. 826(a), and other relevant factors including the 2016 year-end inventories, initial 2017 manufacturing and import quotas, 2017 export requirements, actual and projected 2017 sales, research and product development requirements, and additional applications received. Based on all of the above, the Administrator is adjusting the 2017 aggregate production quotas and assessment of annual needs for 4-Anilino-N-Phenethyl-4-Piperidine (ANPP), dihydrocodeine, ephedrine (for sale),

fentanyl, hydrocodone (for sale), meperidine, methadone intermediate, morphine (for sale), opium (tincture), Oripavine, oxycodone (for sale), Oxymorphone (for conversion), Oxymorphone (for sale), phenylpropanolamine (for conversion), phenylpropanolamine (for sale), pseudoephedrine (for sale), tapentadol, and thiafentanil. This final order reflects those adjustments.

Regarding diphenoxylate (for sale), heroin, levorphanol, and noroxymorphone (for conversion) the Administrator hereby determines that the proposed adjusted 2017 aggregate production quotas and assessment of annual needs for these substances and list I chemicals as published on August 4, 2017, (82 FR 36449) are sufficient to meet the current 2017 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock. This final order establishes these aggregate production quotas at the same amounts as proposed.

Pursuant to the above, the Administrator hereby finalizes 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	**Final Revised 2017 Quotas (g)**
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)	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)	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	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-Methylenedioxypyrovalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
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
Acetyl Fentanyl	100
Acetyl-*alpha*-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	2
ADB-FUBINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide)	30
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	330
Desomorphine	25
Diethyltryptamine	25
Difenoxin	8,750
Dihydromorphine	1,566,000
Dimethyltryptamine	35
Dipipanone	5
Etorphine	30
Fenethylline	30
Furanyl Fentanyl	30
gamma-Hydroxybutyric acid	56,200,000
Heroin	45
Hydromorphinol	2
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	472,000
Mecloqualone	30
Mescaline	25
Methaqualone	60
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
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	409,000
Thiofentanil	25

THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30
Tilidine	25
Trimeperidine	2
U-47700	30
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
Schedule II	
1-Phenylcyclohexylamine	4
1-Piperidinocyclohexanecarbonitrile	4
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,050,000
Alfentanil	4,200
Alphaprodine	2
Amobarbital	20,100
Amphetamine (for conversion)	12,000,000
Amphetamine (for sale)	42,400,000
Carfentanil	20
Cocaine	103,400
Codeine (for conversion)	40,000,000
Codeine (for sale)	45,000,000
Dextropropoxyphene	35
Dihydrocodeine	360,000
Dihydroetorphine	2
Diphenoxylate (for conversion)	15,000
Diphenoxylate (for sale)	1,110,000
Ecgonine	99,000
Ethylmorphine	30
Etorphine Hydrochloride	32
Fentanyl	1,350,000
Glutethimide	2
Hydrocodone (for conversion)	122,000
Hydrocodone (for sale)	51,900,000
Hydromorphone	5,140,800
Isomethadone	30
Levo-alphacetylmethadol (LAAM)	5
Levomethorphan	30
Levorphanol	12,900
Lisdexamfetamine	19,000,000
Meperidine	2,904,000
Meperidine Intermediate-A	5

Meperidine Intermediate-B	30
Meperidine Intermediate-C	5
Metazocine	15
Methadone (for sale)	23,700,000
Methadone Intermediate	28,700,000
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)	35,000,000
Nabilone	19,000
Noroxymorphone (for conversion)	17,700,000
Noroxymorphone (for sale)	400,000
Opium (powder)	90,000
Opium (tincture)	500,000
Oripavine	28,900,000
Oxycodone (for conversion)	2,610,000
Oxycodone (for sale)	101,500,000
Oxymorphone (for conversion)	23,000,000
Oxymorphone (for sale)	3,600,000
Pentobarbital	27,500,000
Phenazocine	5
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,002
Sufentanil	4,000
Tapentadol	18,600,000
Thiafentanil	30
Thebaine	100,000,000
List I Chemicals	
Ephedrine (for conversion)	50,000
Ephedrine (for sale)	4,810,000

Phenylpropanolamine (for conversion)	13,600,000
Phenylpropanolamine (for sale)	7,000,000
Pseudoephedrine (for conversion)	40
Pseudoephedrine (for sale)	186,000,000

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: October 27, 2017.

Robert W. Patterson,
Acting Administrator.

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