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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-471A]

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 2018

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

ACTION: Final order.

SUMMARY: This final order establishes the final adjusted 2018 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: This order is effective **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

FOR FURTHER INFORMATION CONTACT: Regulatory Drafting and Policy Support Section (DPW), 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 2018 established aggregate production quotas for controlled substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the *Federal Register* on November 8, 2017. 82 FR 51873. The DEA is committed to preventing and limiting diversion by enforcing laws and regulations regarding controlled substances and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, in order to meet the demand of legitimate medical, scientific, and export needs of the United States. This notice stated that the Administrator would adjust, as needed, the established aggregate production quotas in 2018 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The 2018 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 23, 2018, (83 FR 42690) 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 24, 2018.

Comments Received

The DEA received 526 comments from doctors, nurses, veterinarians, nonprofit organizations, associations, patients, caregivers, DEA-registered entities, and non-DEA entities. The comments included concerns about drug shortages, interference with doctor-

patient relationships, increase in the production of marihuana, requests for a hearing, requests for increases in specific production quotas, and comments that were outside the scope of this final order.

There were 200 commenters that expressed general concerns about the decrease to the production quotas of controlled substances and shortages of controlled substances. There were 27 commenters that expressed general concerns alleging that decreases to the aggregate production quotas interfered with doctor-patient relationships. The DEA sets aggregate production quotas in a manner to ensure that the estimated medical needs of the United States are met. In determining the aggregate production quota, the DEA does take into account the prescriptions that have been issued. The DEA does not interfere with doctor-patient relationships. Doctors who are authorized to dispense controlled substances are responsible for adhering to the laws and regulations set forth under the CSA, which requires doctors to only write prescriptions for a legitimate medical need. The DEA is responsible for enforcing controlled substance laws and regulations. The DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet the demand of legitimate medical, scientific, and export needs of the United States. The decrease or increase in the aggregate production quota for controlled substances is based on factors set forth in 21 CFR 1303.13. In the event of a shortage, the CSA provides a mechanism under which the DEA will, in appropriate circumstances, increase quotas to address shortages. 21 U.S.C. 826(h). When DEA is notified of an alleged shortage, DEA will confer with the FDA and relevant manufacturers regarding the amount of material in physical inventory, current quota granted, and the estimated legitimate medical need, to determine whether a quota adjustment is necessary to alleviate any factually valid shortage.

Four non-DEA registered entities expressed support to increase the production quota of marihuana for research purposes. The DEA increased the production quota for marihuana based solely on increased usage projections for federally approved research projects.

Two non-DEA-registered individuals urged DEA to hold a public hearing in connection with their view that reducing quotas will not be effective in preventing the deaths and other harms associated with the opioid crisis in the United States. One of these individuals stated that the purpose of the hearing would be to obtain input from various medical professionals and patients. The second commenter expressed his view that reduction in quotas could lead to the under treatment of pain. Under the DEA regulations, the decision of whether to grant a hearing on the issues raised by the comments lies solely within the discretion of the Administrator. 21 CFR 1303.11(c) and 1303.13(c). I find that neither of the foregoing two comments, or any of the other comments, presented any evidence that would lead me to conclude that a hearing is necessary or warranted. Therefore, I decline to order a hearing on the issues presented by the comments.

Five DEA-registered entities submitted comments regarding a total of 30 schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for 3-methylfentanyl, 4-ANPP, acetyl fentanyl, acryl fentanyl, beta-hydroxythiofentanyl, butyryl fentanyl, carfentanil, cyclopentyl fentanyl, cyclopropyl fentanyl, d-amphetamine (for conversion), diphenoxylate (for sale), fentanyl, fentanyl related substances, furanyl fentanyl, isobutyryl fentanyl, levorphanol, meperidine, methoxyacetyl fentanyl, noroxymorphone (for conversion), ocfentanil, oripavine, oxymorphone (for conversion), para-chloroisobutyryl fentanyl, para-fluorofentanyl, para-fluorobutyryl fentanyl, para-methyoxybutyryl fentanyl, remifentanil, tetrahydrofuranyl fentanyl, U-47700, and valeryl fentanyl 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 288 comments which addressed issues that are outside the scope of this final order. The comments were general in nature and raised issues of specific medical illnesses, medical treatments, and medication costs and therefore, are outside of the scope of this Final Order for 2018 and do not impact the original analysis involved in finalizing the 2018 aggregate production quotas.

The DEA received no comments from DEA-registered or non-DEA registered entities for previously established values of the 2018 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine.

Analysis for Final Adjusted 2018 Aggregate Production Quotas and Assessment of Annual Needs

In determining the final adjusted 2018 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 2018 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 2017 year-end inventories, initial 2018 manufacturing and import quotas, 2018 export requirements, actual and projected 2018 sales, research and product development requirements, additional applications received, and the extent of any diversion of the controlled substance in the class. Based on all of the above, the Administrator is adjusting the 2018 aggregate production quotas for the following: lower for codeine (for sale), hydrocodone (for sale), morphine (for sale), and oxycodone (for sale) based on the data received since the publication of the 2018 Proposed Revised Aggregate Production Quotas

and Assessment of Annual Needs in the *Federal Register* on August 23, 2018, (83 FR 42690); higher for cyclopentyl fentanyl, fentanyl related substances, methoxyacetyl fentanyl, para-chloroisobutyryl fentanyl, and para-methyoxybutyryl fentanyl due to the publication of their schedule I temporary controlled status; higher for noroxymorphone (for conversion) and oripavine based on their involvement in the synthesis pathway to produce the FDA approved drugs used in the medically assisted treatment of opioid addiction. This final order reflects those adjustments.

Regarding 3-methyl fentanyl, 4-ANPP, acetyl fentanyl, acryl fentanyl, beta-hydroxythiofentanyl, butyryl fentanyl, carfentanil, cyclopropyl fentanyl, d-amphetamine (for conversion), diphenoxylate (for sale), fentanyl, furanyl fentanyl, isobutyryl fentanyl, levorphanol, meperidine, ocfentanil, oxymorphone (for conversion), para-fluorofentanyl, para-fluorobutyryl fentanyl, remifentanil, tetrahydrofuranyl fentanyl, U-47700, and valeryl fentanyl, the Administrator hereby determines that the proposed adjusted 2018 aggregate production quotas and assessment of annual needs for these substances and list I chemicals as published on August 23, 2018, (83 FR 42690) are sufficient to meet the current 2018 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 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	**Final Revised 2018 Quotas** (g)
Temporarily Scheduled Substances	
1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1 H-indazole-3-carboxamide	25
1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3carboxamide	25
Cyclopropyl Fentanyl	20
Cyclopentyl fentanyl	30
Fentanyl related substances	40
Isobutyryl Fentanyl	25
Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
Methoxyacetyl fentanyl	30
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate	25
Ocfentanil	25
Ortho-fluorofentanyl	30
Para-chloroisobutyryl fentanyl	30
Para-fluorobutyryl fentanyl	25
Para-methoxybutyryl fentanyl	30
Tetrahydrofuranyl fentanyl	5
Valeryl fentanyl	25
Schedule I	
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	15
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM-694)	30
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
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)	30

ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	
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 (2C-B)	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)-1H-indazole-3-carboxamido)-3-methylbutanoate)	30
5F-APINACA; 5F-AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	30
5-Fluoro-PB-22; 5F-PB-22	20

5-Fluoro-UR-144, XLR11 [1-(5-Fluoro-pentyl)-1Hindol-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)-1H-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-1H-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
Anileridine	20
APINACA, AKB48 (N-(1-Adamantyl)-1-pentyl-1H-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
Diampromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	8,225
Dihydromorphine	1,000,160
Dimethyltryptamine	50
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-3,3dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30
MDMB-CHMICA; MMB-CHMINACA(Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
Marihuana	1,140,216
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-Ethyl-3-piperidyl benzilate	10
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	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	1,342,000
Alfentanil	6,200
Alphaprodine	2
Amobarbital	20,100

Amphetamine (for conversion)	12,000,000
Amphetamine (for sale)	39,856,000
Carfentanil	20
Cocaine	92,120
Codeine (for conversion)	13,536,000
Codeine (for sale)	36,114,260
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)	43,027,640
Hydromorphone	4,547,720
Isomethadone	30
Levo-alphacetylmethadol (LAAM)	5
Levomethorphan	2,200
Levorphanol	38,000
Lisdexamfetamine	19,000,000
Meperidine	1,913,148
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
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)	29,353,676
Nabilone	62,000
Noroxymorphone (for conversion)	17,804.670
Noroxymorphone (for sale)	376,000
Opium (powder)	84,600
Opium (tincture)	564,000
Oripavine	26,629,500

Oxycodone (for conversion)	2,453,400
Oxycodone (for sale)	79,596,606
Oxymorphone (for conversion)	20,962,000
Oxymorphone (for sale)	3,137,240
Pentobarbital	25,850,000
Phenazocine	5
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	1,880
Tapentadol	18,388,280
Thebaine	84,600,000
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)	1,000
Pseudoephedrine (for sale)	180,000,000

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: December 3, 2018.

Uttam Dhillon,
Acting Administrator.

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