DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-688A]

Proposed Adjustments to the 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 2021

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration proposes to adjust the 2021 aggregate production quotas for several controlled substances in schedules I and II of the Controlled Substances Act and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: Interested persons may file written comments on this notice in accordance with 21 CFR 1303.13(c) and 1315.13(d). Electronic comments must be submitted, and written comments must be postmarked, on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the *Federal Register*. After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will publish in the *Federal Register* a final order establishing the 2021 adjusted aggregate production quotas for schedule I and II controlled substances, and an adjusted assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-688A" on all correspondence, including any attachments. DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (571) 776-2265.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority and 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 the list I chemicals ephedrine,

pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of DEA pursuant to 28 CFR 0.100.

DEA established the 2021 aggregate production quotas for substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine on November 30, 2020 (85 FR 76604). That order stipulated that, in accordance with 21 CFR 1303.13 and 1315.13, all aggregate production quotas and assessments of annual need are subject to adjustment.

Analysis for Proposed Adjusted 2021 Aggregate Production Quotas and Assessment of Annual Needs

DEA proposes to adjust the established 2021 aggregate production quotas to be manufactured in the United States in 2021 to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes. However, DEA's analysis does not suggest the need for adjustment of the 2021 assessment of annual needs for the List I chemicals.

Factors for Determining the Proposed Adjustments

In determining the proposed adjustments, the Administrator has taken into account the criteria in accordance with 21 CFR 1303.13 (adjustment of aggregate production quotas for controlled substances) and 21 CFR 1315.13 (adjustment of the assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine). The Administrator is authorized to increase or reduce the aggregate production quota at any time. 21 CFR 1303.13(a) and 1315.13(a). DEA regulations state that there are five factors that shall be considered in determining to adjust the aggregate production quota and the assessment of annual needs. 21 CFR 1303.13(b) and 1315.13(b).

DEA determined whether to propose an adjustment of the aggregate production quotas and assessment of annual needs for 2021 by considering the factors summarized

below:

> (1) changes in the demand for that class or chemical, changes in the national rate of net disposal of the class or chemical, changes in the national rate of net disposal of the class or chemical by registrants holding individual manufacturing quotas for that class or chemical, and changes in the extent of any diversion in the class of controlled substance;
>
> (2) whether any increased demand for that class or chemical, the national and/or individual rates of net disposal of that class or chemical are temporary, short term, or long term;
>
> (3) whether any increased demand for that class or chemical can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota or assessment of annual needs, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to Sec. 1303.24(b) and 1315.24(b);
>
> (4) whether any decreased demand for that class or chemical will result in excessive inventory accumulation by all persons registered to handle that class or chemical (including manufacturers, distributors, practitioners, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to Sec. 1303.24(b) and 1315.24(b) or abandoned pursuant to Sec. 1303.27 and 1315.27; and
>
> (5) other factors affecting medical, scientific, research, and industrial needs in the United States, lawful export requirements, and other factors affecting importation needs of listed chemicals in the United States as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires. 21 CFR 1303.13(b) and 1315(b).

DEA considered the change in the extent of diversion of all controlled substances in proposing adjustments to the aggregate production quotas as required by 21 CFR 1303.13(b)(1). Pursuant to these factors, DEA has determined that any calculated changes from the previously determined initial calculations are slight and not statistically significant from the quantities originally calculated for the extent of diversion that were applied to the initial aggregate production quota valuations.

DEA also considered updated information obtained from 2020 year-end inventories, 2020 disposition data submitted by quota applicants, estimates of the medical

needs of the United States, product development, and other information made available to DEA after the initial aggregate production quotas and assessment of annual needs had been established. Other factors the Administrator considered in calculating the aggregate production quotas, but not the assessment of annual needs, include product development requirements of both bulk and finished dosage form manufacturers, and other pertinent information.

In evaluating whether there is a need for adjustment of the 2021 assessment of annual needs for List I chemicals, DEA used the calculation methodology previously described in the 2010 and 2011 assessment of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively). However, DEA's analysis does not suggest the need for adjustment of the 2021 assessment of annual needs.

Considerations Based Upon the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

Pursuant to 21 U.S.C. 826(a)(1), "production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance." However, the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act of 2018 (SUPPORT Act), (Pub. L. 115-271), provides an exception to that general rule by now giving DEA the authority to establish quotas in terms of pharmaceutical dosage forms if the agency determines that doing so will assist in avoiding the overproduction, shortages, or diversion of a controlled substance.

DEA has stated before that while there is the authority to set aggregate production quotas in terms of pharmaceutical dosage form, DEA will not be using that authority at this time. Furthermore, when DEA does utilize the authority, it will be doing so at the individual dosage-form manufacturing level, as that is where it is most appropriate to do so. As such, there are no adjustments to set any controlled substances in terms of

pharmaceutical dosage forms.

Under the SUPPORT Act, when setting the aggregate production quota, DEA must estimate the amount of diversion of any substance that is considered a "covered controlled substance," as defined by the SUPPORT Act. 21 USC 826(i)(1)(A). The covered controlled substances are fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone. The SUPPORT Act also requires DEA to "make appropriate quota reductions, as determined by the [Administrator],[1] from the quota the [Administrator] would have otherwise established had such diversion not been considered." 21 U.S.C. 826(i)(1)(C). When estimating diversion, the "[Administrator] -- (i) shall consider information the [Administrator], in consultation with the Secretary of Health and Human Services, determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and (ii) may take into consideration whatever other sources of information the [Administrator] determines reliable." 21 U.S.C. 826(i)(1)(B).

In February 2021, DEA sent letters to the Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), and the states requesting overdose death and overprescribing data that could be considered for estimating diversion. DEA did not receive information from CMS. However, DEA did receive information from the CDC in June 2021 and has started to receive information from the states. DEA has begun to receive Prescription Drug Monitoring Program (PDMP) data from the states in a format that will allow the Agency to develop a more robust methodology to assist in the determination of the diversion estimate in the future. This information will be considered in determining the estimates of diversion for the five covered controlled substances in the Proposed Aggregate Production Quotas for Schedule

[1] All functions vested in the Attorney General by the CSA have been delegated to the Administrator of DEA. 28 CFR 0.100(b).

I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2022.

To update the estimates of diversion, DEA used data from the Drug Theft and Loss Report, Statistical Management Analysis & Reporting Tools System (SMARTS), and System to Retrieve Information on Drug Evidence (STRIDE) databases to aggregate the active pharmaceutical ingredient (API) of each covered controlled substance by metric weight. From the databases, DEA gathered data involving employee theft, break-ins, armed robberies, and material lost in transit. DEA also used seizure data obtained from reports submitted by law enforcement agencies nationwide. This data was categorized by basic drug class and the amount of API in the dosage form was delineated with an appropriate metric for use in proposing the adjusted aggregate production quota values. Using the data, DEA calculated the estimates for the amount of diversion by multiplying the strength of the API listed for each finished dosage form by the total amount of units reported to estimate the metric weight in grams of the controlled substance being diverted. Below, DEA has updated the chart to include estimations of diversion for each of the covered controlled substances.

Diversion Estimates for 2020 (g)	
Fentanyl	184
Hydrocodone	20,759
Hydromorphone	946
Oxycodone	47,316
Oxymorphone	534

DEA considered the change in the extent of diversion of all controlled substances in proposing adjustments to the aggregate production quotas as required by 21 CFR 1303.13(b)(1). Pursuant to these factors, DEA has determined that any calculated changes from the previously determined initial calculations are slight and not statistically significant from the quantities originally calculated for the extent of diversion that were

applied to the initial aggregate production quota valuations.

Proposed Adjustments for the 2021 Aggregate Production Quotas and Assessment of Annual Needs

DEA is proposing significant increases to the APQs of the schedule I substances psilocybin, psilocin, marihuana, and marihuana extract, which are directly related to increased interest by DEA registrants in the use of hallucinogenic controlled substances for research and clinical trial purposes. DEA firmly believes in supporting regulated research of schedule I controlled substances. Therefore, the APQ increases reflect the need to fulfill research and development requirements in the production of new drug products, and the study of marijuana effects in particular, as necessary steps toward potential Food and Drug Administration (FDA) approval of new drug products.

The DEA established the 2021 aggregate production quotas for substances in schedules I and II on November 30, 2020 (85 FR 76604). Subsequent to that publication, DEA published in the Federal Register two final rules to permanently schedule 14 specific fentanyl-related substances under the CSA (86 FR 22113, April 27, 2021, and 86 FR 23602, May 4, 2021). The specific fentanyl-related substances are 2'-fluoro 2-fluorofentanyl, 4′-Methyl acetyl fentanyl, beta-Methyl fentanyl, beta-Phenyl fentanyl, Fentanyl carbamate, ortho-Fluoroacryl fentanyl, ortho-Fluorobutyryl fentanyl, ortho-Fluoroisobutyryl fentanyl, ortho-Methyl acetylfentanyl, ortho-Methyl methoxyacetyl fentanyl, para-Fluoro furanyl fentanyl, para-Methylfentanyl, Phenyl fentanyl, and Thiofuranyl fentanyl. As a result, these substances will continue to be subject to the CSA schedule I controls and are now being assigned individual aggregate production quotas.

On March 1, 2021, DEA published a temporary scheduling order placing Brorphine in schedule I of the CSA (86 FR 11862), making all regulatory controls pertaining to schedule I controlled substances applicable to the manufacture of these substances, including the requirement to establish an aggregate production quota pursuant

to 21 U.S.C. 826 and 21 CFR Part 1303. This notice proposes to establish an aggregate production quota for this substance.

On May 7, 2021, DEA published an interim final rule placing serdexmethylphenidate, a component in a combination drug product recently approved by FDA for the treatment of ADHD in patients six years of age and older, in schedule IV of the CSA (86 FR 24487). Serdexmethylphenidate is manufactured from methylphenidate, a schedule II controlled substance. In order to more accurately estimate and manage the quantity of methylphenidate necessary for direct formulation into schedule II drug products versus the quantity of methylphenidate necessary for the manufacturing of serdexmethylphenidate or other substances, DEA has delineated methylphenidate into methylphenidate (for sale) and methylphenidate (for conversion). This notice proposes to establish an aggregate production quota for methylphenidate (for conversion).

On June 20, 2021, DEA published the final rule to place oliceridine, a medication recently approved by FDA for medical use as an intravenous drug for the management of acute pain severe enough to require an intravenous opioid analgesic and for patients for whom alternative treatments are inadequate, in schedule II of the CSA effective July 12, 2021 (86 FR 30772). The placement of oliceridine in schedule II of the CSA, makes all regulatory controls pertaining to schedule II controlled substances applicable to the manufacture of this substance, including the requirement to establish an aggregate production quota pursuant to 21 U.S.C. 826 and 21 CFR Part 1303.

The Administrator, therefore, proposes to adjust the 2021 aggregate production quotas for certain schedule I and II controlled substances. The Administrator does not propose an adjustment to the assessments of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The proposed adjusted APQs, as expressed in grams of anhydrous acid or base, are as follows:

Basic Class	Established 2021 Quotas (g)	Proposed Revised 2021 Quotas (g)
Temporarily Scheduled		
Brorphine	N/A	30
Schedule I		
1-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20	no change
1-(1-Phenylcyclohexyl)pyrrolidine	15	30
1-(2-Phenylethyl)-4-phenyl-4-acetoxypiperidine	10	no change
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	30	no change
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	30	no change
1-Benzylpiperazine	25	no change
1-Methyl-4-phenyl-4-propionoxypiperidine	10	no change
1-[1-(2-Thienyl)cyclohexyl]piperidine	15	no change
2'-fluoro 2-fluorofentanyl	N/A	30
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30	no change
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30	no change
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30	no change
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30	no change
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	100	no change
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	30	no change
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30	no change
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25	no change
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30	no change
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	30	no change
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25	no change
2,5-Dimethoxy-4-n-propylthiophenethylamine	25	no change
2,5-Dimethoxyamphetamine (DMA)	25	no change
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30	no change
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30	no change
3,4,5-Trimethoxyamphetamine	30	no change
3,4-Methylenedioxyamphetamine (MDA)	55	no change
3,4-Methylenedioxymethamphetamine (MDMA)	50	no change
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40	no change
3,4-Methylenedioxy-N-methylcathinone (methylone)	40	no change
3,4-Methylenedioxypyrovalerone (MDPV)	35	no change
3-FMC; 3-Fluoro-N-methylcathinone	25	no change
3-Methylfentanyl	30	no change
3-Methylthiofentanyl	30	no change
4′-Methyl acetyl fentanyl	N/A	30

4-Bromo-2,5-dimethoxyamphetamine (DOB)	30	no change
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25	no change
4-Chloro-α-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25	no change
4CN-Cumyl-Butanica, 1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboximide	25	no change
4-Fluoroisobutyryl fentanyl	30	no change
4-FMC; Flephedrone	25	no change
4-MEC; 4-Methyl-N-ethylcathinone	25	no change
4-Methoxyamphetamine	150	no change
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25	no change
4-Methylaminorex	25	no change
4-Methyl-N-methylcathinone (mephedrone)	45	no change
4-Methyl-α-ethylaminopentiophenone (4-MEAP)	25	no change
4-Methyl-α-pyrrolidinohexiophenone (MPHP)	25	no change
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25	no change
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50	no change
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40	no change
5F-CUMYL-PINACA	25	no change
5F-EDMB-PINACA	25	no change
5F-MDMB-PICA	25	no change
5F-AB-PINACA; N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25	no change
5F-CUMYL-P7AICA; (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboximide)	25	no change
5F-ADB; 5F-MDMB-PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change
5F-AMB (methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate)	30	no change
5F-APINACA; 5F-AKB48 (*N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide)	30	no change
5-Fluoro-PB-22; 5F-PB-22	20	no change
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25	no change
5-Methoxy-3,4-methylenedioxyamphetamine	25	no change
5-Methoxy-N,N-diisopropyltryptamine	25	no change
5-Methoxy-N,N-dimethyltryptamine	35	no change
AB-CHMINACA	30	no change
AB-FUBINACA	50	no change
AB-PINACA	30	no change
ADB-FUBINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide)	30	no change
Acetorphine	25	no change
Acetyl Fentanyl	100	no change
Acetyl-*alpha*-methylfentanyl	30	no change
Acetyldihydrocodeine	30	no change
Acetylmethadol	25	no change
Acryl Fentanyl	25	no change

ADB-PINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide)	50	no change
AH-7921	30	no change
All other tetrahydrocannabinol	1,000	no change
Allylprodine	25	no change
Alphacetylmethadol	25	no change
alpha-Ethyltryptamine	25	no change
Alphameprodine	25	no change
Alphamethadol	25	no change
Alphaprodine	25	no change
alpha-Methylfentanyl	30	no change
alpha-Methylthiofentanyl	30	no change
alpha-Methyltryptamine (AMT)	25	no change
alpha-Pyrrolidinobutiophenone (α-PBP)	25	no change
alpha-Pyrrolidinoheptaphenone (PV8)	25	no change
alpha-Pyrrolidinohexanophenone (α-PHP)	25	no change
alpha-Pyrrolidinopentiophenone (α-PVP)	25	no change
Aminorex	25	no change
Anileridine	20	no change
APINCA, AKB48 (*N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide)	25	no change
Benzethidine	25	no change
Benzylmorphine	30	no change
Betacetylmethadol	25	no change
beta-Hydroxy-3-methylfentanyl	30	no change
beta-Hydroxyfentanyl	30	no change
beta-Hydroxythiofentanyl	30	no change
beta-Methyl fentanyl	N/A	30
beta-Phenyl fentanyl	N/A	30
Betameprodine	25	no change
Betamethadol	4	no change
Betaprodine	25	no change
Bufotenine	15	no change
Butylone	25	no change
Butyryl fentanyl	30	no change
Cathinone	40	no change
Clonitazene	25	no change
Codeine methylbromide	30	no change
Codeine-N-oxide	192	no change
Cyclopentyl Fentanyl	30	no change
Cyclopropyl Fentanyl	20	no change
Cyprenorphine	25	no change
d-9-THC	384,460	no change
Desomorphine	25	no change
Dextromoramide	25	no change
Diapromide	20	no change
Diethylthiambutene	20	no change
Diethyltryptamine	25	no change

Difenoxin	9,200	no change
Dihydromorphine	753,500	no change
Dimenoxadol	25	no change
Dimepheptanol	25	no change
Dimethylthiambutene	20	no change
Dimethyltryptamine	50	no change
Dioxyaphetyl butyrate	25	no change
Dipipanone	25	no change
Drotebanol	25	no change
Ethylmethylthiambutene	25	no change
Etorphine	30	no change
Etoxeridine	25	no change
Fenethylline	30	no change
Fentanyl carbamate	N/A	30
Fentanyl related substances	600	no change
FUB-144	25	no change
FUB-AKB48	25	no change
FUB-AMB, MMB-Fubinaca, AMB-Fubinaca	25	no change
Furanyl fentanyl	30	no change
Furethidine	25	no change
gamma-Hydroxybutyric acid	29,417,000	no change
Heroin	45	no change
Hydromorphinol	40	no change
Hydroxypethidine	25	no change
Ibogaine	30	no change
Isobutyryl Fentanyl	25	no change
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35	no change
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45	no change
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45	no change
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30	no change
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30	no change
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35	no change
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30	no change
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30	no change
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30	no change
Ketobemidone	30	no change
Levomoramide	25	no change
Levophenacylmorphan	25	no change
Lysergic acid diethylamide (LSD)	40	no change
MAB-CHMINACA; ADB-CHMINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide)	30	no change
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30	no change
MMB-CHMICA-(AMB-CHMICA); Methyl-2-(1-	25	no change

(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate		
Marihuana	1,500,000	2,000,000
Marihuana extract	200,000	500,000
Mecloqualone	30	no change
Mescaline	25	no change
Methaqualone	60	no change
Methcathinone	25	no change
Methyoxyacetyl fentanyl	30	no change
Methyldesorphine	5	no change
Methyldihydromorphine	25	no change
Morpheridine	25	no change
Morphine methylbromide	5	no change
Morphine methylsulfonate	5	no change
Morphine-N-oxide	150	no change
MT-45	30	no change
Myrophine	25	no change
NM2201; Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate	25	no change
N,N-Dimethylamphetamine	25	no change
Naphyrone	25	no change
N-Ethyl-1-phenylcyclohexylamine	25	no change
N-Ethyl-3-piperidyl benzilate	10	no change
N-Ethylamphetamine	24	no change
N-Ethylhexedrone	25	no change
N-Ethylpentylone, ephylone	30	no change
N-Hydroxy-3,4-methylenedioxyamphetamine	24	no change
N-Methyl-3-Piperidyl Benzilate	30	no change
Nicocodeine	25	no change
Nicomorphine	25	no change
Noracymethadol	25	no change
Norlevorphanol	2,550	no change
Normethadone	25	no change
Normorphine	40	no change
Norpipanone	25	no change
Ocfentanil	25	no change
Ortho-fluorofentanyl, 2-fluorofentanyl	30	no change
ortho-Fluoroacryl fentanyl	N/A	30
ortho-Fluorobutyryl fentanyl	N/A	30
ortho-Fluoroisobutyryl fentanyl	N/A	30
ortho-Methyl acetylfentanyl	N/A	30
ortho-Methyl methoxyacetyl fentanyl	N/A	30
Para-chloroisobutyryl fentanyl	30	no change
Para-fluorofentanyl	25	no change
Para-fluorobutyryl fentanyl	25	no change
para-Fluoro furanyl fentanyl	N/A	30
para-Methylfentanyl	N/A	30
Para-methoxybutyryl fentanyl	30	no change

Parahexyl	5	no change
PB-22; QUPIC	20	no change
Pentedrone	25	no change
Pentylone	25	no change
Phenadoxone	25	no change
Phenampromide	25	no change
Phenomorphan	25	no change
Phenoperidine	25	no change
Phenyl fentanyl	N/A	30
Pholcodine	5	no change
Piritramide	25	no change
Proheptazine	25	no change
Properidine	25	no change
Propiram	25	no change
Psilocybin	30	1,500
Psilocyn	50	1,000
Racemoramide	25	no change
SR-18 and RCS-8 (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole)	45	no change
SR-19 and RCS-4 (1-Pentyl-3-[(4-methoxy)-benzoyl]indole)	30	no change
Tetrahydrofuranyl fentanyl	15	no change
Thebacon	25	no change
Thiafentanil	25	no change
Thiofentanyl	25	no change
Thiofuranyl fentanyl	N/A	30
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone)	30	no change
Tilidine	25	no change
Trimeperidine	25	no change
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25	no change
U-47700	30	no change
Valeryl fentanyl	25	no change
Schedule II		
1-Phenylcyclohexylamine	15	no change
1-Piperidinocyclohexanecarbonitrile	25	no change
4-Anilino-N-phenethyl-4-piperidine (ANPP)	937,758	no change
Alfentanil	3,260	no change
Alphaprodine	25	no change
Amobarbital	20,100	no change
Bezitramide	25	no change
Carfentanil	20	no change
Cocaine	68,576	no change
Codeine (for conversion)	1,612,500	no change
Codeine (for sale)	27,616,684	no change
D-amphetamine (for sale)	21,200,000	no change
D,l-amphetamine	21,200,000	no change
D-amphetamine (for conversion)	14,137,578	16,068,789
Dextropropoxyphene	35	no change

Dihydrocodeine	156,713	no change
Dihydroetorphine	25	no change
Diphenoxylate (for conversion)	14,100	no change
Diphenoxylate (for sale)	770,800	no change
Ecgonine	68,576	no change
Ethylmorphine	30	no change
Etorphine hydrochloride	32	no change
Fentanyl	731,452	no change
Glutethimide	25	no change
Hydrocodone (for conversion)	1,250	no change
Hydrocodone (for sale)	30,821,224	no change
Hydromorphone	2,827,940	2,743,101
Isomethadone	30	no change
L-amphetamine	30	no change
Levo-alphacetylmethadol (LAAM)	25	no change
Levomethorphan	30	no change
Levorphanol	26,495	no change
Lisdexamfetamine	21,000,000	no change
L-methamphetamine	587,229	no change
Meperidine	856,695	no change
Meperidine Intermediate-A	30	no change
Meperidine Intermediate-B	30	no change
Meperidine Intermediate-C	30	no change
Metazocine	15	no change
Methadone (for sale)	25,619,700	no change
Methadone Intermediate	27,673,600	no change
Methamphetamine	50	no change
D-methamphetamine (for conversion)	485,020	no change
D-methamphetamine (for sale)	40,000	no change
Methylphenidate (for conversion)	0	15,300,000
Methylphenidate (for sale)	57,438,334	no change
Metopon	25	no change
Moramide-intermediate	25	no change
Morphine (for conversion)	3,376,696	no change
Morphine (for sale)	27,784,062	26,505,995
Nabilone	62,000	no change
Norfentanyl	25	no change
Noroxymorphone (for conversion)	22,044,741	no change
Noroxymorphone (for sale)	376,000	no change
Oliceridine	N/A	22,500
Opium (powder)	250,000	no change
Opium (tincture)	530,837	no change
Oripavine	33,010,750	no change
Oxycodone (for conversion)	620,887	no change
Oxycodone (for sale)	57,110,032	no change
Oxymorphone (for conversion)	28,204,371	no change
Oxymorphone (for sale)	563,174	no change
Pentobarbital	25,850,000	30,766,670

Phenazocine	25	no change
Phencyclidine	35	no change
Phenmetrazine	25	no change
Phenylacetone	40	no change
Piminodine	25	no change
Racemethorphan	5	no change
Racemorphan	5	no change
Remifentanil	3,000	no change
Secobarbital	172,100	no change
Sufentanil	4,000	no change
Tapentadol	13,447,541	no change
Thebaine	57,137,944	no change
List I Chemicals		
Ephedrine (for conversion)	100	no change
Ephedrine (for sale)	4,136,000	no change
Phenylpropanolamine (for conversion)	14,878,320	no change
Phenylpropanolamine (for sale)	16,690,000	no change
Pseudoephedrine (for conversion)	1,000	no change
Pseudoephedrine (for sale)	174,246,000	no change

The Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain 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 2021 aggregate production quotas and assessment of annual needs as needed**.**

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will issue and publish in the *Federal Register* a final order establishing any adjustment of 2021 aggregate production quota for each basic class of controlled substances in schedules I and II and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 CFR 1303.13(c) and 1315.13(f).

Anne Milgram,

Administrator.

[FR Doc. 2021-18935 Filed: 9/1/2021 8:45 am; Publication Date: 9/2/2021]