DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-688P]

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 2021

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2021 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) 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 1303.11(c) and 1315.11(d). Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 30 DAYS AFTER 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 his 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 aggregate production quotas for schedule I and II controlled substances, and an 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-688P" 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/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (571) 362-3261.

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 (FOIA) 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

Section 306 of the 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.

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

The proposed 2021 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, to be manufactured in the United States (U.S.) in 2021 to provide for the estimated medical, scientific, research, and 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.

Aggregate Production Quotas

In determining the proposed 2021 aggregate production quotas, the Acting Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1303.11.[1] The DEA proposes the aggregate production quotas for 2021 by considering the following seven factors:

(1) Total net disposal of the class by all manufacturers during the current and 2 preceding years;

(2) Trends in the national rate of net disposal of the class;

(3) Total actual (or estimated) inventories of the class and of all substances manufactured from the class, and trends in inventory accumulation;

(4) Projected demand for such class as indicated by procurement quotas requested pursuant to § 1303.12;

(5) The extent of any diversion of the controlled substance in the class;

(6) Relevant information obtained from the Department of Health and Human Services (HHS), including from the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare and Medicaid Services (CMS), and relevant information obtained from the states; and

(7) Other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, 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

[1] Two additional aggregate production quotas factors were added when DEA published the Final Rule "Controlled Substances Quotas" in the *Federal Register*, 83 FR 32784, on July 16, 2018.

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.

Assessment of Annual Needs

In similar fashion, in determining the proposed 2021 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, the Acting Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1315.11 and considered the five following factors:

(1) Total net disposal of the chemical by all manufacturers and importers during the current and 2 preceding years;

(2) Trends in the national rate of net disposal of each chemical;

(3) Total actual (or estimated) inventories of the chemical and of all substances manufactured from the chemical, and trends in inventory accumulation;

(4) Projected demand for each chemical as indicated by procurement and import quotas requested pursuant to § 1315.32; and

(5) Other factors affecting medical, scientific, research, and industrial needs in the United States, lawful export requirements, and the establishment and maintenance of reserve stocks, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the chemicals or the substances which are manufactured from them, 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 1315.11(b).

As may be noted, the five assessment of annual needs factors considered are similar, but not identical, to five of the seven factors considered in determining the aggregate production quotas. In determining the proposed 2021 assessment of annual needs, 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).

Information from the Food and Drug Administration

In accordance with part 1303 of Title 21, of the CFR, 21 U.S.C. 826, and 42 U.S.C. 242, HHS continues to provide DEA with estimates of the quantities of select schedule I and II controlled substances and three list I chemicals that will be required to meet the legitimate medical domestic needs of the United States for a given calendar year. The FDA is responsible for providing these estimates and predictions of legitimate medical needs to DEA. FDA provides DEA with its predicted estimates of medical usage for selected controlled substances based on information available to them at a specific point in time to meet statutory requirements. FDA's predicted levels of medical need for the United States was expected to decline on average 36.52 percent for calendar year 2021. These declines were expected to occur across a variety of schedule II opioids including fentanyl, hydrocodone, hydromorphone, codeine, and morphine. However, FDA's predicted level of medical need for the United States was calculated by FDA at the beginning of the Coronavirus Disease 2019 (COVID-19) pandemic and, therefore, did

not take into account changes in usage that are necessary to treat patients who require schedule II controlled substances. DEA has considered both the potential for diversion as well as the anticipated increase in demand for opioids used to treat patients with COVID-19 in the table of proposed 2021 aggregate production quotas listed below as is required pursuant to 21 CFR 1303.11(b)(7).

With regard to certain schedule II stimulants (amphetamine, methylphenidate, and lisdexamfetamine) that are widely used to treat patients with attention deficit hyperactivity disorder (ADHD), FDA predicted a 0.5 percent decline in domestic medical use. DEA noted that although usage is not forecasted to have a significant increase in demand, FDA raised concerns over receiving a large volume of drug shortage notifications from patients for these medications as well as multiple recalls for out-of-specification lots of specific ADHD medications. DEA did consider FDA's concerns when calculating the aggregate production quota for these substances. While FDA's predicted estimate of usage remains stable, DEA has observed increases in the number of quota applications for product development efforts as well as exports for medical use for these controlled substances, and has proposed increases in these APQs to meet these demands. However, DEA is closely monitoring trends in licit stimulant use as DEA has grown increasingly concerned over the misuse of prescription stimulants among young adults and the demand for methamphetamine here in the U.S.

For the factors listed in 21 CFR 1303.11(b)(3) and (4), DEA registered manufacturers of controlled substances in schedules I and II provided the information by submitting their individual data to several DEA database systems used for reporting inventory, distribution, manufacturing, and estimated quota requirements to meet sales

forecasts for each class of controlled substance as required by regulations. *See* 21 CFR 1303.12, 1303.22, and part 1304. Factor 1303.11(b)(5) requires DEA to consider the extent of diversion of controlled substances. The estimates of diversion as required by the SUPPORT Act are discussed later in the document. Diversion is defined as all distribution, dispensing, or other use of controlled substances for other than a legitimate medical purpose. In order to consider the extent of diversion, Federal, state, and local law enforcement seizures and registrant reports of diversion of controlled substances from 2019 were extracted from several DEA supported databases. The databases used include:

- Theft Loss Report database comprised of DEA registrant reported entries documenting diversion consisting of employee theft, break-ins, armed robberies, and material lost in transit;
- Statistical Management Analysis & Reporting Tools System (SMARTS) database comprised of laboratory drug submissions from seizure data and drug purchases made by DEA task force groups, tactical diversion squads, enforcement groups, and High Intensity Drug Trafficking Area (HIDTA) task force groups;
- System to Retrieve Information on Drug Evidence (STRIDE) database comprised of material seized by numerous law enforcement groups across the country including the Federal Bureau of Investigation (FBI) field offices; DEA field offices; U.S. Immigration and Customs Enforcement (ICE) offices; Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) offices; and metropolitan police departments.

The data was categorized by basic drug class and the amount of active pharmaceutical ingredient (API) in the dosage form was delineated with an appropriate metric for use in proposing aggregate production quota values (*i.e.*, weight). Because of the factor required by 21 CFR 1303.11(b)(6), DEA formally solicited HHS components CDC and CMS, in February 2020, requesting information including rates of overdose deaths and abuse and overall public health impact related to schedule II controlled substances, including the covered controlled substances. In April 2020, DEA formally solicited the states regarding information that would be helpful to DEA in estimating the amount of diversion, including PDMP data for the covered controlled substances. This information is considered pursuant to the SUPPORT Act discussed below. The Acting Administrator considered the effects of the COVID-19 pandemic pursuant to 21 CFR 1303.11(b)(7) as discussed under Information from the FDA section.

Estimates of Diversion Pursuant to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act), Pub. L. 115-271, mandates that DEA, in consultation with HHS, determine reliable rates of overdose deaths, abuse, and overall public health impact as factors for the purpose of estimating diversion for each of the following five covered controlled substances: fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone. The SUPPORT Act further mandates that DEA "make appropriate quota reductions, as determined by the [Administrator], from the quota the [Administrator] would have otherwise established

had such diversion not been considered."[2] 21 U.S.C. 826(i)(1).

In accordance with this mandate, DEA requested information from several reliable sources. In February 2020, DEA met with representatives from FDA, CDC, and CMS to discuss sharing relevant data that each agency maintains. For example, the CDC maintains information regarding unintentional overdose deaths and CMS maintains data regarding prescriptions for controlled substances filled under the Medicare Part D program. Following that meeting, DEA requested information on overdose deaths, overprescribing, and the public health impact of these categories from each of these federal partners.

Overdose Death Data Provided by the Centers for Disease Control and Prevention.

In May 2020, the CDC provided DEA with data from their National Vital Statistics System Mortality files for 2015 through 2017, which provided numerical, crude, and age-adjusted rates of drug overdose deaths involving the covered controlled substances aggregated by public health regions of the United States. The CDC noted that if the death involved more than one controlled substance, the death was counted in all involved substances. Further, CDC informed DEA that calendar year 2018 data would not be available until the fall of 2020. The number of overdose deaths in which the covered controlled substance was identified, as provided by the CDC, is provided in Table 1 below. With respect to fentanyl, the data includes the covered controlled substance fentanyl and all known fentanyl analogues, which are not covered controlled

[2] On October 23, 2019, DEA published a proposal to amend its quota regulations. 84 FR 56712. When finalized, the regulations will implement the amendments to the CSA made by the SUPPORT Act. However, the statutory requirements stated above became effective upon enactment of the SUPPORT Act, and DEA is therefore obligated to adhere to them in issuing these adjusted aggregate production quotas.

substances under the SUPPORT Act.

Table 1: Overdose Deaths of Covered Controlled Substances, 2015-2017

	2015	2016	2017	Trend (Percent change from 2015 to 2017)
Fentanyl and its Analogues	8,251	18,335	27,299	231%
Hydrocodone	3,051	3,199	3,072	1%
Hydromorphone	793	743	786	-1%
Oxycodone	5,792	6,199	6,053	5%
Oxymorphone	1,006	1,077	900	-11%

Fentanyl and its analogues are the substances that continue to be the opioids involved in the vast majority of overdose deaths in the United States, increasing by 231 percent from 2015 through 2017.[3] However, based on the data presented to DEA by the CDC, which did not differentiate between licit fentanyl and illicit fentanyl and its analogues, as well as analyzed seizure data from law enforcement activities, DEA believes that the vast majority of deaths involving fentanyl were not from products that were lawfully manufactured and distributed pursuant to the CSA but were from unlawfully manufactured and distributed fentanyl and fentanyl related substances. The information from the CDC also demonstrates a relatively stable number of overdose deaths involving oxycodone, hydrocodone, and hydromorphone. Overdose deaths involving oxymorphone show an 11 percent decline during this period. Whereas DEA is required to consider rates in overdose deaths pursuant to changes made by the SUPPORT

[3] According to the CDC, there were an estimated 47,506 unintentional overdose deaths involving a natural, semi-synthetic or synthetic opioid in 2017. More than half (57 percent) involved fentanyl and substances chemically similar to fentanyl. At the time of this publication, the CDC has released unintentional overdose statistics for 2018 and provisional estimates for 2019; however, deaths involving each of the five covered substances are not available for those years. Information about CDC's current mortality data may be found at: https://www.cdc.gov/drugoverdose/data/index.html.

Act, DEA has concluded that this data on overdose deaths for 2015 through 2017 cannot be reliably utilized to estimate the amount of diversion for the five covered controlled substances for the quota setting year (2021). However, this information continues to serve as an important reminder of the persistent role that controlled prescription opioids play in our Nation's opioid epidemic.

Data from the Centers for Medicare and Medicaid Services

In further consultation with HHS, DEA was advised that the Centers for Medicare and Medicaid Services (CMS) may have information related to diversion, such as reliable rates of overprescribing (doctor shopping and being prescribed significantly more medicine than is medically necessary). DEA was informed by CMS that CMS had reviewed their internal databases and does not have the ability to systematically distinguish between appropriate and inappropriate prescriptions without investigations. While CMS was unable to generate a report, DEA will attempt to solicit the raw data from CMS to determine overprescribing rates based on CDC prescription guidance for schedule II substances and DEA's own parameters for doctor shopping.

Information from States' Attorneys General

DEA also obtains information from the states to be considered in setting the aggregate production quotas. As such, DEA sent a letter to each state attorney general soliciting information that would be helpful in estimating the amount of diversion for the five covered controlled substances identified in the SUPPORT Act. In that letter, DEA indicated that it was specifically interested in obtaining information from each state's Prescription Drug Monitoring Program (PDMP) or any analysis of prescription data that would assist DEA in estimating diversion of covered controlled substances and setting

appropriate quotas in compliance with the SUPPORT Act. DEA requested the data be provided to the agency by June 1, 2020, in order to provide the agency with adequate time to analyze the data and determine a methodology for inclusion in diversion estimates to be considered in proposing APQ values for the 2021 calendar year. Twenty states and U.S. territories acknowledged receipt of DEA's correspondence and nine of those states provided DEA with de-identified aggregated PDMP data. The list of states and territories responding to DEA's request for data is listed in Table 2.

Table 2. States/Territories that Responded to DEA's Data Request

State/Territory	**Acknowledged Letter**	**Submitted PDMP Data**
1. Connecticut	X	
2. Delaware	X	
3. District of Columbia	X	
4. Florida	X	X
5. Guam	X	X
6. Illinois	X	
7. Louisiana	X	X
8. Maine	X	
9. Massachusetts	X	
10. Michigan	X	
11. Missouri	X	
12. Montana	X	
13. New Hampshire	X	

14. Ohio	X	X
15. Oklahoma	X	X
16. Oregon	X	
17. South Dakota	X	X
18. Texas	X	X
19. West Virginia	X	X
20. Wyoming	X	X

The data that DEA received varied in its form and content and was ultimately determined to be inapplicable at the national level.

Data from PDMPs can be evaluated to identify common diversion schemes such as "doctor shopping," a scheme in which a patient obtains controlled substances from multiple treatment providers without the providers knowing of the other prescriptions. In addition, information from PDMPs can assist in identifying "red flags" that could be evidence of diversion and misuse of covered controlled substances, such as: over-prescribing; patients traveling long distances or across state lines to have prescriptions filled; early refills; and dangerous drug combinations such as the "holy trinity," a cocktail of drugs consisting of an opioid, a benzodiazepine, and a commonly prescribed muscle relaxant such as carisoprodol, which when misused in combination, can be lethal. DEA has determined that analysis of raw data from state PDMPs on these five covered substances is essential for DEA to effectively estimate diversion of the covered controlled substances pursuant to the SUPPORT Act. DEA is currently exploring additional means to obtain PDMP data so that it may fulfill this statutory obligation while protecting the

privacy of patients who obtain such prescriptions.

DEA Law Enforcement Data

DEA extracted data from its Drug Theft and Loss, Statistical Management Analysis & Reporting Tools System (SMARTS) and System to Retrieve Information on Drug Evidence (STRIDE) databases, and aggregated the quantity of active pharmaceutical ingredient (API) of each covered controlled substance by metric weight where the data was available. From the databases, DEA gathered data involving employee theft, break-ins, armed robberies, and material lost in transit. DEA also used seizure data by law enforcement 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. DEA calculated the estimated 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 kilograms of the controlled substance being diverted. The estimate of diversion for each of the covered controlled substances is reported below:

Table 3: Estimate of Diversion for Covered Controlled Substances.

Diversion Estimates for 2019 (kg)	
Fentanyl	0.090
Hydrocodone	30.294
Hydromorphone	1.424
Oxycodone	60.959
Oxymorphone	1.311

In accordance with the SUPPORT Act, after estimating the amount of diversion for the foregoing five controlled substances, DEA made adjustments to the individual aggregate production quotas for each covered controlled substance by the corresponding

quantities listed in the table.

In determining the proposed 2021 assessment of annual needs, the 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).

The Acting Administrator, therefore, proposes to establish the 2021 aggregate production quotas for certain schedule I and II controlled substances and 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	Proposed 2021 Quotas (g)
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 (AM694)	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
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)	100
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 (DMA)	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-Fluoro-N-methylcathinone (3-FMC)	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Chloro-alpha-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25
1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1 H-indazole-3-carboximide (4CN-Cumyl-Butinaca)	25
4-Fluoroisobutyryl fentanyl	30
4-Fluoro-N-methylcathinone (4-FMC; Flephedrone)	25
4-Methyl-N-ethylcathinone (4-MEC)	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-alpha-ethylaminopentiophenone (4-MEAP)	25
4-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25
4-Methyl-alpha-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-CUMYL-PINACA	25
5F-EDMB-PINACA	25
5F-MDMB-PICA	25
5F-AB-PINACA; N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
5F-CUMYL-P7AICA; (1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboximide)	25
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)-1H-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)-1H-indazole-3-carboxamide)	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
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
All other tetrahydrocannabinol	1,000
Allylprodine	25
Alphacetylmethadol	25
Alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
Alphaprodine	25
Alpha-Methylfentanyl	30
Alpha-Methylthiofentanyl	30
Alpha-Methyltryptamine (AMT)	25
Alpha-Pyrrolidinobutiophenone (α-PBP)	25
Alpha-Pyrrolidinoheptaphenone (PV8)	25
Alpha-Pyrrolidinohexanophenone (α-PHP)	25
Alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
Anileridine	20
APINACA, AKB48 (*N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Betacetylmethadol	25
Beta-Hydroxy-3-methylfentanyl	30
Beta-Hydroxyfentanyl	30
Beta-Hydroxythiofentanyl	30

Betameprodine	25
Betamethadol	4
Betaprodine	25
Bufotenine	15
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
Delta 9-THC	384,460
Desomorphine	25
Dextromoramide	25
Diampromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,200
Dihydromorphine	753,500
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	50
Dioxaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Etorphine	30
Etoxeridine	25
Fenethylline	30
Fentanyl related substances	600
FUB-144	25
FUB-AKB48	25
FUB-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
Gamma Hydroxybutyric Acid	25,417,000
Heroin	45
Hydromorphinol	40
Hydroxypethidine	25
Ibogaine	30

Isobutyryl Fentanyl	25
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
Ketobemidone	30
Levomoramide	25
Levophenacylmorphan	25
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)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB-CHMICA (AMB-CHMICA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
Marihuana	1,500,000
Marihuana extract	200,000
Mecloqualone	30
Mescaline	25
Methaqualone	60
Methcathinone	25
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT-45	30
Myrophine	25
NM2201; Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate	25
N,N-Dimethylamphetamine	25
Naphyrone	25
N-Ethyl-1-phenylcyclohexylamine	25

N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
N-Methyl-3-Piperidyl Benzilate	30
Nicocodeine	25
Nicomorphine	25
Noracymethadol	25
Norlevorphanol	55
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
Ortho-fluorofentanyl, 2-fluorofentanyl	30
Para-chloroisobutyryl fentanyl	30
Para-fluorofentanyl	25
Para-fluorobutyryl fentanyl	25
Para-methoxybutyryl fentanyl	30
Parahexyl	5
PB-22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphan	25
Phenoperidine	25
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Psilocybin	30
Psilocyn	50
Racemoramide	25
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
Tetrahydrofuranyl fentanyl	15
Thebacon	25
Thiafentanil	25
Thiofentanyl	25
THJ-2201 ([1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-	30

yl)methanone)	
Tilidine	25
Trimeperidine	25
UR-144 (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	25
U-47700	30
Valeryl fentanyl	25
Schedule II	
1-Phenylcyclohexylamine	15
1-Piperidinocyclohexanecarbonitrile	25
4-Anilino-N-phenethyl-4-piperidine (ANPP)	666,249
Alfentanil	3,260
Alphaprodine	25
Amobarbital	20,100
Bezitramide	25
Carfentanil	20
Cocaine	68,576
Codeine (for conversion)	1,612,500
Codeine (for sale)	27,616,684
D-amphetamine (for sale)	21,200,000
D-amphetamine (for conversion)	14,137,578
D-methamphetamine (for conversion)	485,02
D-methamphetamine (for sale)	25,491
D,L-amphetamine	21,200,000
D,L-methamphetamine	50
Dextropropoxyphene	35
Dihydrocodeine	156,713
Dihydroetorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	68,576
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	666,249
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	30,821,224
Hydromorphone	2,827,940
Isomethadone	30
L-amphetamine	30
L-methamphetamine	587,229
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30

Levorphanol	26,495
Lisdexamfetamine	21,000,000
Meperidine	856,695
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	25,619,700
Methadone Intermediate	27,673,600
Methylphenidate	57,438,334
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	3,376,696
Morphine (for sale)	27,784,062
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	22,044,741
Noroxymorphone (for sale)	376,000
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	33,010,750
Oxycodone (for conversion)	620,887
Oxycodone (for sale)	57,110,032
Oxymorphone (for conversion)	28,204,371
Oxymorphone (for sale)	563,174
Pentobarbital	25,850,000
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	13,447,541
Thebaine	57,137,944
List I Chemicals	
Ephedrine (for conversion)	100
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,878,320
Phenylpropanolamine (for sale)	16,690,000

Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	174,246,000

The Acting 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.

Adjustments to the Aggregate Production Quotas During the COVID-19 Public Health Emergency

The establishment (and adjustment) of the aggregate production quotas for schedule I and II substances is a critical component of DEA's response to the threat posed by the ongoing COVID-19 public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, and as has been renewed in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)). On April 10, 2020, DEA increased the 2020 aggregate production quotas for certain schedule II controlled substances and list I chemicals after concluding that this action was necessary to ensure that there would be no supply disruptions for these substances for ventilated patients with this infectious disease.[4] Despite this public health emergency, DEA remains focused on the challenges presented by opioid addiction and its effect on the health and wellbeing of the millions of Americans and their families who have become dependent upon or addicted to them. The potential for addiction and misuse exists in every community and remains a pressing health issue with significant social and economic implications.

[4] 85 FR 20302 (April 10, 2020).

These proposed 2021 quotas reflect the quantity that DEA believes is necessary to meet the estimated medical, scientific, research, and industrial needs of the United States, to include any increase in demand for certain controlled substances used to treat patients with COVID-19. DEA remains committed to conducting continuous surveillance on the supply of schedule II controlled substances and list I chemicals necessary to treat patients with COVID-19, and, pursuant to his authority, the Acting Administrator will move swiftly and decisively to increase any 2021 aggregate production quota that he determines is necessary to address an unforeseen increase in demand, should that occur.

In accordance with 21 CFR 1303.13 and 1315.13, upon consideration of the relevant factors, the Acting 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 Acting Administrator will issue and publish in the *Federal Register* a final order establishing the 2021 aggregate production quotas for controlled substances in schedule I and II and establishing an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, 21 CFR 1303.11(c) and 1315.11(f).

Timothy J. Shea,
Acting Administrator.

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