operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* since the *Order Date,* and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

**Authority:** This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: August 21, 2020.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2020–18774 Filed 8–31–20; 8:45 am]

**BILLING CODE 7020–02–P**

## 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 October 1, 2020. 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 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

[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.

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), Public Law 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 substances under the SUPPORT Act.

[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.

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 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 |

[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.*

TABLE 2—STATES/TERRITORIES THAT RESPONDED TO DEA'S DATA REQUEST—Continued

| State/territory | Acknowledged letter | Submitted PDMP data |
|---|---|---|
| 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-nitrophenyl)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 |

| Basic class | Proposed 2021 quotas (g) |
|---|---|
| 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 |

| Basic class | Proposed 2021 quotas (g) |
|---|---|
| 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-yl)methanone) | 30 |
| 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.

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.*

[FR Doc. 2020–19285 Filed 8–31–20; 8:45 am]

**BILLING CODE P**

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

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. DEA–508A2]**

### 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 2020

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice with request for comments.

**SUMMARY:** The Drug Enforcement Administration proposes to adjust the 2020 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 October 1, 2020. 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 2020 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–508A2'' 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 to 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) 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 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