internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2018 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2018 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to 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* after 2013, 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 section 207.61 of the Commission's rules.

By order of the Commission.

Issued: November 25, 2019.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2019–25941 Filed 11–29–19; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–508E]

Established 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: Final order.

SUMMARY: This final order establishes the initial 2020 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: *Effective Date:* This order is effective December 2, 2019.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for each basic class of controlled substance listed in schedule I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100.

Background

The 2020 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 that may be manufactured in the United States in 2020 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 include imports of ephedrine, pseudoephedrine, and phenylpropanolamine, but do not include imports of controlled substances for use in industrial processes.

On September 12, 2019, a notice titled ''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 2020'' was published in the **Federal Register**. 84 FR 48170. This notice proposed the 2020 aggregate production quotas for each basic class of controlled substance listed in schedules I and II, and the 2020 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed aggregate production quotas and the proposed assessment of annual needs on or before October 15, 2019.

Comments Received

Within the public comment period, DEA received 731 comments from DEA registrants, hospital associations, professional associations, doctors, nurses, health system organizations, State Attorneys General, and others. The comments included concerns about the quota process, concerns that further quota reductions will lead to drug shortages, requests for less interference in the doctor-patient relationship, availability of prescription drugs for chronic pain patients, requests for hearings, requests for increase in specific production quotas, and other comments outside the scope of this notice. DEA received a joint comment from two Senators urging DEA to apply DEA's new authorities to prevent and limit opioid diversion due to excessively high production levels. Although this comment was received after the close of the comment period, DEA shares the Senators' concerns and is working to improve its ability to use available databases to better quantify diversion as part of the quota process.

Shortages

There were non-DEA registered commenters that expressed concerns about the decrease in aggregate production quotas. These commenters alleged that decreases to the aggregate production quotas have resulted in a shortage of injectable opioid medications and interfere with the treatment of patients. Some of these commenters also suggested that DEA separate quotas for solid oral controlled substances and injectable controlled substances, and that DEA allow consideration by individual pharmaceutical dosage forms.

DEA also received letters from many doctors, nurses, hospital administrators, and others in the medical field regarding the proposed quota reduction for fentanyl and other schedule II narcotics. These letters characterized the reductions as ''extremely problematic for American healthcare providers,'' stating that the reduction for fentanyl and other schedule II narcotics will lead to drug shortages, raise drug prices, lead to hardships on hospitals and surgical facilities, and negatively impact patients. These letters discussed fentanyl's appearance on the Food and Drug Administration's (FDA) drug shortage list and that fentanyl is the least diverted among the covered controlled substances.

DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet legitimate medical, scientific, and export needs of the United States. Although DEA sets the aggregate production quota, it is possible that manufacturers' business practices may lead to a shortage of controlled substances at the consumer level, despite the adequacy of the aggregate production quota set by DEA. The aggregate production quotas are set by DEA in a manner to include both injectable opioids and solid oral opioids in order to ensure that the estimated medical needs of the United States are met.

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. While DEA is now allowed to issue quotas in terms of pharmaceutical dosage form, it is not required to do so. DEA will not be utilizing this authority at the aggregate production quota level, but will be doing so at the individual dosage-form manufacturing level where it will have a greater impact on averting potential shortages. Because quotas set at the individual dosage-form manufacturing level are more directly connected to distributions of current and new FDA-approved drug products, they allow DEA to manage manufacturing quotas to alleviate any potential shortage in a more timely manner than with quotas set at the aggregate production quota level. This is also true because the aggregate production quota is initially established prior to the start of the quota calendar year.

Additionally, DEA and FDA can coordinate efforts to prevent or alleviate drug shortages pursuant to 21 U.S.C. 826(h). Such efforts may include adjusting domestic competitors' quota, completion of FDA approval to increase the number of competitors, and determining a foreign manufacturer that can meet FDA approval. For example, the domestic shortage of injectable hydromorphone that occurred in 2018 was alleviated through the collaboration of FDA and DEA to determine who were the other dosage-form manufacturers with injectable hydromorphone products in the market, whether other dosage-form manufacturers had the capability to increase their production levels to meet legitimate patient need in a timely manner, and when it was determined that the domestic manufacturers could not increase production significantly to meet legitimate patient need, DEA and FDA coordinated their regulatory authority to allow for the limited importation of injectable hydromorphone into the United States.

Relevant Information Obtained From the States

Pursuant to 21 CFR 1303.11, DEA must consider relevant information from the States when setting the aggregate production quota. Seven State Attorneys General submitted a joint comment expressing concerns about the estimation of diversion for all controlled substances, not accounting for over-prescribing, and the consideration of additional information to set quotas. Their concerns are addressed in more detail below.

I. Diversion Analysis for All Controlled Substances

The seven State Attorneys General commented that DEA should not take different approaches when accounting for diversion for the five covered controlled substances and the remaining controlled substances. In the letter, they discussed the mandates from the SUPPORT Act, as well as the requirements implemented through 21 CFR 1303.11 by the Controlled Substances Quota rule. 83 FR 32784. They expressed that they have similar language and purposes, even though the SUPPORT Act goes a bit further in its mandate by requiring the estimation of diversion for the five covered controlled substances. They pointed out that DEA

estimated diversion and made straightforward quota reductions by the corresponding quantities, whereas DEA only noted that the databases contained usable information in regards to the remaining controlled substances. DEA did not indicate that diversion estimates were conducted for any other controlled substance, nor did DEA indicate that any corresponding decreases were made for other controlled substances. They commented that if DEA believes they have a sound method for estimating diversion, then it is unreasonable not to apply that method for estimating diversion to all controlled substances.

The States also commented that there is a lack of transparency in the setting of quotas. The States believe that DEA needs to explain the logic behind using different approaches in setting quotas. They commented that DEA must include the findings of fact when setting the quota and that transparency is essential in allowing parties to evaluate DEA's 2020 Proposed Aggregate Production Quota notice.

DEA considered various data sources in order to determine the extent of diversion of all controlled substances as is required by the recent amendments to the CSA and changes to DEA's own regulations. In accordance with factor six in 21 CFR 1303.11(b), DEA formally solicited the Department of Health and Human Services (HHS), U.S. Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), and the states in August 2018, requesting information including rates of overdose deaths and abuse and overall public health impact related to controlled substances. This information was also considered pursuant to the SUPPORT Act. DEA determined that due to the grouping of drug classes in all of the sources provided, the data could not be used to estimate diversion for the purpose of setting the aggregate production quotas. However, DEA estimated diversion of the covered controlled substances defined in the SUPPORT Act utilizing DEA's internal data sources. DEA will continue to further define sources that will be useful in analyzing diversion of the remaining controlled substances.

II. Methods and Data That Capture Over-Prescribing as Part of its Diversion Analysis

The States acknowledged that DEA's current approach for accounting for diversion is a significant improvement but commented that DEA does not adequately account for over-prescribing. They commented that over-prescribing results when there is overproduction, which allows legitimate prescriptions to be diverted. Assuming a controlled substance is validly dispensed for a legitimate medical purpose, both the physician and patient will use their judgement to determine how much medication will be prescribed and how much they will consume. The physician's decisions may be influenced by recommendations from CDC, FDA, and professional medical organizations that have conducted and/or reviewed clinical studies used to determine prescription guidelines. Patients are ultimately going to decide for themselves how much of the legitimately prescribed medication they will consume. DEA does not control the quantity of a substance prescribed to a patient, and DEA cannot control how much of the prescription a patient decides to consume. DEA also receives assistance in curbing overprescribing from programs in place, such as the President's Safer Prescribing Plan, which seeks to reduce nationwide opioid prescription fills by one-third. DEA has observed a decline in the number of prescriptions written for schedule II opioids since 2014 and will continue to set aggregate production quotas to meet the medical needs of the United States while combating the opioid crisis. These decreases take into account the combined efforts of DEA, FDA, and CDC enforcing regulations and issuing guidance documents, as well as many states enacting prescription monitoring database programs to stem the opiate/opioid epidemic.

There are ample reasons not to pursue the methods suggested by the State Attorneys General, including that the studies on which they relied are limited in scope of procedures and number of hospitals, such that the methodology is insufficient to expand to a national level.

As pointed out by the States, ''there is no perfect system of measuring other sources of diversion like over-prescription.'' The States pointed to data from drug takeback programs, but currently that data is not usable for consideration in determining the aggregate production quota. There is no method in place to determine how much of the prescription medications are schedule I or II substances and which controlled substances are being returned. DEA and HHS are working together to consider options for quantifying Take-Back Program data.

III. Consideration of Additional Information To Determine Production Quotas

The State Attorneys General commented that DEA should expand its sources of data used to set aggregate production quotas. They suggested three steps that DEA should take to gather information to set quotas which are listed below.

1: Improve Usability of the Automated Reports and Consolidated Ordering System (ARCOS) and the Suspicious Order Reporting System (SORS)

The State Attorneys General commented that DEA should improve usability of the ARCOS and SORS databases to gather better information on prescribing practices. They also note that DEA did not indicate whether SORS was used and minimally referred to ARCOS not being used because it contained identical information to the Theft Loss Report Database. The States commented that DEA needs to reform its process to upload SORS reports into the SORS database. Further, they commented that overdose data received from States and the CDC should be cross-referenced with ARCOS to provide context that should inform the quota-setting process.

SORS was not centralized until its recent launch on October 23, 2019. DEA will need time to sort through the system to determine its utility for aggregate production quota purposes. The submission of a suspicious order alone is not an automatic determination that the order is illicit in nature. Further investigations need to be completed to determine if a transgression has occurred.

The differences in reporting frequencies to ARCOS are specified in 21 CFR 1304.33(b). Acquisition and distribution transaction reports must be completed every quarter no later than the 15th day of the month succeeding the quarter for which it is being submitted. In the same section of the CFR, it does mention that a registrant may be given permission to file a report more frequently, but no more than on a monthly basis. The State Attorneys General request to change this regulation is outside of the scope of this final order.

2: Improve Data Collection in Prescription Drug Takeback Programs To Capture the Quantities of Drugs Overprescribed in Particular Areas

The State Attorneys General expressed that DEA should expand the National Take Back Program to assist with gathering more precise data on over-prescribing. They noted that the takeback programs do not track the types and quantities of what the public turns in, limiting their value. Currently, DEA and HHS are working together to consider methods that improve data

collection and subsequently the usability of data obtained from the Take-Back Program.

3: Consider Medical Best Practices as Part of the Holistic Diversion Analysis

The letter submitted by the State Attorneys General also suggested that DEA study the best practices developed by the medical community and state regulators to determine what opioid quantities are ''medically necessary.'' They expressed that relying exclusively on evidence of illegal activity assumes that any legally-sold controlled substance is a part of the medical and scientific needs of the United States.

DEA is responsible for enforcing the provisions of the CSA and DEA regulations that require prescriptions for controlled substances to be issued by a practitioner for a legitimate medical purpose in the usual course of his/her professional practice. However, beyond that context, DEA does not regulate the practice of medicine generally and thus does not have a role in establishing the type of ''best practices'' to which the commenter refers.

Pain Management and Medical Associations Letters

DEA also received 106 comments that expressed concern that DEA's proposed reduction of opioids would adversely impact the availability of pain relieving prescription drugs for people with chronic pain. These comments were general in nature, and raised issues of specific medical illnesses and medical treatment, and therefore are outside of the scope of this Final Order. As a result, these comments did not provide new discrete data for consideration, and they do not impact the original analysis involved in establishing the 2020 aggregate production quotas.

DEA sets aggregate production quotas in a manner to ensure that all prescriptions that are authorized for legitimate medical purposes can be filled. Prescribers who are authorized to dispense controlled substances are responsible for adhering to the laws and regulations set forth under the CSA, which require doctors to only write prescriptions for legitimate medical needs. Any practitioner issuing an invalid prescription for controlled substances, and any pharmacy knowingly filling such a prescription, would be in violation of the CSA.

Hearings

Two commenters urged DEA to hold a public hearing to receive feedback from stakeholders. They asked that DEA bring together all stakeholders, allowing stakeholders to publicly discuss their concerns.

Under the DEA regulations, the decision of whether to grant this type of a hearing on the issues raised by the commenters lies solely within the discretion of the Administrator. (21 CFR 1303.11(c) and 21 CFR 1303.13(c)). I find that neither of the foregoing two requests presented any evidence that would lead me to conclude that a hearing is necessary or warranted. Therefore, I decline to order a hearing on the issues presented by the commenters.

Specific Quota for DEA-Registered Manufacturers

The DEA received comments from five DEA-registered manufacturers regarding twenty-four different schedule I and II controlled substances. Commenters stated the proposed aggregate production quotas for amphetamine (for sale), fentanyl, hydromorphone, methylphenidate, morphine, noroxymorphone (for conversion), and oxycodone (for sale) were potentially insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. Commenters requested the proposed aggregate production quotas for FUB–144, 5F–AB–PINACA, 5F–EDMB–PINACA, 5F–MDMB–PICA, MMB–CHMICA, FUB–AKB48 (FUB–APINACA), 5F–CUMYL–PINACA, 5F–CUMYL–P7AICA, 4–CN–CUMYL–BUTINACA, NM2201, 4-Methyl-alpha-ethylaminopentiophenone (4–MEAP), N-Ethylhexedrone, 4-Chloro-alpha-pyrrolidinovalerophenone (4-Chloro-alpha-PVP), 4′-Methyl-alpha-pyrrolidinohexiophenone (MPHP), N-Ethylpentylone, alpha-Pyrrolidinohexanophenone (alpha-PHP), and alpha-Pyrrolidinoheptaphenone (PV8), be sufficient for additional quota requests.

DEA has considered the comments for specific controlled substances and made adjustments as needed which are described below in the section titled Determination of 2020 Aggregate Production Quotas and Assessment of Annual Needs. DEA received one comment to the proposed established 2020 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine regarding the difficulty in procuring finished dosage-forms of ephedrine. DEA has considered this comment in the section regarding drug shortages of controlled substances. This letter characterized the reductions of controlled substances and ephedrine as ''extremely problematic for American healthcare providers,'' stating that these reductions will lead to drug shortages, raise drug prices, lead to hardships on hospitals and surgical facilities, and negatively impact patients.

DEA is required under the CSA to establish quotas for ephedrine, pseudoephedrine, and phenylpropanolamine 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. Although DEA sets the assessment of annual needs, it is possible that manufacturers' business practices may lead to a shortage of ephedrine drug products at the consumer level, despite the adequacy of the assessment of annual needs set by DEA. For instance, DEA does not have the authority to dictate when during the calendar year the manufacturer actually utilizes the quota granted to them. Also, DEA cannot dictate how much of the granted quota the manufacturer allocates for use in a single production run. The assessment of annual needs is set by DEA in a manner to include all dosage forms of ephedrine in order to ensure that the estimated medical needs of the United States are met.

Additionally, DEA and FDA can coordinate efforts to prevent or alleviate drug shortages. Such efforts may include adjusting competitors' domestic or import quotas and completion of FDA approval to increase the number of competitors.

Out of Scope

DEA received comments which addressed issues that are outside the scope of this final order. The comments were general in nature and raised issues of specific medical illnesses, medical treatments, and medication costs and, therefore, are outside of the scope of this Final Order. DEA also received comments asserting that illicit drug use, and not prescription drug use, is the main factor in the opioid crisis. Although DEA is genuinely concerned with illicit drug use and its involvement in the opioid crisis, the manufacturing of illicit substances is not considered when determining the aggregate production quotas because such illicit manufacturing cannot be tempered by adjusting the aggregate production quotas, therefore it is outside the scope of this final order.

All of these out of scope issues do not impact the original analysis involved in establishing the 2020 aggregate production quotas.

Determination of 2020 Aggregate Production Quotas and Assessment of Annual Needs

In determining the 2020 aggregate production quotas and assessment of annual needs, DEA has taken into consideration the above comments along with the factors set forth in 21 CFR 1303.11 and 21 CFR 1315.11, in accordance with 21 U.S.C. 826(a), and other relevant factors, including the 2019 manufacturing quotas, current 2019 sales and inventories, anticipated 2020 export requirements, industrial use, additional applications for 2020 quotas, as well as information on research and product development requirements. Based on all of the above, the Administrator is adjusting the 2020 aggregate production quotas for 4-Methyl-alpha-ethylaminopentiophenone (4–MEAP), N-Ethylhexedrone, 4-Chloro-alpha-pyrrolidinovalerophenone (4-Chloro-alpha-PVP), 4'-Methyl-alpha-pyrrolidinohexiophenone (MPHP), alpha-Pyrrolidinohexanophenone (alpha-PHP), alpha-Pyrrolidinoheptaphenone (PV8), amphetamine (for sale), oxycodone (for sale), and oxymorphone (for sale).

Regarding FUB-144, 5F-AB-PINACA, 5F-EDMB-PINACA, 5F-MDMB-PICA, MMB-CHMICA, FUB-AKB48 (FUB-APINACA), 5F-CUMYL-PINACA, 5F-CUMYL-P7AICA, 4-CN-CUMYL-BUTINACA, NM2201, N-Ethylpentylone, fentanyl, hydromorphone, methylphenidate, morphine, noroxymorphone (for conversion), and oxycodone (for sale), DEA has determined the proposed aggregate production quotas and assessment of annual needs are sufficient to provide for the 2020 estimated medical, scientific, research, industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these aggregate production quotas and assessment of annual needs at the same amounts as proposed.

Estimates of Diversion Pursuant to the SUPPORT Act

The SUPPORT Act (21 U.S.C. 826(i)(1)(a)) requires that ''in establishing any quota under this section . . ., for [the covered controlled substances], the Attorney General shall estimate the amount of diversion of the [covered controlled substances] that occurs in the United States.'' To estimate diversion as is required by the SUPPORT Act, DEA aggregated the active pharmaceutical ingredient (API) of each covered controlled substance by metric weight where the data was available in the aforementioned databases. Based on the individual entries into the aforementioned databases, 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.

DIVERSION ESTIMATES FOR 2018 (KG)

Fentanyl	0.109
Hydrocodone	24.259
Hydromorphone	1.219
Oxycodone	57.051
Oxymorphone	1.157

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2020 aggregate production quotas for the following schedule I and II controlled substances and the 2020 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	Established 2020 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-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30

Basic class	Established 2020 quotas (g)
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25
4-Chloro-α-pyrrolidinovalerophenone (4-chloro-alpha-PVP)	25
4CN-Cumyl-Butanica, 1-(4-Cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboximide	25
4-Fluoroisobutyryl fentanyl	30
4-FMC; Flephedrone	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl-α-ethylaminopentiophenone (4-MEAP)	25
4-Methyl-α-pyrrolidinohexiophenone (MPHP)	25
4-Methyl-α-pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	50
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	40
5F-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)-1*H*-indazole-3-carboxamide)	30
5-Fluoro-PB-22; 5F-PB-22	20
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
ADB-FUBINACA (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-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-1*H*-indazole-3-carboxamide)	50
AH-7921	30
Allylprodine	25
Alphacetylmethadol	2
alpha-Ethyltryptamine	25
Alphameprodine	2
Alphamethadol	2
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
APINCA, AKB48 (*N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Betacetylmethadol	2
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

Basic class	Established 2020 quotas (g)
Codeine methylbromide	30
Codeine-N-oxide	192
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,200
Dihydromorphine	753,500
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	50
Dioxyaphetyl butyrate	25
Dipipanone	5
Drotebanol	25
Ethylmethylthiambutene	25
Etorphine	30
Fenethylline	30
Fentanyl related substances	40
FUB-144	25
FUB-AKB48	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)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB-CHMICA-(AMB-CHMICA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
Marihuana	3,200,000
Mecloqualone	30
Mescaline	25
Methaqualone	60
Methcathinone	25
Methyoxyacetyl 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	5
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25

Basic class	Established 2020 quotas (g)
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
Tetrahydrocannabinols	384,460
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)	813,005
Alfentanil	3,260
Alphaprodine	2
Amobarbital	20,100
Amphetamine (for conversion)	14,137,578
Amphetamine (for sale)	47,000,000
Bezitramide	25
Carfentanil	20
Cocaine	82,127
Codeine (for conversion)	3,225,000
Codeine (for sale)	30,731,558
Dextropropoxyphene	35
Dihydrocodeine	156,713
Dihydroetorphine	2
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	88,134
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	813,005
Glutethimide	25
Hydrocodone (for conversion)	1,250

Basic class	Established 2020 quotas (g)
Hydrocodone (for sale)	34,836,854
Hydromorphone	3,054,479
Isomethadone	30
Levo-alphacetylmethadol (LAAM)	5
Levomethorphan	30
Levorphanol	38,000
Lisdexamfetamine	21,000,000
Meperidine	1,463,873
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	22,278,000
Methadone Intermediate	24,064,000
Methamphetamine	1,213,603
[678,878 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 505,231 grams for methamphetamine mostly for conversion to a schedule III product; and 29,494 grams for methamphetamine (for sale)]	
Methylphenidate	57,438,334
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	4,089,000
Morphine (for sale)	29,353,655
Nabilone	62,000
Noroxymorphone (for conversion)	19,169,340
Noroxymorphone (for sale)	376,000
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	28,705,000
Oxycodone (for conversion)	914,010
Oxycodone (for sale)	67,593,983
Oxymorphone (for conversion)	24,525,540
Oxymorphone (for sale)	829,051
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	70,829,235
List I Chemicals	
Ephedrine (for conversion)	25
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,100,000
Phenylpropanolamine (for sale)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	174,246,000

The Administrator also establishes aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 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 2020 aggregate production quotas and assessment of annual needs as needed.

Dated: November 27, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019-26119 Filed 11–29–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0311]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Reinstatement, With Change, of Previously Approved Collection: National Inmate Survey in Prisons (NIS–4P)

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until January 31, 2020.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Amy Lauger, Supervisory Statistician, Institutional Research and Special Projects Unit, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *Amy.Lauger@ojp.usdoj.gov;* telephone: 202–307–0711).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether, and if so how, the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1 *Type of Information Collection:* Reinstatement, with change, of a previously approved collection.

2 *The Title of the Form/Collection:* National Inmate Survey in Prisons (NIS–4P).

3 *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* There is no agency form number at this time. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

4 *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents will primarily be State, Local, or Tribal Government entities. The work under this clearance will be used to produce estimates for the incidence and prevalence of sexual victimization within correctional facilities as required under the Prison Rape Elimination Act of 2003 (Pub. L. 108–79). The Bureau of Justice Statistics uses this information in published reports and for the U.S. Congress, Executive Office of the President, practitioners, researchers, students, the media, and others interested in criminal justice statistics.

In 2003, the Prison Rape Elimination Act (PREA or the Act) was signed into law. The Act requires BJS to ''carry out, for each calendar year, a comprehensive statistical review and analysis of the incidence and effects of prison rape.'' The Act further instructs BJS to collect survey data: ''. . . the Bureau shall . . . use surveys and other statistical studies of current and former inmates . . .''

To implement the Act, BJS developed the National Prison Rape Statistics Program (NPRS), which includes four separate data collection efforts: The Survey on Sexual Violence (SSV), the National Inmate Survey (NIS), the National Survey of Youth in Custody (NSYC), and the National Former Prisoner Survey (NFPS). The NIS collects information on sexual victimization self-reported by inmates held in adult correctional facilities, both prisons and jails. The NIS has been conducted three times, in 2007 (NIS–1), in 2008–09 (NIS–2), and in 2011–12 (NIS–3). Each iteration of NIS was conducted in at least one facility in all 50 states and the District of Columbia. In each iteration of the survey, inmates completed the survey using an audio computer-assisted self-interview (ACASI), whereby they heard questions and instructions via headphones and responded to the survey items via a touch-screen interface.

The collection requested in this notice is the fourth iteration of the National Inmate Survey. For NIS–4, administration of the survey in prisons will take place separately from survey administration in jails. This collection request is specific to conducting the survey in adult prison facilities.

The survey instrument for the NIS–4 in Prisons is slightly modified from the previous iterations. The main difference is the addition of a new set of incident-specific questions administered to respondents who affirmatively indicate they were sexually victimized at some point in the previous 12 months while housed in their current prison facility. These incident-specific questions will provide information to the public on the nature of sexual victimization in prisons, such as where incidents occurred within the facility, the relationship between the victim and the alleged perpetrator(s), and whether the victim suffered any injuries as a result of the incident, among other incident characteristics.

5 *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Prior to data collection commencing in 2020, BJS will coordinate the logistics of NIS–4 survey administration with staff at state, local, and tribal correction facilities. Because the administration of this survey in jails is not included in this request, the overall number of burden hours is lower than in the last request approved in 2010 (the jail survey will be submitted under a new OMB number). It is estimated that 150 facility respondents will devote 180 minutes of time to this coordination effort. During data collection in 2020, 77,000 state, local, and tribal adult inmates held in prisons