SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on September 12, 2022, National Center for Natural Products Research, Coy Waller Research Center, 806 Hathorn Road, University, Mississippi 38677–1848, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to manufacture the listed controlled substances for product development and reference standards. In reference to drug codes 7360 (Marihuana) and 7370 (Tetrahydrocannabinols), the company plans to isolate these controlled substances from procured 7350 (Marihuana Extract). In reference to drug code 7360, no cultivation activities are authorized for this registration. No other activities for these drug codes are authorized for this registration.

Kristi O'Malley,

Assistant Administrator.

[FR Doc. 2022–22579 Filed 10–17–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1051P]

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 2023

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2023 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

DATES: 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 November 17, 2022. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Based on comments received in response to this notice, the Administrator may hold a public hearing on one or more issues raised. In the event the Administrator decides in her sole discretion to hold such a hearing, the Administrator will publish a notice of any such hearing in the **Federal Register**. After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will publish in the **Federal Register** a final order establishing the 2023 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–1051P'' 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, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

Comments containing personal identifying information or confidential business information identified and located as directed above will generally be made available in redacted form. If a comment contains so much confidential business information or personal

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

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

Legal Authority

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

Analysis for Proposed 2023 Aggregate Production Quotas and Assessment of Annual Needs

The proposed 2023 aggregate production quotas (APQ) 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 2023 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 2023 aggregate production quotas, the Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1303.11, including the following seven factors:

(1) Total net disposal of the class by all manufacturers during the current and two 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 [21 CFR] 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 of 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 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.

DEA formally solicited input from FDA and CDC in February of 2022 and from the states in April 2022, as required by 21 U.S.C. 826 and 21 CFR part 1303. DEA did not solicit input from CMS for reasons discussed in previous notices (*see* 85 FR 54414; 85 FR 54407). DEA requested information on trends in the legitimate use of select schedule I and II controlled substances from FDA and rates of overdose deaths for covered controlled substances from CDC. DEA's request for information from the states was made directly to the Prescription Drug Monitoring Program (PDMP) Administrators in each state as well as through the National Association of State Controlled Substances Authorities (NASCSA).

Assessment of Annual Needs

In similar fashion, in determining the proposed 2023 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, the Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1315.11, including the five following factors:

(1) Total net disposal of the chemical by all manufacturers and importers during the current and two 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 [21 CFR] 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 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).

In determining the proposed 2023 assessment of annual needs, DEA used the calculation methodology previously described in the 2010 and 2011 assessments of annual needs (74 FR 60294, Nov. 20, 2009, and 75 FR 79407, Dec. 20, 2010, respectively).

Estimates of Medical Need for Schedule II Opioids and Stimulants

In accordance with 21 CFR part 1303, 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 needs of the United States for a given calendar year. The responsibility to provide these estimates of legitimate domestic medical needs resides with FDA. FDA provides DEA with predicted estimates of domestic medical usage for selected controlled substances based on information available to them at a specific point in time in order to meet statutory requirements.

FDA predicts that levels of medical need for schedule II opioids in the United States in calendar year 2023 will decline on average 5.3 percent from calendar year 2022 levels. These declines are expected to occur across a variety of schedule II opioids including fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone. DEA considered the potential for diversion of schedule II opioids, as required by 21 CFR 1303.11(b)(5), as well as a potential increase in demand for certain opioids identified as being necessary to treat ventilated patients with COVID–19, pursuant to 21 CFR 1303.11(b)(7), in the proposed 2023 aggregate production quotas.

FDA predicted less than a 0.1 percent decline in domestic medical use of the schedule II stimulants amphetamine, methylphenidate (including

dexmethylphenidate), and lisdexamfetamine, which are widely used to treat patients with attention deficit hyperactivity disorder (ADHD). FDA also raised concerns over drug shortage notifications it received from patients for specific ADHD medications containing methylphenidate and amphetamine. DEA considered FDA's concerns when calculating the aggregate production quota for these substances.

DEA has grown increasingly concerned over the forces that may be impacting the misuse of prescription stimulants among young adults, which coincides with an increase in demand for illicit methamphetamine and cocaine. These medications are all placed in schedule II because of their high abuse liability and associated risk of addiction. Due to the expansion of diagnostic criteria and treatment of ADHD, the domestic demand for these products (in terms of prescriptions written) has increased over the past two decades and so have the number of FDA approved drug products used to treat the condition. For example, Concerta (long-acting methylphenidate) was introduced in 2000, Ritalin LA (methylphenidate) in 2002, Adderall (dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate) in 2002, and Vyvanse (lisdexamfetamine) in 2007. Patients respond in different ways to different medications; therefore, a variety of products to treat ADHD are available now, but domestic demand is no longer increasing as it was in the past.

Stimulants prescribed to treat ADHD are some of the most diverted drugs among those adolescents that are at risk of substance abuse and dependence.[1] The diversion of ADHD medications for the purposes of recreational use or performance enhancement is common,[2] with approximately 5–10 percent of high school students and 5–35 percent of college students, depending on the study, misusing and diverting stimulants prescribed for ADHD.[3] As a consequence, DEA continues to consult with federal partners at HHS and is closely monitoring trends in licit and illicit stimulant use and corresponding diversion and misuse.

DEA Estimated Projected Trends for Certain Schedule I Controlled Substances

There has been a significant increase in the use of schedule I hallucinogenic controlled substances for research and clinical trial purposes. DEA has received and subsequently approved new registration applications for schedule I researchers and new applications for registration from manufacturers to grow, synthesize, extract, and prepare dosage forms containing specific schedule I hallucinogenic substances for clinical trial purposes. DEA supports regulated research with schedule I controlled substances, as evidenced by increases proposed for 2023 as compared with aggregate production quotas for these substances in 2022. Further, DEA published the final rule, ''Controls to Enhance the Cultivation of Marihuana for Research in the United States'' in December 2020, and the agency continues to review and approve applications for schedule I manufacturers of marihuana that conform to the federal requirements contained in the CSA. *See* 21 CFR part 1318. DEA has proposed increases in 5-Methoxy-N,N-dimethyltryptamine, Lysergic acid diethylamide (LSD), Marijuana, Mescaline, Psilocyn, and All Other Tetrahydrocannabinols to support manufacturing activities related to the increased level of research and clinical trials with these schedule I controlled substances.

Information Received for Consideration of the Remaining Factors

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 information by submitting their individual data to DEA database systems used for reporting inventory, and for distribution, manufacturing, and estimated quota requirements to meet sales forecasts, for each class of controlled substance. *See* 21 CFR 1303.12, 1303.22, and part 1304.

The regulation at 21 CFR 1303.11(b)(5) requires DEA to consider the extent of diversion of controlled substances.[4] Diversion is defined as all distribution, dispensing, or other use of controlled substances for other than legitimate medical purposes. In order to consider the extent of diversion, DEA analyzed reports of diversion of controlled substances from 2021 submitted to its Theft Loss Report database. This database is comprised of DEA registrant reports documenting diversion from the legitimate distribution chain, including employee thefts, break-ins, armed robberies, and material lost in transit. 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).

In this proposed 2023 aggregate production quota, DEA also considered the effects of the COVID–19 pandemic, pursuant to 21 CFR 1303.11(b)(7), relative to the continued increase in demand for opioids necessary to treat ventilated patients.

Estimates of Diversion of Covered Controlled Substances

DEA is required:

In establishing any quota . . ., or any procurement quota established by [DEA] by regulation, for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (in this subsection referred to as a ''covered controlled substance''), [to] estimate the amount of diversion of the covered controlled substance that occurs in the United States.

21 U.S.C. 826(i)(1)(A).

In estimating diversion under that provision, DEA:

(i) shall consider information, in consultation with the Secretary of Health and Human Services, [it] determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and

(ii) may take into consideration whatever other sources of information [it] determines reliable.

21 U.S.C. 826(i)(1)(B).

The statute further mandates that DEA ''make appropriate quota reductions, as determined by [DEA], from the quota [it] would have otherwise established had such diversion not been considered.'' [5]

In estimating the amount of diversion of each covered controlled substance that occurs in the United States, DEA considered information from state PDMP Administrators and from legitimate distribution chain participants.

[1] Epstein-Ngo QM, et al., Diversion of ADHD Stimulants and Victimization Among Adolescents, 41 J Ped Psychol 788–798 (2015).

[2] Wilens TE, et al., Misuse and Diversion of Stimulants Prescribed for ADHD: A Systematic Review of the Literature, 47 J Amer Acad Child Adolesc Psychiatry 21–31 (2008).

[3] Epstein-Ngo QM, et al., Diversion of ADHD Stimulants and Victimization Among Adolescents, 41 J Ped Psychol 788–798 (2015).

[4] The estimates of diversion for five ''covered controlled substances'' as required by 21 U.S.C. 826(i) are discussed later in the document.

[5] 21 U.S.C. 826(i)(1)(C).

Consideration of Information From Certain State PDMPs and From National Sales Data

Pursuant to 21 CFR 1303.11(b)(6), DEA requested state PDMP data for the purpose of establishing its aggregate production quotas. DEA believes state PDMPs to be an essential, reliable source of information for use in effectively estimating diversion of the five covered controlled substances. In April 2022, DEA sent a letter to NASCSA requesting its assistance in obtaining aggregated PDMP data for the five covered controlled substances from each state covering the years 2019–2021. The letter indicated that DEA was specifically interested in an analysis of prescription data from each state's PDMP that would assist DEA in estimating diversion and setting appropriate quotas in compliance with 21 U.S.C. 826(i). In its request, DEA provided specific questions, discussed in detail below, based on common indicia of potential diversion known as ''red flags'' by physicians, pharmacists, manufacturers, distributors, and federal and state regulatory and law enforcement agencies.[6]

DEA requested responses from state PDMP Administrators by June 1, 2022. NASCSA disseminated DEA's request to its PDMP Administrators and provided them with a report tool to ensure that responses to DEA's questions were extracted consistently across all responsive states. Twenty-seven states and three territories provided DEA with summarized PDMP data between April 12 and June 27, 2022, utilizing the standardized report developed by NASCSA.[7] See Table 1a below.

TABLE 1A—STATES/TERRITORIES THAT RESPONDED TO DEA'S DATA REQUEST

State/territory
1. Alabama.
2. Alaska.
3. Arizona.
4. Arkansas.
5. Delaware.
6. District of Columbia.
7. Guam.
8. Hawaii.
9. Indiana.
10. Iowa.
11. Kansas.
12. Kentucky.
13. Louisiana.
14. Maryland.
15. Michigan.
16. Mississippi.
17. Montana.
18. Nevada.
19. New Jersey.
20. New Mexico.
21. North Carolina.
22. North Dakota.
23. Oregon.
24. Puerto Rico.
25. Rhode Island.
26. South Carolina.
27. South Dakota.
28. Texas.
29. Utah.
30. Virginia.

Pharmacies are required by state law to enter controlled substance dispensing data into the state's PDMP database, including the prescriber's name, registered address and DEA number; prescription information (such as drug name); dispensing date; dosage dispensed; pharmacy registered address; and patient name and address. DEA considers PDMP data to be an accurate representation of dispensing activities in states. DEA received data for the following red-flag metrics:

- The total number of patients who saw three or more prescribers in a 90-day period and were dispensed an opioid following each visit. For this metric, DEA requested and was provided the number of prescriptions for the five covered controlled substances dispensed to these patients, as a percentage of the total prescriptions dispensed for that particular covered controlled substance, as well as the corresponding quantity of the covered controlled substance dispensed. This metric (patients being prescribed covered controlled substances from three or more prescribers in a 90-day period) is used to identify potential doctor shopping, a common technique to obtain a high number of controlled substances, which may lead to abuse or diversion of controlled substances. DEA has long considered doctor shopping to be an indicator of potential diversion.[8]
- The number of patients that were dispensed prescriptions for each of the five covered controlled substances that exceeded 240 morphine milligram equivalents (MME) daily. States provided the raw number of such prescriptions dispensed, the number of prescriptions as a percentage of the total covered controlled substance prescriptions dispensed, and the corresponding quantity of the covered controlled substance dispensed. The CDC has advised prescribers to avoid increasing dosages of opioids beyond 90 MME for patients with chronic pain.[9] DEA believes that accounting for quantities in excess of 240 MME daily allows for consideration of oncology patients with legitimate medical needs for covered controlled substance prescriptions in excess of 90 MME daily. Higher dosages place individuals at higher risk of overdose and death. Prescriptions involving dosages exceeding 240 MME daily may indicate diversion, such as illegal distribution of controlled substances or prescribing outside the usual course of professional practice.
- The number of patients that paid cash for covered controlled substance prescriptions, without submitting for insurance reimbursement.[10] States also provided the number of prescriptions paid entirely with cash as a percentage of the total prescriptions for the five covered controlled substances dispensed, as well as the corresponding quantity of the covered controlled substances dispensed. When investigating potential diversion, cash payments are one element considered in identifying prescriptions filled for nonmedical purposes. Unusually high percentages of cash payments made to a prescriber or pharmacy for controlled substances may indicate diversion.[11]

DEA received PDMP data from the states in a standardized format that allowed DEA to aggregate the data. The PDMP data sample represents a population of approximately 125.9

[6] National Association of Boards of Pharmacy (NABP) coalition consensus document ''Stakeholders Challenges and Red Flags and Warning Signs Related to Prescribing and Dispensing Controlled Substances'' (2015). www.nabp.pharmacy/resources/reports. For example, DEA investigators and administrative prosecutors rely on Agency case law in which these red flags of diversion have been upheld as indicia of potential diversion. *See, e.g.,* The Medicine Shoppe, 79 FR 59504, 59507, 59512–13 (2014); Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 FR 62316 (2012). Certain state regulations also now include red flag circumstances as potential indicators of illegitimate prescriptions, and thus of potential abuse and diversion of controlled substances. *See* The Pharmacy Place Order, 86 FR 21008, at 21012 (2021) (citing 22 Tex. Admin. Code 291.29(c)(4), specifying the geographical distance between the practitioner and the patient or between the pharmacy and the patient). This rule discusses only the use of red flags by DEA as an analytical tool to estimate diversion, not for any other purpose.

[7] NASCSA formatted DEA's request into an analytics model developed by one of its associates, Appriss Inc.

[8] Frank's Corner Pharmacy, 60 FR 17574 (1995); Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 FR 62316 (2012).

[9] *www.cdc.gov/drugoverdose/pdf/prescribing/Guidelines_factsheet-a.pdf.*

[10] This total does not include insurance co-payments made with cash.

[11] Suntree Pharmacy and Suntree Medical Equipment, LLC, 85 FR 73753 (2018) (finding that the pharmacy filled prescriptions despite the presence of multiple unresolved red flags, including cash payments); Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy, 83 FR 10876 (2018) (revoking pharmacy's registration for filling prescriptions that raised the red flag of customers paying cash for their prescriptions, among other red flags).

million people, which is approximately 38 percent of the U.S. population. DEA believes this sample is sufficient to derive a reasonable nationwide estimate.

While PDMP data is useful in estimating diversion, it is not conclusive. Further investigation would be required before concluding that any of the subject prescriptions were actually diverted. DEA continues to evaluate its methodologies in estimating diversion in an effort to adjust quotas more efficiently. State participation is crucial to accurate data analysis, and DEA anticipates working closely with states, as well as other federal and state entities, in future quota determinations.

To calculate a national diversion estimate for each of the covered controlled substances from the responses received from state PDMP Administrators, DEA relied upon the number of individuals who received a prescription for a covered controlled substance that met any of the three diversion metrics for each of calendar years 2019–2021. Using the population of the states responding to DEA's request, DEA then calculated the percentage of the population issued a prescription with a red flag. Using this estimated percentage for 2019–2021, DEA analyzed trends in the data to predict the estimated percentage of patients who would be expected to meet these diversion metrics for 2023.

DEA also reviewed aggregate sales data for each of the covered controlled substances, which it extracted from IQVIA's National Sales Perspective.[12] IQVIA sales data was selected to help quantify diversion at the national level because it reflects the best national estimate for all prescriptions written and filled, including the total quantity available for diversion or misuse. DEA analyzed trends in IQVIA sales data from January 2019–May 2022, in order to predict the estimated national sales for 2023.

To estimate diversion for each of the covered controlled substances, DEA multiplied the forecasted percentage of patients likely to receive a prescription for a covered controlled substance that meet any of the three diversion-related metrics in 2023 by the forecasted sales data from IQVIA for 2023. The resulting estimate of diversion from data submitted by state PDMP Administrators is summarized below in Table 1b. This data contributed to the final diversion estimate set forth in Table 3.

TABLE 1b—DIVERSION ESTIMATES BASED ON STATE PDMP DATA FOR COVERED CONTROLLED SUBSTANCES

Controlled substance	(g)
Fentanyl	58
Hydrocodone	112,346
Hydromorphone	355
Oxycodone	146,201
Oxymorphone	0

Consideration of Registrant Reported Diversion in the Legitimate Distribution Chain

DEA extracted data from its Theft Loss Report database and categorized it by each basic drug class. DEA calculated the estimated amount of diversion by multiplying the quantity of API in each finished dosage form by the total amount of units reported stolen or lost to estimate the metric weight in grams of the controlled substance being diverted. This estimate of diversion from the legitimate supply chain for each of the covered controlled substances is displayed in Table 2. This data contributed to the final diversion estimates set forth in Table 3.

TABLE 2—DIVERSION ESTIMATES BASED ON SUPPLY CHAIN DIVERSION DATA FOR COVERED CONTROLLED SUBSTANCES

Controlled substance	(g)
Fentanyl	6
Hydrocodone	4,048
Hydromorphone	227
Oxycodone	16,750
Oxymorphone	109

In accordance with 21 U.S.C. 826(i), DEA's estimate of diversion for the five controlled substances was calculated by combining the values in Tables 1b and 2. DEA reduced the aggregate production quotas for each covered controlled substance by the quantities listed in Table 3.

TABLE 3—TOTAL ESTIMATES OF DIVERSION FOR COVERED CONTROLLED SUBSTANCES

Total diversion estimates applied to the 2023 APQ (g)
Fentanyl 64
Hydrocodone 116,394
Hydromorphone 582
Oxycodone 162,951
Oxymorphone 109

The Administrator, therefore, proposes to establish the 2023 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 2023 quotas (g)
Schedule I	
-[1-(2-Thienyl)cyclohexyl]pyrrolidine	20
1-(1-Phenylcyclohexyl)pyrrolidine	30
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-[1-(2-Thienyl)cyclohexyl]piperidine	15
2′-fluoro 2-fluorofentanyl	30
1-Benzylpiperazine	25
1-Methyl-4-phenyl-4-propionoxypiperidine	10
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C–N)	30
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C–P)	30

[12] DEA has purchased this data from IQVIA for decades and routinely uses this information to administer several regulatory functions, including the administration of DEA's quota program.

Basic class	Proposed 2023 quotas (g)
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	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)	200
3,4-Methylenedioxymethamphetamine (MDMA)	8,200
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	40
3,4-Methylenedioxypyrovalerone (MDPV)	35
3–FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4,4′-Dimethylaminorex	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
4–CN-Cumyl-Butinaca	25
4-Fluoroisobutyryl fentanyl	30
4F–MDMB–BINACA	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-alpha-ethylaminopentiophenone (4–MEAP)	25
4-Methyl-alpha-pyrrolidinohexiophenone (MPHP)	25
4′-Methyl acetyl fentanyl	30
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–AB–PINACA; (1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide	25
5F–ADB; 5F–MDMB–PINACA (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	25
5F–CUMYL–P7AICA; 1-(5-Fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3carboximide	25
5F–CUMYL–PINACA	25
5F–EDMB–PINACA	25
5F–MDMB–PICA	25
5F–AMB (methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate)	25
5F–APINACA; 5F–AKB48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide)	25
5-Fluoro-PB–22; 5F–PB–22	25
5-Fluoro-UR144, XLR11 ([1-(5-fluoro-pentyl)-1Hindol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	6,000
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	15,000
Allylprodine	25
Alphacetylmethadol	25
alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
alpha-Methylfentanyl	30
alpha-Methylthiofentanyl	30

Basic class	Proposed 2023 quotas (g)
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-pyrrolidinoheptaphenone (PV8)	25
alpha-pyrrolidinohexabophenone (alpha-PHP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Aminorex	25
Anileridine	20
APINCA, AKB48 (N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide)	25
Benzethidine	25
Benzylmorphine	30
Betacetylmethadol	25
beta-Hydroxy-3-methylfentanyl	30
beta-Hydroxyfentanyl	30
beta-Hydroxythiofentanyl	30
beta-Methyl fentanyl	30
beta′-Phenyl fentanyl	30
Betameprodine	25
Betamethadol	4
Betaprodine	25
Brorphine	30
Bufotenine	15
Butonitazene	30
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Crotonyl Fentanyl	25
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
d-9-THC	384,460
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,300
Dihydromorphine	653,548
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	3,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Ethylone	25
Etodesnitazene	30
Etonitazene	25
Etorphine	30
Etoxeridine	25
Fenethylline	30
Fentanyl carbamate	30
Fentanyl related substances	600
Flunitazene	30
FUB–144	25
FUB–AKB48	25
Fub-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
gamma-Hydroxybutyric acid	29,417,000
Heroin	150
Hydromorphinol	40
Hydroxypethidine	25
Ibogaine	30
Isobutyryl Fentanyl	25
Isotonitazine	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

Basic class	Proposed 2023 quotas (g)
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
Levophenyacylmorphan	25
Lysergic acid diethylamide (LSD)	1,200
MAB–CHMINACA; ADB–CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30
MDMB–CHMICA; MMB–CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB–FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB–CHMICA-(AMB–CHIMCA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
Metodesnitazene	30
Metonitazene	30
Marijuana	6,675,000
Marijuana extract	1,000,000
Mecloqualone	30
Mescaline	1,200
Methaqualone	60
Methcathinone	25
Methoxetamine	30
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-fluorpentyl)-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
Nicocodeine	25
Nicomorphine	25
N-methyl-3-piperidyl benzilate	30
N-Pyrrolidino Etonitazene	30
Noracymethadol	25
Norlevorphanol	2,550
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
ortho-Fluoroacryl fentanyl	30
ortho-Fluorobutyryl fentanyl	30
Ortho-Fluorofentanyl,2-Fluorofentanyl	30
ortho-Fluoroisobutyryl fentanyl	30
ortho-Methyl acetylfentanyl	30
ortho-Methyl methoxyacetyl fentanyl	30
Para-Chlorisobutyrl fentanyl	30
Para-flourobutyryl fentanyl	25
Para-fluorofentanyl	25
para-Fluoro furanyl fentanyl	30
Para-Methoxybutyrl fentanyl	30
Para-methoxymethamphetamine	30
para-Methylfentanyl	30
Parahexyl	5
PB–22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphan	25

Basic class	Proposed 2023 quotas (g)
Phenoperidine	25
Phenyl fentanyl	30
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Protonitazene	30
Psilocybin	8,000
Psilocyn	8,000
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
Thiofuranyl fentanyl	30
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)	886,415
Alfentanil	5,000
Alphaprodine	25
Amobarbital	20,100
Bezitramide	25
Carfentanil	20
Cocaine	60,492
Codeine (for conversion)	1,085,024
Codeine (for sale)	21,003,397
D-amphetamine (for sale)	21,200,000
D,L-amphetamine	21,200,000
D-amphetamine (for conversion)	20,000,000
Dexmethylphenidate (for sale)	6,200,000
Dexmethylphenidate (for conversion)	4,200,000
Dextropropoxyphene	35
Dihydrocodeine	132,658
Dihydroetorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	60,492
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	691,447
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	27,239,822
Hydromorphone	1,994,117
Isomethadone	30
L-amphetamine	30
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	23,010
Lisdexamfetamine	26,500,000
Meperidine	681,289
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
Methamphetamine	150
d-methamphetamine (for conversion)	485,020
d-methamphetamine (for sale)	40,000

Basic class	Proposed 2023 quotas (g)
l-methamphetamine	587,229
Methylphenidate (for sale)	41,800,000
Methylphenidate (for conversion)	15,300,000
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	2,458,460
Morphine (for sale)	21,747,625
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	22,044,741
Noroxymorphone (for sale)	1,000
Oliceridine	25,100
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	33,010,750
Oxycodone (for conversion)	437,827
Oxycodone (for sale)	53,840,608
Oxymorphone (for conversion)	28,204,371
Oxymorphone (for sale)	516,351
Pentobarbital	33,843,337
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	100
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	11,941,416
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)	7,990,000
Pseudoephedrine (for conversion)	1,000
Pseudoephedrine (for sale)	174,246,000

The Administrator further proposes that aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

These proposed 2023 quotas reflect the quantities that DEA believes are necessary to meet the estimated medical, scientific, research, and industrial needs of the United States, including any increase in demand for certain controlled substances used to treat patients with COVID–19; lawful export requirements; and the establishment and maintenance of reserve stocks. 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 her authority, the Administrator will move swiftly and decisively to increase any 2023 aggregate production quota that she 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 Administrator may adjust the 2023 aggregate production quotas and assessment of annual needs as needed. These assessments are subject to reevaluation pursuant to 21 U.S.C. 826 and 21 CFR 1303.13(a)–(b).

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will issue and publish in the **Federal Register** a final order establishing the 2023 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, as directed by 21 CFR 1303.11(c) and 1315.11(f).

Signing Authority

This document of the Drug Enforcement Administration was signed on October 13, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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