Dated: November 12, 2021.

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Management Analyst, Rules Committee Staff.

[FR Doc. 2021–22549 Filed 10–15–21; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–888P]

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 2022

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice with request for comments.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to establish the 2022 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, 2021. 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 2022 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–888P'' 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) 776–2265.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

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

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

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

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

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

Legal Authority

Section 306 of the CSA (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 the DEA pursuant to 28 CFR 0.100.

Analysis for Proposed 2022 Aggregate Production Quotas and Assessment of Annual Needs

The proposed 2022 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 2022 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 2022 aggregate production quotas, the Administrator has taken into account the criteria of 21 U.S.C. 826(a) and 21 CFR 1303.11. DEA proposes the aggregate production quotas for 2022 by considering 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 Sec. 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.

Assessment of Annual Needs

In similar fashion, in determining the proposed 2022 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 and considered 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 Sec. 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 2022 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).

DEA formally solicited input from FDA, CDC, CMS, and the states in February and March of 2021, as required by 21 U.S.C. 826 and 21 CFR part 1303. Specifically, DEA requested information on trends in the legitimate use of select schedule I and II controlled substances from FDA, rates of overdose deaths for covered controlled substances from CDC, and diversion of covered controlled substances from CMS. DEA's request for information from the states was made to Prescription Drug Monitoring Program (PDMP) Administrators through the National Association of State Controlled Substances Authorities (NASCSA).

Information From the Food and Drug Administration—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 medical needs resides with FDA. FDA provides DEA with its predicted estimates of medical usage for selected controlled substances based on information available to them at a specific point in time in order to meet statutory requirements. With regard to medical usage of schedule II opioids, FDA predicts levels of medical need for the United States will decline on average 18.88 percent between calendar years 2021 and 2022. 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 well as a potential increase in demand for certain opioids identified as necessary to treat ventilated patients with COVID–19 in the table of proposed 2022 aggregate production quotas listed below, as is required pursuant to 21 CFR 1303.11(b)(7).

With regard to the schedule II stimulants amphetamine, methylphenidate, and lisdexamfetamine, which are widely used to treat patients with attention deficit hyperactivity disorder (ADHD), FDA predicted a 1.66 percent decline in domestic medical use. FDA also raised concerns over drug shortage notifications it received from patients for certain medications as well as recalls for specific ADHD medications. DEA considered FDA's concerns when calculating the aggregate production quota for these substances. In addition, DEA has observed a significant increase in the number of quota applications for product development efforts as well as exports for medical use for these controlled substances. For example, exports of schedule II stimulant products in calendar year 2020 totaled 75 percent more than FDA's estimated domestic medical need for stimulant products manufactured from these three controlled substances, which demonstrated that significant quantities of schedule II stimulants produced domestically are intended for export.

While DEA has observed a significant increase in demand among domestic manufacturers to bring generic ADHD-products to a relatively stable domestic market, it has also grown increasingly concerned over how these market forces may impact the misuse of prescription stimulants among young adults, which in turn coincides with an increase in demand for illicit stimulants (*i.e.,* methamphetamine and cocaine). It is notable that major increases in diagnosis and treatment of ADHD coincide with FDA approval of various stimulants: Concerta (long-acting methylphenidate) in 2000, Ritalin LA (methylphenidate) in 2002, Adderall (dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate) in 2002, and Vyvanse (lisdexamfetamine) in 2007. These medications are all placed in schedule II because of their high abuse liability and associated risk of addiction.

Stimulants prescribed to treat ADHD are some of the most diverted drugs among adolescents with risk for the development of abuse and dependence.[1] [2] Increasing diagnoses of

[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

Continued

this disorder have led to increases in filled prescriptions and changes to the APQ to meet patients' medical needs. The diversion of ADHD medications for the purposes of recreational abuse or performance enhancement is common, 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 is consulting with federal partners at HHS and closely monitoring trends in licit and illicit stimulant use and corresponding diversion and misuse.

Information Received by DEA Regarding 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 applications for schedule I research registrations and new applications for registration from manufacturers and corresponding quota applications to grow, synthesize, extract, and manufacture 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 2022 as compared with aggregate production quotas for these substances in 2021. 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 is working diligently to review and approve applications for schedule I manufacturers of marihuana that conform to the federal requirements contained in the CSA. *See* 85 FR 82333. Based on the increase in research and clinical trial applications, DEA has proposed increases in 3,4-Methylenedioxyamphetamine (MDA), 3,4-Methylenedioxymethamphetamine (MDMA), 5-Methoxy-N,N-dimethyltryptamine, Dimethyltryptamine, Lysergic acid diethylamide (LSD), Marihuana, Marihuana Extract, Mescaline, Psilocybin, 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 by DEA 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.

Factor 1303.11(b)(5) requires DEA to consider the extent of diversion of controlled substances. 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 extracted individual registrant reports of diversion of controlled substances from 2020 from its Theft Loss Report database. This database is comprised of DEA registrant reported entries documenting diversion in the legitimate distribution chain consisting of employee theft, 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). The estimates of diversion as required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act of 2018 (SUPPORT Act) (Pub. L. 115–271) are discussed later in the document.

In this proposed 2022 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 Pursuant to the SUPPORT Act

The SUPPORT Act mandates that in establishing any quota under 21 U.S.C. 826, or any procurement quota established by regulation, for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (referred to as a ''covered controlled substance''), DEA ''shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.'' In estimating diversion under 21 U.S.C. 826(i)(1), DEA:

(1) ''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

(2) ''may take into consideration'' whatever other sources of information it determines reliable.

The SUPPORT Act 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.'' 21 U.S.C. 826(i)(1)(C).

In determining an estimate of the amount of diversion of the covered controlled substance that occurs in the United States, DEA considered information from state PDMP Administrators and legitimate distribution chain participants as described in detail below.

Information From PDMPs Provided by Certain States for Consideration in the Estimate of Diversion

Pursuant to 21 CFR 1303.11(b)(6), DEA requested state PDMP data for the purpose of establishing its aggregate production quota. DEA believes state PDMPs to be an essential, reliable source of information from which it can effectively estimate diversion of the five covered controlled substances. This year, in March 2021, DEA sent a letter to NASCSA requesting its assistance in obtaining aggregated PDMP data for the five covered controlled substances from each state. DEA indicated that it was specifically interested in obtaining an analysis of prescription data from each state's PDMP that would assist DEA in estimating diversion and setting appropriate quotas in compliance with the SUPPORT Act. In its request, DEA provided specific questions, discussed in detail below, based on common indicia of potential diversion well-known as ''red flags'' by physicians, pharmacists, manufacturers, distributors, and federal and state regulatory and law enforcement agencies.[4] DEA investigators and administrative prosecutors also rely on Agency case law in which these red flags of diversion have been upheld as indicia of potential diversion.[5] [6] Certain

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] 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.

[5] The Medicine Shoppe, 29 FR 59504, 59507, 59512–13 (2014); Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 57 FR 62316 (2012).

[6] The mere indicia of red flags alone is not proof of violation of 21 U.S.C. 824 or any other violation

state regulations 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).

DEA requested responses from state PDMP Administrators by June 1, 2021. 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 states that responded. Sixteen states and one county provided DEA with summarized PDMP data between June 2 and July 13, 2021, utilizing the standardized report developed by NASCSA.[7] See Table 1a below.

TABLE 1a—STATES/COUNTIES THAT RESPONDED TO DEA'S DATA REQUEST

State/territory
1. Alabama.
2. Alaska.
3. Arizona.
4. Delaware.
5. Hawaii.
6. Iowa.
7. Indiana.
8. Michigan.
9. Mississippi.
10. Montana.
11. New Jersey.
12. New Mexico.
13. Nevada.
14. Rhode Island.
15. St. Louis County, Missouri.
16. South Carolina.
17. Virginia.

Pharmacies are required by state law to enter controlled substance dispensing data into the state's PDMP database, which includes, among other things, the prescriber's name, registered address and DEA number, prescription information (such as drug name), dispensing date, dosage dispensed, pharmacy registered address information, and patient address. DEA considers PDMP data to be an accurate representation of dispensing activities in states. DEA, through NASCSA, requested information from state PDMP Administrators covering 2018–2020 regarding the five covered controlled substances. 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 received an opioid at each visit. For this metric, DEA was specifically interested in the number of prescriptions dispensed for the five covered controlled substances to these patients, expressed 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 used 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 prescriptions for each of the five covered controlled substances dispensed that exceeded 240 morphine milligram equivalents (MME) daily, expressed as a percentage of the total covered controlled substance prescriptions dispensed as well as 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. Numerous dispensings of prescriptions with 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 covered controlled substance prescriptions paid for entirely by cash and not submitted for insurance reimbursement.[10] This response was expressed 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 when identifying prescriptions filled for nonmedical purposes. Prescribers or pharmacies with unusually high percentages of cash payments 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 of each state. The PDMP data sample comes from a population of approximately 78.5 million people, which represents approximately 24 percent of the U.S. population. DEA believes this sample is sufficient to derive a reasonable nationwide estimate.

DEA recognizes that the PDMP data received does not show that meeting any single one of the criteria listed above is enough to establish conclusively that the subject prescriptions were 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.

DEA's Analysis of Reports Received From State PDMP Administrators

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 2018–2020. That number was then compared to the corresponding population for the states responding to DEA's request in order to estimate a percentage of the population issued a prescription with a red flag. Using this estimated percentage for 2018–20, DEA analyzed trends in the data to predict the estimated percentage of patients who would be expected to meet these diversion metrics for 2022.

DEA also reviewed aggregate sales data for each of the covered controlled substances, which it extracted from

of the CSA. This rule discusses only their use by DEA as an analytical tool used to estimate diversion.

[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, 57 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).

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 2018–May 2021, in order to predict the estimated national sales for 2022.

DEA multiplied the forecasted percentage of patients who received a prescription for a covered controlled substance that met any of the three diversion-related metrics for 2022 by the forecasted sales data from IQVIA for 2022 to estimate diversion for each of the covered controlled substances. 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 applied in Table 3.

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

Controlled substance	(g)
Fentanyl	16
Hydrocodone	135,591
Hydromorphone	274
Oxycodone	164,838
Oxymorphone	0

Registrant Reported Legitimate Distribution Chain Diversion

DEA extracted data from its Drug Theft and Loss database, and categorized it by each basic drug class. The quantity of API in each dosage form was delineated with the appropriate metric, and then the quantity of API of each covered controlled substance was aggregated by metric weight where the data was available. 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 grams of the controlled substance being diverted. The estimate of diversion 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	77
Hydrocodone	19,448
Hydromorphone	901
Oxycodone	45,582
Oxymorphone	528

In accordance with the SUPPORT Act, DEA's estimate of diversion for the five controlled substances was calculated by combining the values in Tables 1b and 2. DEA made reductions to the aggregate production quotas for each covered controlled substance by the resulting quantities listed in Table 3.

TABLE 3—TOTAL ESTIMATES OF DIVERSION FOR COVERED CONTROLLED SUBSTANCES

Total diversion estimates applied to the 2022 APQ (g)	
Fentanyl	93
Hydrocodone	155,039
Hydromorphone	1,175
Oxycodone	210,420
Oxymorphone	528

The Administrator, therefore, proposes to establish the 2022 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 2022 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
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

[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 2022 quotas (g)
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)	3,200
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-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	550
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	2,000
Allylprodine	25
Alphacetylmethadol	25
alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
alpha-Methylfentanyl	30
alpha-Methylthiofentanyl	30
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

Basic class	Proposed 2022 quotas (g)
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
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	9,200
Dihydromorphine	653,548
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	250
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Ethylone	25
Etonitazene	25
Etorphine	30
Etoxeridine	25
Fenethylline	30
Fentanyl carbamate	30
Fentanyl related substances	600
FUB-144	25
FUB-AKB48	25
Fub-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
gamma-Hydroxybutyric acid	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
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)	500
MAB-CHMINACA; ADB-CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30

Basic class	Proposed 2022 quotas (g)
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
Marijuana	3,200,000
Marijuana extract	1,000,000
Mecloqualone	30
Mescaline	100
Methaqualone	60
Methcathinone	25
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT-45	30
Myrophine	25
NM2201: Naphthalen-1-yl 1-(5-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
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
Phenoperidine	25
Phenyl fentanyl	30
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Psilocybin	3,000
Psilocyn	2,000
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

Basic class	Proposed 2022 quotas (g)
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	3,260
Alphaprodine	25
Amobarbital	20,100
Bezitramide	25
Carfentanil	20
Cocaine	60,492
Codeine (for conversion)	1,364,981
Codeine (for sale)	22,260,178
D-amphetamine (for sale)	21,200,000
D,l-amphetamine	21,200,000
d-amphetamine (for conversion)	18,000,000
Dexmethylphenidate (for sale)	6,200,000
Dexmethylphenidate (for conversion)	6,500,000
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	691,511
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	29,599,888
Hydromorphone	2,097,255
Isomethadone	30
L-amphetamine	30
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	23,010
Lisdexamfetamine	24,000,000
Meperidine	770,588
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
l-methamphetamine	587,229
Methylphenidate (for sale)	41,800,000
Methylphenidate (for conversion)	15,300,000
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	2,584,860
Morphine (for sale)	22,525,461
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	22,044,741
Noroxymorphone (for sale)	1,000
Oliceridine	22,500
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	33,010,750

Basic class	Proposed 2022 quotas (g)
Oxycodone (for conversion)	519,061
Oxycodone (for sale)	54,003,559
Oxymorphone (for conversion)	28,204,371
Oxymorphone (for sale)	516,469
Pentobarbital	30,766,670
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	40
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	13,447,541
Thebaine	57,137,944
List I Chemicals	
Ephedrine (for conversion)	100
Ephedrine (for sale)	4,136,000
Phenylpropanolamine (for conversion)	14,878,320
Phenylpropanolamine (for sale)	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 2022 quotas reflect the quantity that DEA believes is necessary to meet the estimated medical, scientific, research, and industrial needs of the United States, to include any increase in demand for certain controlled substances used to treat patients with COVID–19. DEA remains committed to conducting continuous surveillance on the supply of schedule II controlled substances and list I chemicals necessary to treat patients with COVID–19, and, pursuant to her authority, the Administrator will move swiftly and decisively to increase any 2022 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 2022 aggregate production quotas and assessment of annual needs as needed.

Conclusion

After consideration of any comments or objections, or after a hearing, if one is held, the Administrator will issue and publish in the **Federal Register** a final order establishing the 2022 aggregate production quotas for controlled substances in schedule I and II and establishing an assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, 21 CFR 1303.11(c) and 1315.11(f).

Anne Milgram,

Administrator.

[FR Doc. 2021–22624 Filed 10–15–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Settlement Agreement Under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA")

On October 12, 2021, the Department of Justice lodged a proposed Settlement Agreement in *In re: LGA3 Corp.,* Civil Action No. 20–11456 with the United States Bankruptcy Court for the District of Delaware (Bankruptcy Court).

On June 1, 2020, Syracuse China Company and certain affiliates filed a voluntary petition for relief under Chapter 11 of the Bankruptcy Code, which was jointly administered as *In re: Libbey Glass Inc. et al.,* Case No. 20–11439. Under the First Amended Joint Plan of Reorganization for Libbey Glass and its Affiliate Debtors Under Chapter 11 of the Bankruptcy Code, as confirmed by the Bankruptcy Court, the Debtors have reserved $900,000 as a General Unsecured Recovery Cash Pool to be distributed on a pro rata basis to holders of Allowed General Unsecured Claims.

The United States, on behalf of the United States Environmental Protection Agency (EPA), filed a proof of claim contending that Syracuse China Company was liable under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9601–9675, for the United States' response costs incurred in response to releases and threats of releases of hazardous substances at or in connection with two Operable Units (OUs) of the Onondaga Lake Superfund Site, located in Syracuse, Onondaga County, New York. These OUs are referred to as the Lower Ley Creek OU and the Ley Creek Deferred Media OUs (collectively, the Ley Creek OUs).

Under the Settlement Agreement, the United States on behalf of EPA shall have an Allowed General Unsecured Claim in the amount of $6,616,976 to be allocated between the Ley Creek OUs in proportion to the alleged remedial action costs as alleged in the United States' proof of claim filed in this action.

The publication of this notice opens a period for public comment on the proposed Settlement Agreement. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources