Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—In September 2016, the Commission determined that a U.S. industry was materially injured by reason of imports of hot-rolled steel flat products from Turkey found by the U.S. Department of Commerce (Commerce) to be sold in the United States at less than fair value (81 FR 66996, Sept. 29, 2016).

On September 10, 2021, the Commission received a request to review its affirmative determination in investigation No. 731–TA–1296 (Final) pursuant to section 751(b) of the Act (19 U.S.C. 1675(b)). The request, filed by Eregli Demir ve Celik Fabrikalari T.A.S. (Erdemir), alleges there have been significant changed circumstances since the issuance of the Commission's 2016 determination. Specifically, Erdemir alleges that Commerce's recalculation of Colakoglu's antidumping duty margin to zero percent and its exclusion from the antidumping duty order as a result of judicial review constitute significantly changed circumstances from those in existence at the time of the original investigation because the facts underlying the Commission's negligibility determination completely changed. According to Erdemir, the exclusion of Colakoglu from the antidumping duty order places this case *in pari materia* with the injury case in the countervailing duty investigation and provides a compelling basis to find that imports from Turkey subject to the antidumping duty investigation are negligible.

Written comments requested.—Pursuant to section 207.45(b) of the Commission's Rules of Practice and Procedure, the Commission requests comments concerning whether the alleged changed circumstances, brought about by the aforementioned changes in the imports of hot-rolled steel flat products from Turkey subject to an antidumping duty order, are sufficient to warrant institution of a review.

The Commission further requests comments concerning the degree to which any changed circumstances proceeding concerning hot-rolled steel flat products from Turkey can be conducted in conjunction with the five-year review of the antidumping duty order on the same subject merchandise that Commerce has initiated and the Commission has instituted on September 1, 2021 (86 FR 49057). If the Commission initiates a changed circumstances review, the review is likely to be conducted on an overlapping basis with the five-year review concerning hot-rolled steel flat products from Turkey. Therefore, commenters are encouraged to address the nature of the respective inquiries, the data and other information necessary for the Commission's evaluation, and procedural considerations for the effective conduct of the reviews.

Written submissions.—Comments must be filed with the Secretary to the Commission by no later than 30 days after publication of this notice or by [XXX]. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Authority: This notice is published pursuant to section 207.45 of the Commission's rules.

By order of the Commission.

Issued: November 29, 2021.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2021–26222 Filed 12–1–21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–888]

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 2022

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2022 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: The initial 2022 aggregate production quotas and assessment of annual needs are effective December 2, 2021.

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, VA 22152, Telephone: (571) 776–2265.

SUPPLEMENTARY INFORMATION:

I. 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.

II. Background

The 2022 aggregate production quotas (APQ) and assessment of annual needs (AAN) 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 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.

On October 18, 2021, 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 2022'' was published in the **Federal Register**. 86 FR 57690. This notice proposed the 2022 APQ for each basic class of controlled substance listed in schedules I and II and the 2022 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. All interested persons were invited to comment on or object to the proposed

APQ and the proposed AAN on or before November 17, 2021.

III. Comments Received

Within the public comment period, DEA received 610 comments from DEA registrants, chronic pain patients, pain advocacy associations, professional associations, doctors, nurses, State Attorneys General, and others. The comments included requests for clarification about the data DEA used to determine diversion for the purposes of the APQ for certain schedule II opioids; concerns about potential drug shortages due to further quota reductions; concerns that medical professionals might be impeded from exercising their medical expertise regarding opioid prescriptions; concerns about the quota process; requests for a public hearing; and comments not pertaining to DEA regulated activities.

DEA's Regulatory Authority

Issue: DEA received comments that raised the question of whether DEA has the authority to regulate activities related to controlled substances, including the manufacture of Food and Drug Administration (FDA)-approved pharmaceutical products containing controlled substances.

DEA Response: The CSA, which was initially enacted in 1970 and has been amended several times, requires DEA to establish production quotas for certain controlled substances. 21 U.S.C. 826(a). In the CSA, Congress granted DEA (as delegated by the Attorney General under 21 U.S.C. 871(a)) the authority to promulgate ''rules and regulations'' relating to the ''registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals'' (21 U.S.C. 821), and to the ''registration and control of importers and exporters of controlled substances'' (21 U.S.C. 958(f)), as well as those ''necessary and appropriate for the efficient execution'' of the authorities granted by the CSA (21 U.S.C. 871(b)), among other provisions. In its findings, Congress acknowledged that many controlled substances ''have a useful and legitimate medical purpose.'' 21 U.S.C. 801(1).

Congress explicitly directed DEA to establish production quotas for controlled substances in schedule I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine. 21 U.S.C. 826(a). In recognition of FDA's related but distinct role in regulating pharmaceutical products, DEA's regulations require DEA to consider relevant information from FDA before DEA establishes the APQs. As DEA has acknowledged in previous **Federal Register** publications relating to quotas, the responsibility to provide estimates of legitimate domestic medical needs resides with FDA. DEA considers this important information in proposing and revising the APQs.

Medication Shortages

Issue: DEA received many comments expressing general concerns that the proposed decreases to the production quotas of certain controlled substances may result in shortages of drug products containing those controlled substances.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet the estimated legitimate medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. DEA sets APQs in a manner to provide for all legitimate medical purposes.

Additionally, DEA and FDA are required to, and routinely do, coordinate efforts to prevent or alleviate drug shortages pursuant to 21 U.S.C. 826(h). Such efforts may include adjusting the APQ, adjusting individual domestic manufacturers' quotas, FDA approval of additional market competitors, and coordination between the agencies to allow importation of foreign-manufactured drug products that meet FDA approval. For example, in 2020, DEA adjusted its quota to increase the aggregate production quota for drug products containing fentanyl, hydromorphone, morphine, and codeine, and the assessments of annual needs for drug products containing pseudoephedrine and ephedrine. The increased production needs for those substances, which are used to treat patients in intensive care units and those on ventilators, was a result of the COVID–19 public health emergency. These actions were taken based on DEA's consultations with federal partners at the Department of Health and Human Services (HHS), drug manufacturers, drug distributors, and hospital associations. Similarly, in 2018, a domestic shortage of injectable hydromorphone was alleviated through FDA and DEA collaboration to identify other dosage-form manufacturers with injectable hydromorphone products in the market, and to determine whether those other dosage-form manufacturers had the capability to increase their production levels to meet legitimate patient need in a timely manner. When the agencies determined that the domestic manufacturers could not increase production adequately to meet legitimate patient need, DEA and FDA coordinated and used their respective regulatory authorities to allow for the limited importation of injectable hydromorphone into the United States.

Prescribing Hesitancy

Issue: Many commenters, most of whom self-identified as chronic pain patients, expressed general concerns that the *CDC Guidelines for Prescribing Opioids for Chronic Pain,* issued in 2016, are preventing doctors from prescribing pain medication in dosages that adequately control chronic pain, forcing them to taper opioid medication dosages inappropriately, and causing them to refuse to prescribe opioid prescriptions to chronic pain patients. These comments also raised concerns that some health insurers have mandated that opioid medication dosages be tapered for continued insurance coverage or have denied coverage for prescriptions from out-of-network providers. Commenters noted that worker's compensation insurers have denied opioid medication coverage for pain patients. One commenter raised concerns that chronic pain patients are not allowed to self-pay for opioid medications.

DEA Response: Provided that the prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice, neither the CSA nor DEA regulations impose a specific minimum or maximum limit on the amount of medication that may be prescribed on a single prescription, or limit the duration of treatment intended with a prescribed controlled substance. DEA has consistently emphasized and supported the authority of individual practitioners under the CSA to administer, dispense, and prescribe controlled substances for the legitimate treatment of pain within acceptable medical standards, as outlined in DEA's policy statement published in the **Federal Register** on September 6, 2006, titled Dispensing Controlled Substances for the Treatment of Pain. 71 FR 52716.

Use of Studies/Guidelines To Determine Medical Need

Issue: Ten State Attorneys General [1] (referred to collectively as State Attorneys General) suggested that DEA consider research studies and best practices developed by individual state-level partnerships with local medical communities and other individual state regulators to determine the extent of

[1] The comment received from the Office of the Attorney General, State of West Virginia, was also signed by the State Attorneys General of Kentucky, Arkansas, Alaska, Idaho, Louisiana, Mississippi, Nebraska, Utah and South Dakota.

overprescribing of controlled substances.

DEA Response: DEA has reviewed the conclusions of these studies and believes they are insufficient to support a reduction in the APQs because the studies examined a limited set of medical procedures that could not be generalized to all prescriptions dispensed in the United States. The studies have found, with respect to certain medical procedures, that physicians prescribe more controlled substances for post-operative pain than patients utilize. While the referenced studies are concerning, DEA believes they are insufficient to impact DEA's APQ determination.

Percentage of Prescription Opioids Being Diverted

Issue: Multiple commenters said that the APQs should not be reduced from calendar year 2021 APQ levels, given that less than 1 percent of prescription controlled substances are diverted. One commenter cited DEA's statements in the 2020 Proposed APQ to support this statistic.

DEA Response: DEA's regulations require it to consider numerous relevant factors in its determination of the APQ. One factor is 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. The commenter is correct that in the *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 (84 FR 48170),* DEA determined that the quantity of FDA-approved drug products containing controlled substances that were diverted in 2018 represented less than one percent of the total quantity of controlled substances distributed to retail purchasers.

However, DEA also considers other relevant factors, as required by regulation, when determining the APQ. 21 U.S.C. 826(a), 21 CFR 1303.11(b). DEA's consideration of all of these relevant factors resulted in the proposed 2022 APQ as published.

Relevant Information From FDA

Issue: Comments raised questions regarding the data provided by FDA, including the methodology it used to determine domestic medical need.

DEA Response: The information DEA received from FDA included the observed and projected domestic usage of schedule II controlled substances, new drug application and abbreviated new drug application approvals, manufacturers discontinuing production, product shortages, and clinical trials for schedule I and II controlled substances. FDA utilizes a variety of data sources in developing its estimates, and also describes certain caveats regarding the forecasts it provides. The data provided by FDA contributed to DEA's estimate of declining legitimate domestic medical need for opioids.

FDA provides an important portion of the data that DEA analyzes in developing the annual APQs, but DEA also utilizes other data sources to meet its statutory and regulatory requirements. For instance, DEA utilized information provided by quota applicants and research protocols submitted directly to DEA to derive the estimates of scientific, research, and industrial needs; lawful export requirements; and current reserve stocks. No single data element is adequate to address all of the legal factors.

Issue: The State Attorneys General raised a concern that the proposed APQ for the five covered controlled substances defined in 21 U.S.C. 826(i)(1)(A) as fentanyl, oxycodone, hydrocodone, oxymorphone, and hydromorphone are not aligned with the decline in medical need for schedule II opioids as projected by FDA.

DEA Response: DEA notes that the decline of 18.88 percent was an average for certain schedule II opioids including but not limited to the five covered controlled substances predicted between 2021 and 2022. This estimated decline was for the domestic medical need only, which is one of several factors that DEA must consider when establishing APQ estimates for the entire calendar year.

Estimates of Diversion Mandated by the SUPPORT Act

Issue: The State Attorneys General inquired about DEA's method of assessing diversion of the five covered controlled substances, as compared with the other basic classes of controlled substances subject to quotas.

DEA Response: Pursuant to 21 CFR 1303.11(b)(5), DEA considered the extent of diversion of the basic class as a factor in setting each APQ for each respective basic class, as well as the extent of diversion for all other schedule I and II controlled substances in proposing the estimated APQ. As the State Attorneys General note, the Substance-Use Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act (SUPPORT Act, Pub. L. 115–271) requires that DEA provide the diversion estimate only for the five covered controlled substances. In compliance with the SUPPORT Act, DEA published the estimated diversion for the five covered controlled substances in its October 18, 2021 notice, and provides revised estimates in Tables 2 and 3 below.

Issue: DEA received comments that raised questions regarding DEA's use of law enforcement data, including seizure data and theft and loss reporting, in its estimation of diversion for the five covered controlled substances.

DEA Response: DEA considered the reliability of all reported law enforcement data for the purpose of calculating estimates of diversion for the APQs of the five covered controlled substances. DEA did not include seizure data in its estimate of diversion because DEA could not conclusively determine that the collected data did not overlap with other data sources used to calculate relevant diversion estimates, nor could DEA determine from the reported data whether the seized substances contained illicitly manufactured fentanyl.

Issue: Commenters questioned the inclusion of losses due to disasters.

DEA Response: DEA registrants are required to report thefts and significant losses to DEA. These reports are often submitted before the registrant has had the opportunity to fully investigate the reason for the loss. Loss reports may include incidents of employee pilferage that may not be reported initially as theft to DEA. A ''loss in transit'' is nominally a loss but may in fact represent diversion by employees or other individuals. Generally, loss is considered diversion because it involves controlled substances falling outside the closed system of distribution. However, DEA agrees that reported losses due to disaster (fire, weather, etc.) should be distinguished from diversion for APQ purposes. DEA therefore has adjusted its estimate of diversion of covered controlled substances in the supply chain by excluding those losses due to disaster, fire, weather, etc., as shown in Table 1.

TABLE 1—SUPPLY CHAIN LOSS DUE TO DISASTER

[Fire, etc]

Controlled substance	(g)
Fentanyl	1
Hydrocodone	123
Hydromorphone	5
Oxycodone	214
Oxymorphone	4

Issue: DEA received numerous comments expressing concerns that DEA's reduction of quotas for pain-relieving controlled substances does not correlate to a reduction in overdose deaths. According to the commenters, DEA and CDC data show that illicit fentanyl and heroin are responsible for the majority of overdose deaths. The commenters state that overdose deaths in the U.S. continue to rise because of illegal fentanyl, heroin, and illegally manufactured pain pills, not from pharmaceutical medications prescribed to chronic pain patients.

DEA Response: In establishing the APQ, DEA considers the legitimate medical need in the United States. DEA strives to ensure that the APQs are sufficient to provide for the legitimate controlled substance prescription requirements while limiting the potential for diversion of controlled substances. DEA also considers changes in currently accepted medical use in treatment as part of the determination of legitimate medical need, and establishes the APQ for specific controlled substances accordingly. 21 CFR 1303.11(b)(7).

Use of PDMP Data in Identifying Potential Diversion

Issue: DEA received numerous comments that raised questions regarding DEA's use of prescriptions filled for the five covered controlled substances in dosages exceeding 240 morphine milligram equivalents (MME) daily as a potential indicator of diversion. The commenters noted that CDC has published guidelines that recommend prescribers consider the medical necessity of exceeding a daily dosage limit of 90 MME. The State Attorneys General also asked whether, in flagging prescriptions that exceed 240 MME daily, DEA considered individual prescriptions, or considered combined prescriptions for patients at any given time.

DEA Response: DEA did not consider prescriptions written for the five covered controlled substances in quantities lower than 240 MME daily because some patients, including oncology patients in particular, have legitimate medical needs for covered controlled substance prescriptions in excess of 90 MME daily. DEA did not wish to inadvertently include legitimate prescriptions for these patients in its calculation of diversion. Daily dosages higher than 240 MME place individuals at a higher risk of overdose and death, and correlate with a heightened risk of diversion. DEA received aggregated data from state PDMPs that reflected only individual prescriptions.

Issue: Commenters asked whether the PDMP data responses from the states covered all time periods requested. If they did not, how did DEA's calculations account for missing data?

DEA Response: All responding states provided summarized PDMP data for 2018–2020, the entire time period requested by DEA.

Issue: Some commenters, including the State Attorneys General, expressed concerns that the PDMP data obtained from responding states that DEA used to identify diversion does not represent the entire U.S. population accurately.

DEA Response: DEA requested data through the National Association of State Controlled Substances Authorities (NASCSA), which includes the forty-nine member states that utilize PDMPs. As indicated in the proposed APQ, DEA did not receive PDMP data from all queried states for use in its determination of diversion. The sixteen states and one county providing PDMP data represent a geographically diverse cross-section of 78.5 million people, or 24 percent of the United States population. Based on publicly available, established statistical methods for sampling very large populations, polling approximately 10 percent of a given large population provides enough statistical power to draw reliable inferences about the population. A sample size of 24 percent therefore is large enough to accurately generalize that data outcome to the whole population of the United States and to be used in the calculation of estimated national levels of diversion of the covered controlled substances.

Issue: Commenters raised questions regarding patient privacy issues relating to the PDMP data provided to DEA by states.

DEA Response: DEA requested and received anonymized, aggregated PDMP data from the states. No individual patient names, addresses, or other discrete, personally identifiable information was shared with DEA.

Issue: The State Attorneys General commented that DEA should have used patient address information from the PDMP data to determine a metric for potential diversion based on geographic distances between patient, prescriber, and pharmacy.

DEA Response: DEA did not request, nor did it receive, any state PDMP data that included individualized identifying data such as patient addresses.

Issue: DEA received comments that raised questions about the accuracy of PDMP data regarding patients' current and discontinued use of opioid prescriptions containing the covered controlled substances within discrete time periods.

DEA Response: DEA requested aggregated PDMP data for filled prescriptions containing the five covered controlled substances. In many instances, prescriptions that are filled but not used by patients create the potential for diversion because of the opportunity for misuse by non-patients. The most common sources of misused pharmaceutical opioids are family and friends. The Substance Abuse and Mental Health Services Administration's 2019 National Survey on Drug Use and Health Annual National Report published data demonstrating that more than half (50.8 percent) of people who self-reported misusing prescription pain relief medicine obtained their most recent pain reliever from a friend or relative, either for free, by purchase, or by taking without asking. Such misuses of prescriptions constitute diversion.

Issue: One commenter questioned whether it is appropriate to use data showing instances of patients receiving specific controlled substance prescriptions issued by three or more doctors within a 90-day period as a metric to determine potential diversion.

DEA Response: DEA developed the metric of patients prescribed covered controlled substances from three or more prescribers in a 90-day period to identify potential doctor shopping, a common technique used to obtain large amounts of controlled substances for the purpose of abuse or diversion. Federal administrative and criminal case law demonstrates that multiple prescriptions from multiple prescribers in a short timeframe is a reliable indicator of diversion.[2]

Issue: DEA received comments from the State Attorneys General and the general public questioning whether DEA derived its diversion estimates from individual prescriptions paid for with cash, and if entire classes of prescribers or pharmacies with large cash transactions were excluded.

DEA Response: DEA received reports from state PDMP administrators which were designed by NASCSA to respond to DEA's request for aggregated information. The reports contained the number of patients and prescriptions that met each of the diversion metrics DEA identified. These reports did not include individualized information that would be contained on prescriptions. DEA did not consider whether this data

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

included specific classes of prescribers or pharmacies.

Issue: The State Attorneys General suggested that DEA consider PDMP data about inconsistent or early refills of prescription opioids in estimating potential diversion.

DEA Response: Prescriptions for schedule II controlled substances cannot be refilled. 21 U.S.C. 829(a). All of the substances for which DEA requested PDMP data were schedule II controlled substances.

Schedule I Controlled Substances

Issue: Several commenters requested that DEA consider increasing production quotas for certain schedule I controlled substances, including: Bufotenine, 5-methoxy-N,N-dimethyltryptamine (5-MEO-DMT), ibogaine, psilocybin, mescaline, 3,4-methylenedioxymethamphetamine (MDMA), and dimethyltryptamine (DMT) for research activities and clinical trials in Canada and the United States.

DEA Response: The APQs established today reflect DEA's estimates of the medical, scientific, research, and industrial needs of the United States for 2022, as well as lawful export requirements and establishment and maintenance of reserve stocks. DEA can adjust the established APQs if these needs change. For instance, if DEA receives additional research protocols from DEA-registered researchers, or additional quota applications from DEA-registered manufacturers, DEA will consider revising the APQ.

DEA did receive additional quota applications from DEA-registered manufacturers for 5-MEO-DMT, psilocybin, and MDMA. DEA considered those applications accordingly, as discussed below. DEA has not received quota applications from DEA-registered manufacturers to support the requested changes in the APQ for the other controlled substances mentioned.

Issue: DEA received a comment from a biotech company suggesting that DEA discuss involving representatives from indigenous communities in determining APQ for controlled substances that are potentially derived from plants traditionally used by indigenous groups in the Americas and beyond.

Response: In accordance with 21 CFR 1303.11(c), DEA invites all interested persons to participate by commenting on proposed APQs. The CSA requires DEA to establish APQ to provide for the estimated medical, scientific, research, and industrial needs of the U.S., for lawful export requirements, and for the establishment and maintenance of reserve stocks. The APQs and the individual manufacturing quotas are informed in part by the quota requests submitted by DEA-registered manufacturers of these substances.

Issue: The Native American Church of North America commented on the proposal to set the APQ for mescaline at 100 grams. They commented that their peyote ceremonies are contingent on the continued availability of peyote in the wild for sacramental use, and that the non-Native use of mescaline in research and clinical studies will have a direct impact upon the church's ability to use, purchase, transport, and possess peyote pursuant to the American Indian Religious Freedom Act (AIRFA), as it will lead to commercialization and exploitation of peyote across its natural range and potential reclassification of its scheduling status.

DEA Response: Mescaline is the schedule I controlled substance naturally occurring in peyote. The 2022 APQ for mescaline will only be used for the production of synthetic mescaline which is utilized to produce analytical reference standards. Thus, the 2022 APQ for mescaline does not have any material effect on the use of peyote by members of the Native American Church.

Schedule II Controlled Substances

Issue: One commenter asked why DEA does not consider significantly reducing the hydrocodone quota to come in line with the rest of the world. The commenter also asked why DEA does not consider global use data in establishing APQ.

DEA Response: DEA is bound by the language of 21 U.S.C. 826 to consider the needs of the United States. After considering the factors defined in 21 CFR 1303.11(b), this APQ represents DEA's best estimate of domestic needs, as well as quantities needed for lawful export and for the establishment and maintenance of reserve stocks.

Issue: DEA received a comment suggesting that DEA evaluate adjustments for the APQ of oral solid and injectable dosage forms of medicines separately. The commenter specifically highlighted differences between dosage forms of certain opioids.

DEA Response: DEA sets APQ in a manner to include dispensings for legitimate medical purposes and, in turn, the APQ takes into consideration both injectable opioids and solid oral opioids to meet the estimated medical needs of the United States. The SUPPORT Act allows, but does not require, DEA to grant individual quotas to DEA-registered manufacturers in terms of dosage forms if the Agency determines that doing so will assist in avoiding the overproduction, shortage, or diversion of controlled substances. By issuing a single APQ covering all dosage forms of the basic class, rather than estimating APQ for each dosage form, DEA retains the flexibility to alleviate potential shortages and to react to unforeseen emergencies by adjusting the individual quotas granted to manufacturers under that APQ.

Assessment of Annual Needs for List I Chemicals

Issue: DEA received comments expressing concerns that the AAN limits the amount of pseudoephedrine (for sale), a chemical found in the allergy medication SUDAFED.

DEA Response: The CSA requires DEA to establish the AAN for ephedrine, pseudoephedrine, and phenylpropanolamine to provide for the estimated legitimate medical, scientific, research, and industrial needs of the United States, lawful exports, and reserve stocks. 21 U.S.C. 826(a). Control of the chemical pseudoephedrine in this manner over the past 15 years has not been shown to limit the availability of over-the-counter products such as Sudafed for legitimate needs. In anticipation of increased need due to the COVID–19 public health emergency, the AAN for pseudoephedrine (for sale) was increased in 2020; however, the expected need did not materialize. Therefore, DEA has reduced the AAN for pseudoephedrine (for sale) back to the 2019 level.

Comments From DEA-Registered Manufacturers

Issue: DEA received comments from three DEA-registered manufacturers regarding 13 different schedule I and II controlled substances, requesting that the proposed APQ for 5-MEO-DMT, d-amphetamine (for conversion), dexmethylphenidate (for sale), DMT, lisdexamfetamine, methadone, methadone intermediate, methylphenidate (for sale), noroxymorphone (for conversion), phenylacetone, psilocybin, psilocin, and remifentanil be established to sufficient levels to allow for manufacturers to meet medical and scientific needs.

DEA Response: DEA considered the comments for specific controlled substances and made adjustments as needed, which are described below in the section titled Determination of 2022 Aggregate Production Quotas and Assessment of Annual Needs.

U.S. Treaty Obligations

Issue: DEA received several comments requesting that the United States become a signatory to the Nagoya Protocol and Convention on Biological Diversity.

DEA Response: DEA does not have the authority to enter into or sign treaty agreements on behalf of the United States. This request is outside the scope of this notice.

Request for Public Hearing

Issue: One commenter requested a public hearing on the data and methodology used by DEA for this 2022 proposed APQ determination. The commenter also raised issues relating to the 2018 and 2019 APQs.

DEA Response: The decision whether to grant a hearing on the issues raised by the commenter lies solely within the discretion of the Administrator. 21 CFR 1303.11(c). This commenter is not a state. This request does not present any evidence that would lead to the conclusion that a hearing is necessary or warranted. The 2018 and 2019 APQs also fall outside of the scope of this order.

Stakeholder Forum

Issue: One commenter requested DEA schedule a public hearing or engage in an organized public process to allow interested parties to express their views and concerns about quota issues at least six months in advance of the proposed APQ.

DEA Response: DEA invites all interested persons to participate by commenting on proposed APQs. 21 CFR 1303.11(c). The **Federal Register** comment period provides an opportunity for all stakeholders to make their issues known to DEA.

Out of Scope Comments

DEA received comments that are outside the scope of this order. The comments were general in nature and raised issues of specific medical illnesses, medical treatments, and medication costs. These comments do not impact the analysis involved in establishing the 2022 APQ.

IV. Determination of 2022 Aggregate Production Quotas and Assessment of Annual Needs

In determining the established 2022 aggregate production quotas and assessment of annual needs, DEA has considered 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). These factors include, but are not limited to, the 2021 manufacturing quotas, current 2021 sales and inventories, anticipated 2022 export requirements, industrial use, additional applications for 2022 quotas, and information on research and product development requirements.

Based on all of the above, the Administrator establishes the 2022 APQ for 5-MEO-DMT, DMT, lisdexamfetamine, MDMA, phenylacetone, psilocybin, and psilocin at higher levels than was proposed.

DEA has determined that the proposed APQs for D-amphetamine (for conversion), dexmethylphenidate (for sale), methadone, methadone intermediate, methylphenidate (for sale), noroxymorphone (for conversion), and remifentanil are sufficient to provide for the 2022 estimated medical, scientific, research, and industrial needs of the United States, export requirements, and the establishment and maintenance of reserve stocks. This final order establishes these APQ at the same amounts as proposed.

Estimates of Diversion Pursuant to the SUPPORT Act

As specified in the proposal, and as required by 21 U.S.C. 826(i), DEA calculated a national diversion estimate for each of the covered controlled substances.

DEA solicited PDMP data through NASCSA from state PDMP Administrators. Based on the data received, DEA considered the number of individuals who received a prescription for a covered controlled substance that met any of the three diversion metrics (''red flags'') mentioned in the October 18, 2021, notice for each of calendar years 2018–20. 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 meeting one of the red flag metrics. 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 IQVIA's National Sales Perspective.[3]

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. This data, which remains unchanged, was published in the 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, and contributed to the final diversion estimates for covered controlled substances, as set forth in Table 3.

Registrant Reported Legitimate Distribution Chain Diversion

DEA extracted data from its Drug Theft and Loss database and categorized it by basic class. The quantity of active pharmaceutical ingredient (API) in each dosage form was determined, 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, which does not contain any loss reported due to fire, weather, or other disaster, is displayed in Table 2. This data contributed to the final diversion estimates for covered controlled substances, as set forth in Table 3.

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

Controlled substance	(g)
Fentanyl	76
Hydrocodone	19,325
Hydromorphone	896
Oxycodone	45,368
Oxymorphone	524

DEA's estimate of diversion for the five covered controlled substances was calculated by combining the diversion estimates from the state PDMP data and the supply chain diversion data. DEA reduced 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

Controlled substance	(g)
Fentanyl	92
Hydrocodone	154,916

[3] 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.

TABLE 3—TOTAL ESTIMATES OF DIVERSION FOR COVERED CONTROLLED SUBSTANCES—Continued

Controlled substance	(g)
Hydromorphone	1,170
Oxycodone	210,206
Oxymorphone	524

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2022 APQ for the following schedule I and II controlled substances and the 2022 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 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
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-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

Basic class	Established 2022 quotas (g)
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 (5–MEO–DMT)	2,550
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
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
delta-9-tetrahydrocannabinol	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 (DMT)	3,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25

Basic class	Established 2022 quotas (g)
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
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

Basic class	Established 2022 quotas (g)
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	8,000
Psilocyn	4,000
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	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)	20,000,000
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

Basic class	Established 2022 quotas (g)
Hydromorphone	2,097,255
Isomethadone	30
L-amphetamine	30
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	23,010
Lisdexamfetamine	26,500,000
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
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	8,000,000
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 also establishes APQ 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 2022 APQ and AAN as needed.

Anne Milgram,

Administrator.

[FR Doc. 2021–26227 Filed 11–29–21; 4:15 pm]

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DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Stipulation and Settlement Under the Comprehensive Environmental Response, Compensation and Liability Act

On November 15, 2021, a proposed Stipulation Resolving the General