of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under §§ 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On October 12, 2022, the Coalition of Domestic Folder Manufacturers, Hastings, Minnesota and Naperville, Illinois filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized imports of paper file folders from India and LTFV imports of paper file folders from China, India, and Vietnam. Accordingly, effective October 12, 2022, the Commission instituted countervailing duty investigation No. 701–TA–683 and antidumping duty investigation Nos. 731–TA–1594–1596 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of October 19, 2022 (87 FR 63526). The Commission conducted its conference on November 2, 2022. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to §§ 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on November 28, 2022. The views of the Commission are contained in USITC Publication 5389 (December 2022), entitled *Paper File Folders from China, India, and Vietnam: Investigation Nos. 701–TA–683 and 731–TA–1594–1596 (Preliminary).*

By order of the Commission.

Issued: November 28, 2022.

William Bishop,

Supervisory Hearings and Information Officer.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1051E]

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 2023

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: This final order establishes the initial 2023 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 order is effective December 2, 2022.

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) 776–3882.

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 2023 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 2023, in order to provide for the estimated medical, scientific, research, and industrial needs of the U.S., 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, 2022, 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 2023'' was published in the **Federal Register**. 87 FR 63091. This notice proposed the 2023 APQ for each basic class of controlled substance listed in schedules I and II and the 2023 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, 2022.

III. Comments Received

Within the public comment period, DEA received 357 comments from DEA registrants, chronic pain patients, patients with attention deficit/hyperactivity disorder, pain advocacy associations, professional associations, nurses, and others. The comments included concerns about potential opioid and stimulant drug shortages due to further quota reductions; concerns that medical professionals might be impeded from exercising their medical expertise regarding opioid prescriptions; one request for a public hearing; and comments not pertaining to DEA regulated activities. DEA restricted eight comments from public view due to confidential business information and/or confidential personal identifying information.

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. 21 CFR 1303.11(b)(6). For instance, FDA provides estimates of legitimate domestic medical needs. DEA considers this important information in proposing and revising the APQs.

Medication Shortages

Issue (Attention Deficit/Hyperactivity Disorder Medications [ADHD]): DEA received comments expressing general concerns regarding the ongoing shortages experienced with ADHD medications produced from amphetamine, dexmethylphenidate, methylphenidate, and lisdexamfetamine. Some commenters expressed a concern that patients will turn to black market or diverted products if they cannot obtain their prescribed medications through legitimate channels. Two manufacturers commented that the proposed quotas for lisdexamfetamine and methylphenidate may not be adequate to meet forecasted increases in foreign demand for exported products.

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 U.S., 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 and for anticipated foreign demand. Additionally, DEA and FDA are required to, and routinely do, coordinate efforts to prevent or alleviate drug shortages. Such efforts may include adjusting the APQ, adjusting individual domestic manufacturers' quotas, FDA's approval of additional market competitors, and coordination between the agencies to allow importation of foreign-manufactured drug products that meet FDA approval.

Based on the data DEA considers in setting the APQs, including new FDA-approved drug products, as well as manufacturing issues that DEA considers under 21 CFR 1303.11(b)(7), DEA determined that the proposed APQs for amphetamine, dexmethylphenidate, methylphenidate, and lisdexamfetamine are sufficient to supply legitimate medical needs, reserve stocks, and export requirements for 2023.

Issue (Adderall Shortages): DEA received comments expressing general concerns regarding the ongoing shortages experienced with ADHD drug medications, specifically mentioning the branded drug product Adderall.

DEA Response: DEA is aware of patient reports that pharmacies are unable to fill prescriptions for their prescribed Adderall or one of its generic versions. DEA consults with FDA to set the APQ for amphetamine each calendar year. The majority of the manufacturers contacted by DEA and/or FDA have responded that they currently have sufficient quota to meet their contracted production quantities for legitimate patient medical needs. According to DEA's data, manufacturers have not fully utilized the APQ for amphetamine in support of domestic manufacturing, reserve stocks, and export requirements for the past three calendar years 2020, 2021 and 2022.

Based on this trend, DEA has not implemented an increase to the APQ for amphetamine at this time. Should the proposed established amphetamine APQ become inadequate to meet legitimate medical and scientific needs, sufficient reserve stocks, and export requirements, DEA has the authority and ability to adjust the APQ during the course of the year. 21 CFR 1303.13. DEA remains in communication with FDA regarding these shortage reports.

Issue (Opioid Shortage): There were commenters including pain associations and DEA-registered medical professionals that expressed concerns about the decrease in aggregate production quotas for opioids. These commenters alleged that decreases to the aggregate production quotas have resulted in a shortage of opioid medications, interfered with the treatment of patients, and impacted the quality of life for patients possibly leading to suicide.

DEA Response: DEA is committed to ensuring an adequate and uninterrupted supply of controlled substances in order to meet legitimate medical, scientific, and export needs of the United States. Although DEA sets the APQs for all schedule II opioids, there can be other factors and manufacturers' business practices that may contribute to a temporary shortage of controlled substances at the point of dispensation, despite the adequacy of the APQ set by DEA. In recent years, this has included plant shutdowns necessary to complete federally-mandated maintenance, labor shortages and a lack of production capacity. In such circumstances, DEA coordinates with FDA and can use the tools at its disposal under its CSA authority to prevent or alleviate drug shortages and ensure that patients are able to fill legitimate prescriptions for controlled substances without undue delay.

Issue (Hospital-Administered Injectable Opioid Shortage): DEA received many comments expressing concern that the proposed decreases to the production quotas of opioid controlled substances may result in shortages of drug products containing those controlled substances. These commenters alleged that decreases to the APQ have resulted in a shortage of injectable opioid medications and interfere with the treatment of patients.

A top U.S. manufacturer of generic sterile injectable medicines to U.S. hospitals and healthcare providers opined that DEA's prior production quota initially prevented manufacturers from addressing and solving the shortage. This commenter noted that today, hospitals are providing ongoing COVID–19 patient care and managing a backlog in elective surgeries. As a result, this commenter suggested that DEA reconsider the APQ reductions for schedule II opioids used in sterile injectable pain medicines.

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 U.S., 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. Opioid injectable products constitute less than 5% of their relevant APQ, therefore injectable shortages do not usually require changes to the relevant APQ. Based on the data that DEA is required to consider for setting the APQs, DEA has determined that the established APQs for opioids are sufficient to meet all legitimate needs for 2023. Additionally, DEA and FDA are required to, and routinely do, coordinate efforts to prevent or alleviate

drug shortages. 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 APQ 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.

Mental Health Concerns

Issue: DEA received a number of comments that raised the issue of mental health diagnoses and treatment becoming more widespread in the last few years. Some commenters expressed the concern that COVID–19 and social media are the reason more people are becoming aware of mental health issues and treatment options. These commenters stated that this awareness has resulted in the increased use of some medicines. One commenter stated that mental health is now being taken seriously, and access to mental health treatment has grown. This commenter further asked why we as a nation would decide to further limit treatment when the medications are already controlled substances, tightly tracked when being prescribed and dispensed, with laws in place to deter and prevent their misuse.

DEA Response: DEA is aware of the sensitivity surrounding the negative impact of COVID–19 on mental health and recognizes that mental health issues are a legitimate medical concern. When setting the APQ for controlled substances used in manufacturing the relevant FDA-approved drug products, DEA considers the legitimate medical need for these medicines, as determined in part through the number of legitimate prescriptions dispensed in prior years and anticipated to be dispensed in the coming quota year.

Supply Chain Disruption

Issue: DEA received several comments raising the concern of the potential cascade effect of limiting List 1 chemicals that are used to manufacture ADHD medications.

DEA Response: DEA is aware of the synthesis process used by the manufacturers of FDA-approved ADHD drug products. DEA considers the manufacturing yields and requirements of all of the controlled substances and List 1 chemicals in the synthesis pathways to ensure that the APQs allow for sufficient quantities at each step to meet the legitimate domestic medical, scientific, and industrial needs of the United States as well as export requirements.

Ryan Haight Act and Telemedicine Flexibilities

Issue: One commenter noted DEA's concern regarding the increased misuse of prescription stimulants among young adults. This commenter questioned why the agency does not end certain flexibilities granted in response to the COVID–19 pandemic that allow these substances to be prescribed and dispensed easily, in particular that which removed the in-person visit requirement generally mandated by the Ryan Haight Act.

DEA Response: On January 31, 2020, the Secretary of HHS declared a public health emergency with regard to COVID–19. Shortly thereafter, on March 16, 2020, the Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine allowance under 21 U.S.C. 802(54)(D) applies to all schedule II–V controlled substances in all areas of the United States. This allowance was part of the Ryan Haight Act's amendments to the CSA. Accordingly, as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, the telemedicine allowance under 21 U.S.C. 802(54)(D) applies. However, the majority of the issues pertaining to telemedicine are outside the scope of this rule, which is limited to setting APQs for Schedule I and II controlled substances and the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

Prescribing Hesitancy and Centers for Disease Control and Prevention (CDC) Guideline Changes

Issue: Many commenters, most of whom self-identified as chronic pain patients, expressed general concerns that DEA has not considered the *CDC Guidelines for Prescribing Opioids for Chronic Pain* which were revised in 2022. Commenters noted that the goal of the 2016 Guidelines was to decrease overdoses, but instead there has been an increase in overdoses nationwide of over 400 percent. A commenter opined that since the initial CDC Guidelines for Prescribing came out (in 2016), the chronic pain community has been targeted. Commenters stated that many chronic pain patients have been harmed, and some have died by suicide, due to the inability to get prescriptions because of the limits set by the CDC and reductions made by DEA. Many commenters mentioned that CDC recently revised its guidelines, allowing doctors to have more latitude in making treatment decisions to prescribe the appropriate dosage based on individual patient needs. A commenter stated that the 2022 Guidelines are supposed to reduce that harm of under-prescribing caused by the misapplication of the 2016 Guidelines. Commenters also stated that DEA needs to take the revised guidelines into consideration since there is no longer a hard limit to what a doctor can prescribe.

DEA Response: The CDC published the updated clinical practice guidelines for prescribing opioids for pain on November 3, 2022,[1] during the comment period for the 2023 Proposed APQ. 87 FR 70823. DEA will consider the impact of CDC's revised guidelines over time, in determining whether DEA may need to publish a revision to the currently proposed APQ values during the 2023 calendar year, when there is sufficient data to provide an understanding of the impact of the guidelines on the actual prescribing as practitioners seek to implement this guidance, provided that the prescriptions issued are for a legitimate medical purpose in the usual course of professional practice.

In addition, DEA's regulations do not impose a maximum limit on the amount of medication that may be prescribed on a single prescription. DEA has consistently emphasized and supported

[1] The CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022, accessed November 23, 2022 from *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w.*

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.

Estimates of Diversion

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, overdose deaths in the United States continue to rise because of illegal fentanyl, heroin, and illegally manufactured pain pills, not from pharmaceutical medications prescribed to chronic pain patients. These commenters discussed that legitimate fentanyl is the least diverted among the covered controlled substances.

DEA Response: DEA is required to consider rates of overdose deaths pursuant to changes made by the SUPPORT Act. The Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act of 2018 (SUPPORT Act) (Pub. L. 115–271), codified at 21 U.S.C. 826(i), mandates that DEA estimate diversion for 5 controlled substances—fentanyl, hydrocodone, hydromorphone, oxycodone, and oxymorphone. This estimation must consider the rates of overdose deaths, among other factors.

While overdose deaths may occur as a result of the use of illicit substances, DEA's quotas help prevent the misuse and diversion of pharmaceutical controlled substances. In this way, these quotas can reduce the occurrence of overdose and death from the use of legitimate controlled substances.

Issue: One commenter suggested that DEA's estimate of diversion for the five covered controlled substances underestimated actual diversion. The commenter stated nonmedical use of prescription opioids is not a legitimate medical purpose, but that DEA (allegedly) rejected this point in calculating diversion. The commenter also asserted that the estimate is incomplete because a number of states did not provide Prescription Drug Monitoring Program (PDMP) data for the five covered controlled substances.

DEA Response: The cited 2016 report [2] provides insightful information regarding the relationship between nonmedical prescription-opioid use and heroin use. However, it does not provided adequate data for DEA to modify the oxycodone diversion estimate. Additionally, as stated in the published 2023 Proposed APQ, DEA used available (hard) data at wholesale distribution and retail dispensing channels, *i.e.,* DEA's Theft/Loss Reports and state PDMP data.

The PDMP data submitted was adequate to allow DEA to draw reliable inferences about the population. The sample is large enough to allow DEA to accurately generalize the data to the whole population of the United States for use 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.

Percentage of Prescription Opioids Being Diverted

Issue: Multiple commenters stated that the APQs should not be reduced from calendar year 2022 APQ levels, given that less than 1 percent of prescription opioids are diverted. Several commenters calculated the percentage of estimated diversion for oxycodone and hydrocodone as 0.3 percent and 0.4 percent respectively.

DEA Response: DEA's regulations require it to consider numerous relevant factors in its determination of the APQ. In the October 18 **Federal Register** Notice, DEA did estimate that less than one percent of the total quantity of FDA-approved drug products containing the five specific opioid controlled substances were diverted. 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, including those discussed above such as legitimate prescriptions dispensed in prior years and anticipated to be dispensed in the coming quota year, resulted in the proposed 2023 APQ as published.

Schedule I Controlled Substances

Issue: Several commenters requested that DEA consider increasing production quotas for certain schedule I controlled substances, including: 5-methoxy-N,N-dimethyltryptamine (5–MeO–DMT), dimethyltryptamine (DMT), 3,4-methylenedioxyamphetamine (MDA), 3,4-methylenedioxymethamphetamine (MDMA), 2–CB, methylone, psilocyn, and psilocybin for research activities and clinical trials in the United States.

DEA also received comments from biotech companies requesting that DEA consider adjusting the relevant schedule I controlled substance APQ to allow for future pre-clinical and clinical trial research for post-traumatic stress disorder (PTSD), treatment-resistant depression, schizophrenia, and anxiety. One pharmaceutical company that intends to initiate clinical trials in 2023 for treatment of post-traumatic stress disorder (PTSD) suggested that DEA significantly increase the APQ for MDMA so that the company can initiate clinical development. Another biopharmaceutical company recommended a significant increase in the APQs for DMT and MDMA for scientific research into potential mental health treatments.

DEA Response: The APQs established today reflect DEA's estimates of the medical, scientific, research, and industrial needs of the United States for 2023, as well as lawful export requirements and the 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 relevant APQ.

DEA did receive additional quota applications from DEA-registered manufacturers for 5–MeO–DMT, marijuana, psilocyn, psilocybin, MDMA, and MDA. 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: One company suggested that DEA involve 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.

DEA Response: DEA has held discussions when requested with representatives of indigenous communities in the past and welcomes further engagement. The APQs and the individual manufacturing quotas are informed in part by the quota requests submitted by DEA-registered manufacturers of these substances, and the current needs of indigenous communities also may be reflected in the requests that DEA has received.

Schedule II Controlled Substances

Issue: DEA received comments suggesting that DEA evaluate and establish the APQ of oral solid and injectable dosage forms of medicines separately. The commenters specifically highlighted differences between dosage forms of certain opioids.

DEA Response: DEA sets APQ in a manner to include dispensing 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 statute, at 21 U.S.C. 826(a)(2), allows but does not require DEA to grant aggregate and individual quotas 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.

Comments From DEA-Registered Manufacturers

Issue: DEA received comments from five DEA-registered manufacturers regarding 10 different schedule I and II controlled substances, requesting that the proposed APQ for d-amphetamine (for conversion), dexmethylphenidate (for conversion), dexmethylphenidate (for sale), isomethadone, lisdexamfetamine, methylphenidate (for conversion), methylphenidate (for sale), noroxymorphone (for conversion), oripavine, and oxymorphone (for conversion) be established at sufficient levels to allow for manufacturers to meet medical and scientific needs.

DEA Response: DEA considered the comments for these specific controlled substances and determined that an increase from DEA's proposed APQs are not necessary at this time, as reflected below in the section titled Determination of 2023 Aggregate Production Quotas and Assessment of Annual Needs.

Request for Public Hearing

Issue: One pharmaceutical company requested a public hearing prior to publishing the Final Order to establish the initial 2023 APQ. This company requested a public hearing ''to correct the omissions and inaccurate diversion calculation in the 2023 oxycodone . . . Quota.'' The company asserted that these omissions led to an inaccurate diversion calculation for oxycodone and that the 2023 APQ requires a significant reduction from the 2022 APQ.

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. DEA has addressed specific points raised by the commenter in Issues and Responses above.

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, and medical treatments. Other commenters suggested (1) making the United States a signatory to the *Nagoya Protocol and the Convention on Biological Diversity;* and (2) creating diversified categories for production and research on psilocybin-containing fungi fruiting bodies/sclerotia/liquid culture similar to cannabis (flower), fruiting body extract (akin to cannabis extract), and psilocybin and psilocyn separately as purified compounds (akin to delta-9-thc). Regarding this last suggestion, the commenter further suggested that the ''same system should then be replicated in regards to lophophora/mescaline, as well as other plants, fungi and lifeforms, which produce these compounds being used in whole or closer to whole ways.'' These comments do not impact the analysis involved in establishing the 2023 APQ.

IV. Determination of 2023 Aggregate Production Quotas and Assessment of Annual Needs

In determining the established 2023 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 2022 manufacturing quotas, current 2022 sales and inventories, anticipated 2023 export requirements, industrial use, additional applications for 2023 quotas, and information on research and product development requirements.

On November 17, 2022, DEA published a final order placing amineptine in schedule I of the CSA (87 FR 68895), making all regulatory controls pertaining to the schedule I controlled substances applicable to the manufacture of this substance, including the requirement to establish an aggregate production quota pursuant to 21 U.S.C. 826 and 21 CFR part 1303. This final order establishes an aggregate production quota for this substance.

Based on all of the above, the Administrator establishes the 2023 APQ for 2–CB, 5–MEO–DMT, MDA, MDMA, methylone, psilocyn, d-methamphetamine (for sale), fentanyl, and 4-anilino-n-phenethyl-4-piperidine (ANPP), at higher levels than was proposed.

DEA has determined that the proposed APQs for d-amphetamine (for conversion), dexmethylphenidate (for conversion), dexmethylphenidate (for sale), isomethadone, lisdexamphetamine, methylphenidate (for conversion), methylphenidate (for sale), and noroxymorphone (for conversion) are sufficient to provide for the 2023 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.

The Administrator establishes the 2023 AAN for ephedrine (for conversion) at a higher level than was 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.

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 2023.*

In accordance with 21 U.S.C. 826, 21 CFR 1303.11, and 21 CFR 1315.11, the Administrator hereby establishes the 2023 APQ for the following schedule I and II controlled substances and the 2023 AAN for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

Basic class	Established 2023 quotas (g)
Schedule I	
-[1-(2-Thienyl)cyclohexyl]-pyrrolidine	20
1-(1-Phenylcyclohexyl)-pyrrolidine	30

Basic class	Established 2023 quotas (g)
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-dimethoxypheny-l)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-dimethoxypheny-l)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-dimethoxypheny-l]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxypheny-l]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	30
3,4-Methylenedioxyamphetamine (MDA)	12,000
3,4-Methylenedioxymethamphetamine (MDMA)	12,000
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methylone)	5,200
3,4-Methylenedioxypyrovalerone (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	30
3-Methylthiofentanyl	30
4,4′-Dimethylaminorex	30
4-Bromo-2,5-dimethoxyamphetamine (DOB)	30
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	5,100
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	11,000
AB-CHMINACA	30
AB-FUBINACA	50
AB-PINACA	30
ADB-FUBINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide)	30
Acetorphine	25
Acetyl Fentanyl	100
Acetyl-alpha-methylfentanyl	30
Acetyldihydrocodeine	30
Acetylmethadol	25
Acryl Fentanyl	25
ADB-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide)	50
AH-7921	30
All other tetrahydrocannabinol	15,000
Allylprodine	25
Alphacetylmethadol	25
alpha-Ethyltryptamine	25
Alphameprodine	25
Alphamethadol	25
alpha-Methylfentanyl	30
alpha-Methylthiofentanyl	30
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone (α-PBP)	25
alpha-pyrrolidinoheptaphenone (PV8)	25
alpha-pyrrolidinohexabophenone (alpha-PHP)	25
alpha-Pyrrolidinopentiophenone (α-PVP)	25
Amineptine	30
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

Basic class	Established 2023 quotas (g)
beta-Methyl fentanyl	30
beta′-Phenyl fentanyl	30
Betameprodine	25
Betamethadol	4
Betaprodine	25
Brorphine	30
Bufotenine	15
Butonitazene	30
Butylone	25
Butyryl fentanyl	30
Cathinone	40
Clonitazene	25
Codeine methylbromide	30
Codeine-N-oxide	192
Crotonyl Fentanyl	25
Cyclopentyl Fentanyl	30
Cyclopropyl Fentanyl	20
Cyprenorphine	25
d-9-THC	384,460
Desomorphine	25
Dextromoramide	25
Diapromide	20
Diethylthiambutene	20
Diethyltryptamine	25
Difenoxin	9,300
Dihydromorphine	653,548
Dimenoxadol	25
Dimepheptanol	25
Dimethylthiambutene	20
Dimethyltryptamine	3,000
Dioxyaphetyl butyrate	25
Dipipanone	25
Drotebanol	25
Ethylmethylthiambutene	25
Ethylone	25
Etodesnitazene	30
Etonitazene	25
Etorphine	30
Etoxeridine	25
Fenethylline	30
Fentanyl carbamate	30
Fentanyl related substances	600
Flunitazene	30
FUB-144	25
FUB-AKB48	25
Fub-AMB, MMB-Fubinaca, AMB-Fubinaca	25
Furanyl fentanyl	30
Furethidine	25
gamma-Hydroxybutyric acid	29,417,000
Heroin	150
Hydromorphinol	40
Hydroxypethidine	25
Ibogaine	30
Isobutyryl Fentanyl	25
Isotonitazine	25
JWH-018 and AM678 (1-Pentyl-3-(1-naphthoyl)indole)	35
JWH-019 (1-Hexyl-3-(1-naphthoyl)indole)	45
JWH-073 (1-Butyl-3-(1-naphthoyl)indole)	45
JWH-081 (1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole)	30
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole)	30
JWH-200 (1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole)	35
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl)indole)	30
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl)indole)	30
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl)indole)	30
Ketobemidone	30
Levomoramide	25
Levophenyacylmorphan	25
Lysergic acid diethylamide (LSD)	1,200
MAB-CHMINACA; ADB-CHMINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide)	30
MDMB-CHMICA; MMB-CHMINACA(methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate)	30
MDMB-FUBINACA (methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate)	30
MMB-CHMICA-(AMB-CHIMCA); Methyl-2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate	25
Metodesnitazene	30
Metonitazene	30
Marijuana	6,675,000
Marijuana extract	1,000,000
Mecloqualone	30
Mescaline	1,200
Methaqualone	60
Methcathinone	25
Methoxetamine	30
Methoxyacetyl fentanyl	30
Methyldesorphine	5
Methyldihydromorphine	25
Morpheridine	25
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	150
MT-45	30
Myrophine	25
NM2201: Naphthalen-1-yl 1-(5-fluorpentyl)-1H-indole-3-carboxylate	25
N,N-Dimethylamphetamine	25
Naphyrone	25
N-Ethyl-1-phenylcyclohexylamine	25
N-Ethyl-3-piperidyl benzilate	10
N-Ethylamphetamine	24
N-Ethylhexedrone	25
N-Ethylpentylone, ephylone	30
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Nicocodeine	25
Nicomorphine	25
N-methyl-3-piperidyl benzilate	30
N-Pyrrolidino Etonitazene	30
Noracymethadol	25
Norlevorphanol	2,550
Normethadone	25
Normorphine	40
Norpipanone	25
Ocfentanil	25
ortho-Fluoroacryl fentanyl	30
ortho-Fluorobutyryl fentanyl	30
Ortho-Fluorofentanyl,2-Fluorofentanyl	30
ortho-Fluoroisobutyryl fentanyl	30
ortho-Methyl acetylfentanyl	30
ortho-Methyl methoxyacetyl fentanyl	30
Para-Chlorisobutyrl fentanyl	30
Para-flourobutyryl fentanyl	25
Para-fluorofentanyl	25
para-Fluoro furanyl fentanyl	30
Para-Methoxybutyrl fentanyl	30
Para-methoxymethamphetamine	30
para-Methylfentanyl	30
Parahexyl	5
PB-22; QUPIC	20
Pentedrone	25
Pentylone	25
Phenadoxone	25
Phenampromide	25
Phenomorphan	25
Phenoperidine	25
Phenyl fentanyl	30
Pholcodine	5
Piritramide	25
Proheptazine	25
Properidine	25
Propiram	25
Protonitazene	30
Psilocybin	8,000
Psilocyn	12,000
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)	937,874
Alfentanil	5,000
Alphaprodine	25
Amobarbital	20,100

Basic class	Established 2023 quotas (g)
Bezitramide	25
Carfentanil	20
Cocaine	60,492
Codeine (for conversion)	1,085,024
Codeine (for sale)	21,003,397
D-amphetamine (for sale)	21,200,000
D,l-amphetamine	21,200,000
d-amphetamine (for conversion)	20,000,000
Dexmethylphenidate (for sale)	6,200,000
Dexmethylphenidate (for conversion)	4,200,000
Dextropropoxyphene	35
Dihydrocodeine	132,658
Dihydroetorphine	25
Diphenoxylate (for conversion)	14,100
Diphenoxylate (for sale)	770,800
Ecgonine	60,492
Ethylmorphine	30
Etorphine hydrochloride	32
Fentanyl	731,452
Glutethimide	25
Hydrocodone (for conversion)	1,250
Hydrocodone (for sale)	27,239,822
Hydromorphone	1,994,117
Isomethadone	30
L-amphetamine	30
Levo-alphacetylmethadol (LAAM)	25
Levomethorphan	30
Levorphanol	23,010
Lisdexamfetamine	26,500,000
Meperidine	681,289
Meperidine Intermediate-A	30
Meperidine Intermediate-B	30
Meperidine Intermediate-C	30
Metazocine	15
Methadone (for sale)	25,619,700
Methadone Intermediate	27,673,600
Methamphetamine	150
d-methamphetamine (for conversion)	485,020
d-methamphetamine (for sale)	47,000
l-methamphetamine	587,229
Methylphenidate (for sale)	41,800,000
Methylphenidate (for conversion)	15,300,000
Metopon	25
Moramide-intermediate	25
Morphine (for conversion)	2,458,460
Morphine (for sale)	21,747,625
Nabilone	62,000
Norfentanyl	25
Noroxymorphone (for conversion)	22,044,741
Noroxymorphone (for sale)	1,000
Oliceridine	25,100
Opium (powder)	250,000
Opium (tincture)	530,837
Oripavine	33,010,750
Oxycodone (for conversion)	437,827
Oxycodone (for sale)	53,840,608
Oxymorphone (for conversion)	28,204,371
Oxymorphone (for sale)	516,351
Pentobarbital	33,843,337
Phenazocine	25
Phencyclidine	35
Phenmetrazine	25
Phenylacetone	100
Piminodine	25
Racemethorphan	5
Racemorphan	5
Remifentanil	3,000
Secobarbital	172,100
Sufentanil	4,000
Tapentadol	11,941,416
Thebaine	57,137,944
List I Chemicals	
Ephedrine (for conversion)	41,100
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 2023 APQ and AAN as needed.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 29, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2022-26351 Filed 11-30-22; 11:15 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 1121]

Bulk Manufacturer of Controlled Substances Application: Bulk Manufacturer of Marihuana: Alm Management

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: The Drug Enforcement Administration (DEA) is providing notice of an application it has received from an entity applying to be registered to manufacture in bulk basic class(es) of controlled substances listed in schedule I. DEA intends to evaluate this and other pending applications according to its regulations governing the program of growing marihuana for scientific and medical research under DEA registration.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before January 31, 2023.

ADDRESSES: DEA requires 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 *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.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.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act (CSA) prohibits the cultivation and distribution of marihuana except by persons who are registered under the CSA to do so for lawful purposes. In accordance with the purposes specified in 21 CFR 1301.33(a), DEA is providing notice that the entity identified below has applied for registration as a bulk manufacturer of schedule I controlled substances. In response, registered bulk manufacturers of the affected basic class(es), and applicants therefor, may submit electronic comments on or objections of the requested registration, as provided in this notice. This notice