

Total Estimated Number of Annual Burden Hours: 758.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2023–21778 Filed 10–2–23; 8:45 am]

BILLING CODE 4312–52–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Advisory Committee on Appellate Rules; Hearing of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Advisory Committee on Appellate Rules; notice of cancellation of open hearing.

SUMMARY: The following public hearing on proposed amendments to the Federal Rules of Appellate Procedure has been canceled: Appellate Rules Hearing on October 18, 2023. The announcement for this hearing was previously published in the **Federal Register** on August 9, 2023.

DATES: October 18, 2023.

FOR FURTHER INFORMATION CONTACT: H. Thomas Byron III, Esq., Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, RulesCommittee_Secretary@ao.uscourts.gov.

(Authority: 28 U.S.C. 2073.)

Dated: September 26, 2023.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2023–21829 Filed 10–2–23; 8:45 am]

BILLING CODE 2210–55–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Committee on Rules of Practice and Procedure; Meeting of the Judicial Conference

AGENCY: Judicial Conference of the United States.

ACTION: Committee on Rules of Practice and Procedure; notice of open meeting.

SUMMARY: The Committee on Rules of Practice and Procedure will hold a meeting in a hybrid format with remote attendance options on January 4, 2024 in Austin, TX. The meeting is open to the public for observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: <https://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books>.

DATES: January 4, 2024.

FOR FURTHER INFORMATION CONTACT: H. Thomas Byron III, Esq., Chief Counsel, Rules Committee Staff, Administrative Office of the U.S. Courts, Thurgood Marshall Federal Judiciary Building, One Columbus Circle NE, Suite 7–300, Washington, DC 20544, Phone (202) 502–1820, RulesCommittee_Secretary@ao.uscourts.gov.

(Authority: 28 U.S.C. 2073.)

Dated: September 26, 2023.

Shelly L. Cox,

Management Analyst, Rules Committee Staff.

[FR Doc. 2023–21830 Filed 10–2–23; 8:45 am]

BILLING CODE 2210–55–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1051M]

Adjustment to the Aggregate Production Quota for Methylphenidate (for Sale) for 2023

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Drug Enforcement Administration is adjusting the 2023 aggregate production quota for the schedule II controlled substance methylphenidate (for sale).

DATES: This final order is effective October 3, 2023.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration, Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

Legal Authority

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

Under 21 U.S.C. 826(h), when a request for individual manufacturing quota is submitted by a DEA-registered manufacturer pertaining to a schedule II controlled substance that is contained in a drug on FDA's list of drugs in shortage, DEA must complete review of such request not later than 30 days after receipt of the request. If, after the review is completed, DEA finds it necessary to address a shortage of that controlled substance, DEA is to increase the aggregate and individual production quotas of that controlled substance and any ingredient therein to the level requested. 21 U.S.C. 826(h)(1)(B)(i). However, if it is determined that the level requested is not necessary to address the shortage, DEA is to provide a written response detailing the basis for the determination. 21 U.S.C. 826(h)(1)(B)(ii).

Background

DEA published the 2023 established APQ for controlled substances in schedules I and II in the **Federal Register** on December 2, 2022. 87 FR 74168. The 2023 established APQ represents those quantities of schedule I and II controlled substances that may be manufactured in the United States to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. These quotas do not include imports of controlled substances for use in industrial processes. The final order stipulated that all APQ are subject to an adjustment, in accordance with 21 CFR 1303.15.¹

Quotas Applicable to Drugs in Shortage Pursuant to 21 U.S.C. 826(h)

DEA received written correspondence from FDA on August 10, 2023, in accordance with 21 U.S.C. 356c, addressing the domestic drug shortage

¹ 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, 87 FR 74168 (December 2, 2022).

of methylphenidate HCl extended-release tablets. In this letter, FDA advised DEA that on July 26, 2023, FDA added methylphenidate hydrochloride (HCl) extended-release tablets to its drug shortage list pursuant to 21 U.S.C. 356e. Under 21 U.S.C. 356c, manufacturers of drugs that are life-supporting, life-sustaining, or intended for the treatment or prevention of debilitating diseases or conditions must notify FDA of any permanent discontinuation or interruption in manufacturing likely to result in a meaningful disruption of the drug's supply in the United States. That provision further requires FDA to assess whether notifications received from manufacturers concern controlled substances subject to production quotas in accordance with 21 U.S.C. 826.

FDA's August 10th letter requested that DEA increase the APQ and individual manufacturing quotas for methylphenidate to a level that FDA deems necessary to address a shortage based on the best available market data.² On September 15, 2023, FDA clarified to DEA that methylphenidate is "intended for use in the prevention or treatment of a debilitating disease or condition" and therefore falls under the notification requirements of 21 U.S.C. 356c.

On September 14, 2023, DEA received a request for increased 2023 manufacturing quota pertaining to methylphenidate from a DEA registrant that is a manufacturer of that Schedule II controlled substance. Pursuant to this request, and following the receipt of the letter from FDA on August 10, DEA began its review under the timeframes specified by 21 U.S.C. 826(h)(1).

Analysis for the Adjustment to the 2023 Methylphenidate (for Sale) Aggregate Production Quota

In conducting the review under 21 U.S.C. 826(h) in order to determine the necessity of this adjustment, the Administrator has considered the criteria in accordance with 21 CFR 1303.13 (adjustment of APQ for controlled substances). The Administrator is authorized to increase or reduce the aggregate production quota at any time. 21 CFR 1303.13(a). DEA regulations state that there are five factors that shall be considered in determining to adjust the aggregate production quota. 21 CFR 1303.13(b). Accordingly, the Administrator has taken into account the following factors described below for 2023: (1) changes in the demand for that class, changes in the national rate of net disposal of the

class, changes in the rate of net disposal of the class by registrants holding individual manufacturing quotas for that class, and changes in the extent of any diversion in the class; (2) whether any increased demand for that class, the national and/or individual rates of net disposal of that class are temporary, short term, or long term; (3) whether any increased demand for that class can be met through existing inventories, increased individual manufacturing quotas, or increased importation, without increasing the aggregate production quota, taking into account production delays and the probability that other individual manufacturing quotas may be suspended pursuant to 21 CFR 1303.24(b); (4) whether any decreased demand for that class will result in excessive inventory accumulation by all persons registered to handle that class (including manufacturers, distributors, practitioners, importers, and exporters), notwithstanding the possibility that individual manufacturing quotas may be suspended pursuant to 21 CFR 1303.24(b) or abandoned pursuant to 21 CFR 1303.27; and (5) other factors affecting medical, scientific, research, and industrial needs in the United States and lawful export requirements, as the Administrator finds relevant, including changes in the currently accepted medical use in treatment with the class or the substances which are manufactured from it, the economic and physical availability of raw materials for use in manufacturing and for inventory purposes, yield and stability problems, potential disruptions to production (including possible labor strikes), and recent unforeseen emergencies such as floods and fires. 21 CFR 1303.13(b).

DEA reviewed domestic data from the latest IQVIA report on stimulant prescribing that described a 9.1 percent increase in prescribing of methylphenidate HCl products from 2021 to 2022.³ However, FDA's estimate of domestic medical need for methylphenidate drug products predicted a 0.11 percent increase for 2023 domestic need when compared to 2022 observed need. DEA believes that manufacturers can easily meet this insignificant increase in domestic medical need with currently established quotas.

DEA also reviewed published reporting of methylphenidate production and consumption globally found in the INCB's *Psychotropic*

Technical Report for 2022.⁴ This report outlines that U.S. production of methylphenidate accounted for 72.5 percent of global production and the U.S. was the leading exporter of methylphenidate in 2021. The number of countries and territories reporting the importation and consumption of methylphenidate drug products increased 5 percent and 8 percent, respectively, from 2020 to 2021. The report states that consumption rates in several European countries increased in 2021. Additionally, DEA reviewed export data extracted from DEA's internal databases and reported to the United Nations as part of the U.S.' treaty obligations for controlled substances. The export data showed that exports of drug products containing methylphenidate increased from 13,083kg in 2021 to 15,792kg in 2022. Extrapolation utilizing previous years' reported export data suggests a similar quantity of drug products containing methylphenidate HCl will be exported from the U.S. in 2023.

After considering these factors, DEA determined that it is necessary to increase the established 2023 APQ for the schedule II-controlled substance methylphenidate (for sale) to be manufactured in the United States to provide for the estimated needs of the United States and export requirements to meet global demand. This adjustment is necessary to ensure that the United States has an adequate and uninterrupted supply of methylphenidate (for sale) to meet legitimate patient needs both domestically and globally.

Additional Legal Considerations

The procedures previously adopted by DEA for adjustment of APQ are set forth in DEA regulations in 21 CFR 1303.13. Under that provision, the Administrator, upon determining that an adjustment of the aggregate production quota of any basic class of controlled substance is necessary, shall publish in the **Federal Register** general notice of an adjustment in the aggregate production quota for that class. The regulation further directs that DEA will allow any interested person to file comments or objections to the adjusted APQ within the time specified by the Administrator in the notice. Section 1303.13 further provides that, "[a]fter consideration of any comments or objections . . . the Administrator shall issue and publish in the **Federal**

² As the FDA's specific requested levels would reveal proprietary manufacturing data, DEA is not specifying the requested levels in this document.

³ Stimulant Prescription Trends in the United States from 2012–2022. IQVIA Government Solutions, Inc., August 31, 2023.

⁴ INCB Psychotropics—Technical Report Psychotropic Substances 2022, Statistics for 2021, Assessments of Annual Medical Scientific Requirements for Substances for 2023.

Register his final order determining the aggregate production quota for the basic class of controlled substance.”

The statutory timeframe applicable to actions taken under 21 U.S.C. 826(h) was enacted by Congress after DEA established its regulations in 21 CFR 1303.13. DEA has determined that it is not possible to increase the APQ within the Congressionally-mandated 30-day period while also complying with the procedures that DEA previously had

laid out in 21 CFR 1303.13. Therefore, the Administrator has determined that, in order to comply with the 30-day timeframe in 21 U.S.C. 826(h), this final order must be published without opportunity for comment and made effective immediately.

Determination of 2023 Adjusted Methylphenidate (for Sale) Aggregate Production Quota

In determining the adjustment of the 2023 methylphenidate (for sale)

aggregate production quota, DEA has taken into consideration the factors set forth in 21 CFR 1303.13(b) in accordance with 21 U.S.C. 826(a) as well as 826(h). Based on all of the above, the Administrator is adjusting the 2023 aggregate production quota for methylphenidate (for sale).

The Administrator hereby adjusts the 2023 APQ for the following schedule II-controlled substance expressed in grams of anhydrous acid or base, as follows:

| Controlled substance | Current APQ (g) | Adjusted APQ (g) |
|----------------------------------|-----------------|------------------|
| Schedule II | | |
| Methylphenidate (for sale) | 41,800,000 | 53,283,000 |

The APQ for all other schedule I and II controlled substances included in the 2023 established APQ remain at this time as previously established.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 29, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023-22059 Filed 9-29-23; 4:15 pm]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, And Liability Act

On September 26, 2023, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Indiana in the lawsuit entitled *United States v. CR-Troy, Inc., et al.*, Case No. 2:23-cv-463.

The proposed Consent Decree settles claims brought by the United States

under sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9606 and 9607 against four defendants including CR-Troy, Inc. (“CR-Troy,” formerly Consolidated Recycling Company, Inc.), GCSC Enterprises, Inc. (“GCSC”), Machine Tool Service, Inc. (“MTS”), and Valvoline LLC (“Valvoline”) seeking reimbursement of response costs and performance of remedial measures with respect to the Elm Street Groundwater Contamination Site in Terre Haute, Indiana. The Consent Decree requires Defendants to pay the United States a total of \$3,650,000 in response costs and perform the remedial “Work” defined in the Scope of Work, attached to the Consent Decree as Appendix B, which consists of soil excavation, groundwater monitoring, and under certain conditions soil vapor extraction to address contamination at the Site.

The publication of this notice opens a period for public comment on the proposed Consent Decrees. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States v. CR-Troy, Inc. et al.*, D.J. Ref. No. 90-11-3-12377. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

| | |
|----------------------------|---|
| <i>To submit comments:</i> | <i>Send them to:</i> |
| By email | <i>pubcomment-ees.enrd@usdoj.gov.</i> |
| By mail | Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611. |

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department website: <https://www.justice.gov/enrd/consent-decrees>.

We will provide a paper copy of the proposed Consent Decrees upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044-7611.

For a copy of the Consent Decree, please enclose a check or money order for \$43 (172 pages at 25 cents per page reproduction cost) payable to the United States Treasury.

Patricia McKenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2023-21755 Filed 10-2-23; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF JUSTICE

[OMB Number 1105-0108]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Complaint Regarding USMS Personnel or Programs

AGENCY: U.S. Marshals Service, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The U.S. Marshals Service (USMS), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously