

**OFFICE OF THE UNITED STATES  
TRADE REPRESENTATIVE**

**15 CFR Part 2004**

**RIN 0350-AA13**

**Technical Amendment: Freedom of  
Information Act Policies and  
Procedures**

**AGENCY:** Office of the United States Trade Representative (USTR).

**ACTION:** Adoption of interim rule as final.

**SUMMARY:** This final rule adopts, without change, an interim final rule with a request for comments published in the **Federal Register** on July 25, 2023, that made a minor technical change to the USTR Freedom of Information Act (FOIA) regulation.

**DATES:** Effective October 2, 2023.

**FOR FURTHER INFORMATION CONTACT:** Janice Kaye or Monique Ricker at [FOIA@ustr.eop.gov](mailto:FOIA@ustr.eop.gov) or 202-395-3150.

**SUPPLEMENTARY INFORMATION:**

**I. Technical Change**

On July 25, 2023, USTR published an interim final rule that made a technical change to § 2004.6 of the USTR FOIA regulation to align it with the statute and Office of Information Policy guidance about the compelling circumstances under which an agency must grant expedited processing. *See* 88 FR 47772. Although the interim final rule was effective upon publication, USTR provided a 30-day comment period, which ended on August 24, 2023. USTR did not receive any comments and is adopting the interim final rule without any changes.

**II. Regulatory Flexibility Act**

USTR considered the impact of this rule and determined that it will not have a significant economic impact on a substantial number of small business entities because it applies only to USTR's internal operations and legal obligations. 5 U.S.C. 605(b).

**III. Paperwork Reduction Act**

The final rule does not contain any information collection requirement that requires the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

**IV. Administrative Procedure Act (APA)**

On July 25, 2023, USTR published an interim final rule (88 FR 47772) and determined that there was a basis under the Administrative Procedure Act for issuing the interim final rule with

immediate effect. USTR provided a 30-day comment period, which ended on August 24, 2023. USTR did not receive any comments and is adopting the provisions of the interim final rule as a final rule with no changes.

**List of Subjects in 15 CFR Part 2004**

Administrative practice and procedure, Courts, Disclosure, Exemptions, Freedom of information, Government employees, Privacy, Records, Subpoenas, Testimony.

**PART 2004—DISCLOSURE OF  
RECORDS AND INFORMATION**

■ Accordingly, the interim final rule published in the **Federal Register** on July 25, 2023, at 88 FR 47772, amending 15 CFR part 2004, is adopted as a final rule without change.

**Janice Kaye,**

*Chief FOIA Officer, Office of the United States Trade Representative.*

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**BILLING CODE 3290-F3-P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Parts 1303 and 1315**

**[Docket No. DEA-455]**

**RIN 1117-AB49**

**Management of Quotas for Controlled  
Substances and List I Chemicals**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** The Drug Enforcement Administration (DEA) is publishing this final rule to manage the quotas for controlled substances and the list I chemicals, ephedrine, pseudoephedrine, and phenylpropanolamine, held by DEA-registered manufacturers. This final rule will define the types of quotas, update the method to abandon quota, clarify the current language to ensure that both manufacturers and distributors are required to obtain certification of a buyer's quota, reduce overall inventories, formalize the existing practice of use-specific subcategories for individual manufacturing and procurement quotas, and modify existing deadlines to fix/issue quotas. This final rule will also amend certain regulations to implement updates to the Controlled Substances Act made by the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act.

**DATES:** This final rule is effective November 29, 2023.

**FOR FURTHER INFORMATION CONTACT:**

Scott A. Brinks, Regulatory Drafting & Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

**SUPPLEMENTARY INFORMATION:**

**Legal Authority**

The Controlled Substances Act (CSA) authorizes the Administrator of the Drug Enforcement Administration (DEA) (by delegation from the Attorney General) to promulgate rules and regulations that he deems necessary and appropriate for the efficient execution of his functions under subchapter I (Control and Enforcement) and subchapter II (Import and Export). 21 U.S.C. 871(b) and 958(f). Subchapter I includes provisions which require the Administrator to establish the aggregate production quota for each basic class of controlled substance listed in schedules I and II and the assessment of annual needs for the ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured in the United States each calendar year 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. 21 U.S.C. 826. The Administrator shall take the following quota actions for a basic class of controlled substance listed in schedules I and II and ephedrine, pseudoephedrine, and phenylpropanolamine pursuant to stipulated conditions: limit or reduce individual production quotas for each registered manufacturer,<sup>1</sup> and fix individual manufacturing quotas for registrants.<sup>2</sup>

On October 24, 2018, Congress revised the CSA through the Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities (SUPPORT) Act. These revisions will be noted and included in these proposed regulations, where applicable. Through this Act, the Administrator, by way of delegation from the Attorney General, may now set quota in terms of the pharmaceutical dosage-form.

<sup>1</sup> 21 U.S.C. 826(b).

<sup>2</sup> 21 U.S.C. 826(d).