as SBSEF–FIN–QTR, SBSEF–FIN–QTR/A, SBSEF–FIN–REQ, and SBSEF–FIN–REQ/A submissions, respectively.[4]

Addition of XBRL Taxonomy for Cybersecurity Disclosures

EDGAR will be updated to allow filers to use the appropriate XBRL Taxonomy for cybersecurity disclosures required to be included in Forms 6–K, 8–K, 10–K, and 20–F (and the variants 10–KT, 10–K/A, 10–KT/A, 20–F/A, 8–K/A, and 6–K/A).[5]

Removal of the Index From Volume II of the EDGAR Filer Manual

Volume II of the Filer Manual will be updated to remove the Index. Filers may continue to use the Table of Contents which links directly to chapters and topics, and the document search function of this online manual.

III. Amendments to Rule 301 of Regulation S–T

Along with the adoption of the updated Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of the current revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual is available at *https://www.sec.gov/edgar/filerinformation/current-edgar-filer-manual.*

IV. Administrative Law Matters

Because the Filer Manual and rule amendments relate solely to agency procedures or practice and do not substantially alter the rights and obligations of non-agency parties, publication for notice and comment is not required under the Administrative Procedure Act (''APA'').[6] It follows that the amendments do not require analysis under requirements of the Regulatory Flexibility Act[7] or a report to Congress under the Small Business Regulatory Enforcement Fairness Act of 1996.[8]

The effective date for the updated Filer Manual and related rule amendments is October 22, 2024. In accordance with the APA,[9] we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with the related system upgrades.

V. Statutory Basis

We are adopting the amendments to Regulation S–T under the authority in sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[10] sections 3, 12, 13, 14, 15, 15B, 23, and 35A of the Securities Exchange Act of 1934,[11] section 319 of the Trust Indenture Act of 1939,[12] and sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[13]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The general authority citation for part 232 continues to read as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78n–1,78*o*(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the EDGAR Filer Manual, Volume I: ''General Information,'' Version 41 (December 2022). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 71 (September 2024). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for inspection at the Commission and at the National Archives and Records Administration (NARA). The EDGAR Filer Manual is available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Operating conditions may limit access to the Commission's Public Reference Room. For information on the availability of the EDGAR Filer Manual at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspection@nara.gov.* The EDGAR Filer Manual may also be obtained from *https://www.sec.gov/edgar/filerinformation/current-edgar-filer-manual.*

By the Commission.

Dated: September 16, 2024.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–24355 Filed 10–21–24; 8:45 am]

BILLING CODE 8011–01–P

[4] Security-Based Swap Execution and Registration and Regulation of Security-Based Swap Execution Facilities, Release No. 34–98845 (Nov. 2, 2023) [88 FR 87156 (Dec. 15, 2023)].

[5] Cybersecurity Risk Management, Strategy, Governance, and Incident Disclosure, Release No. 33–11216 (July 26, 2023) [88 FR 51896 (Aug. 4, 2023)].

[6] 5 U.S.C. 553(b)(A).

[7] 5 U.S.C. 601 through 612.

[8] 5 U.S.C. 804(3)(c).

[9] 5 U.S.C. 553(d)(3).

[10] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[11] 15 U.S.C. 78c, 78*l,* 78m, 78n, 78*o,* 78*o*–4, 78w, and 78*ll.*

[12] 15 U.S.C. 77sss.

[13] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1142]

Schedules of Controlled Substances: Placement of Ethylphenidate in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places ethylphenidate (chemical name: ethyl 2-phenyl-2-(piperidin-2-yl)acetate), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. When finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import,

export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle ethylphenidate.

DATES: *Effective date:* November 21, 2024.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of Health and Human Services (Secretary),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.[2] In the event that the Secretary did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control.

Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of the Drug Enforcement Administration (DEA) pursuant to 28 CFR 0.100) may, by rule, and upon the recommendation of the Secretary, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

Ethylphenidate is a central nervous system stimulant and shares structural and pharmacological similarities with other schedule II stimulants, such as methylphenidate. On April 21, 2017, the Secretary-General of the United Nations advised the Secretary of State of the United States that, during its 60th session on March 16, 2017, the Commission on Narcotic Drugs (CND) voted to place ethyl 2-phenyl-2-(piperidin-2-yl)acetate (ethylphenidate) in Schedule II of the 1971 Convention (CND Dec/60/7). Because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for ethylphenidate were not followed, as discussed above in the legal authority section, DEA is utilizing the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control ethylphenidate. Permanently scheduling ethylphenidate satisfies the United States' international obligations.

DEA and HHS Eight Factor Analyses

In a letter dated October 26, 2020, in accordance with 21 U.S.C. 811(b), and in response to DEA's April 3, 2019 request, HHS provided to DEA a scientific and medical evaluation and scheduling recommendation for ethylphenidate. DEA reviewed the scientific and medical evaluation and scheduling recommendation for schedule I placement provided by HHS, and all other relevant data, pursuant to 21 U.S.C. 811(b) and (c), and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 811(b)(1), that this substance warrants control in schedule I. Both DEA and HHS Eight-Factor analyses are available in their entirety under the tab Supporting Documents of the public docket for this action at *https://www.regulations.gov* under docket number DEA–1142.

Notice of Proposed Rulemaking To Schedule Ethylphenidate

On September 22, 2023, DEA published a notice of proposed rulemaking (NPRM) to permanently control ethylphenidate in schedule I.[3] Specifically, DEA proposed to add ethylphenidate to the list of stimulant substances under 21 CFR 1308.11(f). The NPRM provided an opportunity for interested persons to file a request for hearing in accordance with DEA regulations on or before October 23, 2023. DEA did not receive any requests for such a hearing. The NPRM also provided an opportunity for interested persons to submit comments on or before November 21, 2023.

Comments Received

DEA received ten comments in response to the notice of proposed rulemaking for the placement of ethylphenidate into schedule I of the CSA. The submissions were from individuals or anonymous commenters. Five commenters provided support for the notice of proposed rulemaking, four commenters were against the placement of ethylphenidate in schedule I of the CSA, and one commenter expressed statements that were neither for nor against the proposed rule.

DEA received five comments in support of the placement of ethylphenidate in schedule I.

DEA Response: DEA appreciates these comments in support of this rulemaking.

DEA received four comments against the placement of ethylphenidate in schedule I of the CSA. The following are DEA's responses to the individual comments against the proposed rulemaking.

DEA received a comment asserting that methylphenidate is already controlled under schedule II of the CSA, thus, ethylphenidate is considered controlled under the Controlled Substances Analogue Act due to their similarities. This commenter concluded that the government should not dictate what researchers may study for legitimate scientific use.

DEA Response: DEA appreciates this comment and would like to provide further clarification regarding the control of ethylphenidate. Ethylphenidate has been placed under international control. In order to comply with treaty obligations, DEA must place ethylphenidate under the most appropriate schedule, taking into consideration all appropriate scientific data. This is true even if this substance could be treated under the Controlled Substances Analogue provision. Additionally, as set forth in the NPRM, ethylphenidate has no currently accepted medical use in treatment in the United States. Therefore, ethylphenidate must be placed in schedule I of the CSA along with other substances which have no currently accepted medical use, lack

[1] As discussed in a memorandum of understanding entered into by the FDA and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (Mar. 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. *Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91–513, As Amended; Delegation of Authority,* 58 FR 35460 (July 1, 1993).

[2] 21 U.S.C. 811(d)(3).

[3] *Schedules of Controlled Substances: Placement of Ethylphenidate in Schedule* I, 88 FR 65330 (Sept. 22, 2023).

accepted safety for use under medical supervision, and possess a high potential for abuse. With respect to scientific research, the placement of substances in schedule I of the CSA does not preclude academic research on these substances. DEA registrants wishing to conduct research on schedule I substances may apply for permission to do so through the schedule I researcher registration program.[4]

DEA received a comment comparing ethylphenidate to methylphenidate. The commenter questioned the reasonable nature of placing ethylphenidate in schedule I of the CSA considering it is a weaker substance when compared to methylphenidate, a schedule II substance.

DEA Response: DEA appreciates this comment and asserts the following: Ethylphenidate belongs to the stimulant class of drugs and possesses abuse liability similar to that of methylphenidate; however, unlike methylphenidate, ethylphenidate has no currently accepted medical use in treatment in the United States. A qualification for placing substances in schedules II thorough IV of the CSA is that they must have a currently accepted medical use in treatment in the United States. Thus, DEA asserts that the placement of ethylphenidate in schedule I of the CSA is warranted.

DEA received a comment with statements against the NPRM placing ethylphenidate in schedule I of the CSA. The commenter stated that, in the NPRM, DEA failed to provide a reason for the placement of ethylphenidate in a more restrictive schedule (here, schedule I) than methylphenidate, considering the two drugs share significant pharmacological similarities and are considered analogues of one another. The commenter further stated that because ethylphenidate is an analog of methylphenidate, it may be possible in the future for ethylphenidate to be marketed as an alternative to methylphenidate. In particular, the commenter stated the placement of ethylphenidate in schedule I of the CSA would completely hamper future legitimate research regarding its medical efficacy. Thus, the commenter states, by imposing criminal sanctions on those who engage in research or chemical analysis of the drug, DEA would prevent the future discovery of its possible medical use.

DEA Response: DEA appreciates this comment and asserts the following: As stated above, ethylphenidate has been placed under international control. In order to comply with treaty obligations, DEA must place ethylphenidate under the most appropriate schedule, taking into consideration all appropriate scientific data. Additionally, a qualification for placing substances in schedules II thorough IV of the CSA is that they must have a currently accepted medical use in treatment in the United States. Ethylphenidate has no currently accepted medical use in treatment in the United States, lacks accepted safety for use under medical supervision, and possesses a high potential for abuse. Thus, DEA asserts that the placement of ethylphenidate in schedule I of the CSA is warranted. With respect to research, the placement of substances in schedule I of the CSA does not preclude research into this substance. DEA registrants wishing to conduct research on schedule I substances, including ethylphenidate, may apply for permission to do so through the schedule I researcher registration program.

DEA received a comment expressing that ethylphenidate should be categorized as a schedule II drug ''until further research has been conducted to prove its viability.''

DEA Response: DEA appreciates this comment and asserts the following: According to the CSA, schedule I substances are defined as drugs that have no known medical use in treatment in the United States, and have a high potential for abuse. Additionally, according to the CSA, schedule II substances also have a high potential for abuse but have a currently accepted medical use in treatment. Accordingly, DEA proposed to place ethylphenidate in schedule I of the CSA, due to its lack of a currently accepted medical use in treatment in the United States, its lack of accepted safety for use under medical supervision, and its high potential for abuse.

DEA received one comment that provided statements that were neither explicitly for nor against the proposed rule.

In this comment, the commenter suggested that instead of creating a new rule for the control of ethylphenidate, DEA should simply clarify the existing rule which controlled methylphenidate. According to this commenter, this suggested amendment would extend control to all derivatives of methylphenidate. The commenter also expressed an understanding of DEA's intent to schedule ethylphenidate but questioned whether a standard notice-and-comment procedure was needed for an action that could be addressed by clarifying existing rulemaking.

DEA Response: DEA appreciates this suggestion and asserts the following: Ethylphenidate was placed under international control on March 16, 2017, during the CND's 60th session. As a signatory to the 1971 Convention on Psychotropic Substances, it is incumbent upon DEA to place ethylphenidate in its most appropriate schedule under the CSA. Therefore, DEA proposed to place ethylphenidate in schedule I of the CSA because it has no currently accepted medical use in treatment in the United States, lacks accepted safety for use under medical supervision, and has an abuse potential similar to that of methylphenidate. As explained in the NPRM, because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for ethylphenidate were not followed, DEA utilized the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control ethylphenidate, which required notice and an opportunity for hearing.

Scheduling Conclusion

After consideration of the public comments, scientific and medical evaluation and accompanying scheduling recommendation from HHS, and after its own eight-factor evaluation, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of ethylphenidate. As such, DEA is permanently scheduling ethylphenidate as a controlled substance under schedule I of the CSA. The permanent scheduling of ethylphenidate will fulfill the United States' obligations as a party to the 1971 Convention.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, II, IV, and V. The CSA also specifies the findings requires to place a drug or other substance in any particular schedule, 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Acting Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) Ethylphenidate has a high potential for abuse that is comparable to other scheduled substances, such as methylphenidate (a schedule II substance);

(2) Ethylphenidate has no currently accepted medical use in treatment in the United States. In HHS' 2020 recommendation to control ethylphenidate, it was noted there are no approved New Drug Applications for ethylphenidate and no known therapeutic applications for ethylphenidate in the United States. DEA is not aware of any other evidence suggesting that ethylphenidate has

[4] *https://apps.deadiversion.usdoj.gov/webforms2/spring/main?execution=e1s2.*

a currently accepted medical use in treatment in the United States.[5]

(3) There is a lack of accepted safety for use of ethylphenidate under medical supervision. Because ethylphenidate has no approved medical use and has not been investigated as a new drug, its safety for use under medical supervision has not been determined.

Based on these findings, the Administrator of DEA concludes that ethylphenidate, as well as its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in schedule I of the CSA.

Requirements for Handling Ethylphenidate

Ethylphenidate is subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

[5] When placing a substance in schedule I, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1)(B) There is no evidence suggesting that ethylphenidate has a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug or substance that has not been approved by the FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. See *Marijuana Scheduling Petition; Denial of Petition; Remand,* 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.,* 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this final rule, there is no evidence that health care providers have widespread experience with medical use of ethylphenidate or that the use of ethylphenidate is recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, ethylphenidate must register with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who currently handles ethylphenidate and is not registered with DEA must submit an application for registration and may not continue to handle ethylphenidate, unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity in a manner not authorized by the CSA is unlawful and those in possession of any quantity may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held ethylphenidate to a person registered with DEA before the effective date of a final scheduling action in accordance with all applicable Federal, State, local, and tribal laws. Ethylphenidate must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Ethylphenidate is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76, as of the effective date of this final scheduling action. Non-practitioners handling ethylphenidate must comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of ethylphenidate must comply with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture ethylphenidate in accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of ethylphenidate must take an inventory of ethylphenidate on hand, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including ethylphenidate) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including ethylphenidate) on hand every two years, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports for ethylphenidate, or products containing ethylphenidate, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1301.74(b) and (c), 1301.76(b), and parts 1304, 1312 and 1317. Manufacturers and distributors must submit reports regarding ethylphenidate to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes ethylphenidate must comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of ethylphenidate must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR parts 1304 and 1312.

10. *Liability.* Any activity involving ethylphenidate not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14094 (Modernizing Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles

reaffirmed in E.O. 13563. E.O. 14094 modernizes the regulatory review process to advance policies that promote the public interest and address national priorities.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[6] Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on state or local governments, individuals, businesses, or organizations. However, this proposed rule would require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. 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.

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance ethylphenidate (chemical name: ethyl 2-phenyl-2-(piperidin-2-yl)acetate), including its salts, isomers, and salts of isomers, in schedule I of the CSA to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle ethylphenidate.

Based on the review of HHS's scientific and medical evaluation and all other relevant data, DEA determined that ethylphenidate has high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for ethylphenidate in the United States. Therefore, this final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.)* that this final rule would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of the final rule to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:
■ a. Redesignate paragraphs (f)(6) through (f)(12) as (f)(7) through (f)(13); and
■ b. Add a new paragraph (f)(6)
The addition reads as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

*	*	*	*	*	*	*
(6) Ethylphenidate (ethyl 2-phenyl-2-(piperidin-2-yl)acetate)						1727
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Signing Authority

This document of the Drug Enforcement Administration was signed on October 10, 2024, 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**.

[6] 44 U.S.C. 3501–3521.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2024–24083 Filed 10–21–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–0924]

Safety Zone: Fireworks Displays Within the Fifth Coast Guard District; The Wharf, Washington, DC

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for a fireworks display at ''The Wharf DC,'' in Washington, DC, to provide for the safety of life on navigable waterways during this event. Our regulation, ''Safety Zones; Fireworks Displays within the Fifth Coast Guard District,'' identifies the precise location. During the enforcement period, vessels may not enter, remain in, or transit through the safety zone unless authorized to do so by the COTP or his representative, and vessels in the vicinity must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulation in 33 CFR 165.506 will be enforced for the location identified in line no. 1 of table 2 to 33 CFR 165.506(h)(2) from 8 p.m. until 9:30 p.m. on December 7, 2024, or if necessary, due to inclement weather, from 8 p.m. until 9:30 p.m. on December 8, 2024.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kate M. Newkirk, Sector Maryland-NCR, Waterways Management Division, U.S. Coast Guard: telephone 410–576–2596, email *MDNCRMarineEvents@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone regulation for a fireworks display at The Wharf DC from 8 p.m. to 9:30 p.m. on December 7, 2024, or, if necessary due to inclement weather, from 8 p.m. until 9:30 p.m. on December 8, 2024. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation, ''Safety Zones; Fireworks Displays within the Fifth Coast Guard District,'' § 165.506, specifies the location of the safety zone for the fireworks show, which encompasses portions of the Washington Channel in the Upper Potomac River. As reflected in 33 CFR 165.23, vessels in the vicinity of the safety zone may not enter, remain in, or transit through the safety zone during the enforcement period unless authorized to do so by the COTP or his representative, and they must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: October 7, 2024.

Patrick C. Burkett,

Captain, U.S. Coast Guard, Captain of the Port, Sector Maryland-National Capital Region.

[FR Doc. 2024–24284 Filed 10–21–24; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[EPA–HQ–OAR–2024–0234; FRL–11945–01–OAR]

Prevention of Significant Deterioration (PSD): Paragraph Designation Corrections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending its Prevention of Significant Deterioration (PSD) regulations to correct the fourth-level paragraph designations to conform with the Office of the Federal Register (OFR) requirements. This is a ministerial final rule action that involves minor technical corrections.

DATES: This rule is effective October 22, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2024–0234. All documents in the docket are listed on the *https://www.regulations.gov* website. Publicly available docket materials are available either electronically through *https://www.regulations.gov* or in hard copy at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding federal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Office of Air and Radiation Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Questions concerning this final rule should be addressed to Mr. Peter Keller, Air Quality Policy Division, Office of Air Quality Planning and Standards (C539–04), U.S. Environmental Protection Agency, Post Office Box 12055, Research Triangle Park, NC 27711; telephone number: (919) 541–2065; email address: *keller.peter@epa.gov.*

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

I. Does this action apply to me?

No entities will be affected by this final action. The EPA is amending its PSD regulations to correct the fourth-level paragraph designations from the Code of Federal Regulations (CFR) to conform with the OFR requirements. The EPA is responsible for making the required paragraph codification corrections in the EPA PSD regulations and communicating those corrections to stakeholders, including state, local, and Tribal (SLT) permitting authorities and regulated entities. SLT permitting authorities are not required to make corresponding corrections to any of their regulations implementing the PSD program including those approved by the EPA into a State Implementation Plan (SIP).

II. Background and Rationale for This Action

Part C of title I of the Clean Air Act (CAA), 42 U.S.C. 7470 *et seq.,* contains the requirements for a component of the major New Source Review (NSR) program known as the PSD program. This program sets forth procedures for the preconstruction review and permitting of new and modified stationary sources of air pollution located in areas meeting the National Ambient Air Quality Standards (NAAQS) (''attainment'' areas) and areas for which there is insufficient information to classify an area as either attainment or nonattainment (''unclassifiable'' areas). The EPA's PSD regulations are contained in 40 CFR