(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2023–0132.

(h) Exceptions to EASA AD 2023–0132

(1) Where EASA AD 2023–0132 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where paragraph (2) of EASA AD 2023–0132 specifies if ''any crack is detected, before next flight, contact Airbus for approved instructions and, within the compliance time(s) specified in those instructions, accomplish those instructions accordingly,'' this AD requires replacing those word with ''if any cracking is detected, the cracking must be repaired before further flight using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.''

(3) This AD does not adopt the ''Remarks'' section of EASA AD 2023–0132.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Dat Le, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2023–0132, dated July 3, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0132, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on September 15, 2023.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–20407 Filed 9–21–23; 8:45 am]

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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: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes 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 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. If 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, or possess) or propose to handle ethylphenidate.

DATES: Comments must be submitted electronically or postmarked on or before November 21, 2023.

Interested persons may file a request for a hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for a hearing and waivers of an opportunity for a hearing or to participate in a hearing, together with a written statement of position on the matters of fact and law asserted in the hearing, must be received on or before October 23, 2023.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference ''Docket No. DEA–1142'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages commenters to submit comments 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 *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *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. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• *Paper comments:* Paper comments that duplicate the electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment, *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

• *Hearing requests:* All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law asserted in the hearing, must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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: In this proposed rule, the Drug Enforcement Administration (DEA) intends to place ethyl 2-phenyl-2-(piperidin-2-yl)acetate (ethylphenidate) including its salts, isomers, and salts of isomers in schedule I of the Controlled Substances Act (CSA).

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. DEA will make comments available, unless reasonable cause is given, for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want DEA to make it publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

DEA will make available publicly in redacted form comments containing personal identifying information or confidential business information identified as directed above. If a comment has so much confidential business information that DEA cannot effectively redact it, DEA may not make available publicly all or part of that comment. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as confidential as directed above.

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Appearance; Waiver

Pursuant to 21 U.S.C. 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA).[1] Interested persons, as defined in 21 CFR 1300.01(b), may file requests for a hearing in conformity with the requirements of 21 CFR 1308.44(a) and 1316.47(a), and such requests must:

(1) state with particularity the interest of the person in the proceeding;

(2) state with particularity the objections or issues concerning which the person desires to be heard; and

(3) state briefly the position of the person with regarding to the objections or issues.

Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(c), together with a written statement of position on the matters of fact and law involved in any hearing.[2]

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the **Federal Register**.[3] Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, she will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall only commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether ethylphenidate meets the statutory criteria for placement in schedule I.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion.[4] This proposed action is supported by a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (HHS).

In addition, the United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 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 HHS (Secretary),[5] 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

[1] 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D.

[2] 21 CFR 1316.49.

[3] 21 CFR 1308.44(b), 1316.53.

[4] 21 U.S.C. 811(a).

[5] 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 (March 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

substance.[6] 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), the Attorney General (as delegated to the Administrator of DEA) may, by rule, 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 (CNS) 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 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, discussed in the above legal authority section, were not followed, DEA is utilizing the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) to control ethylphenidate. Such scheduling would satisfy the United States' international obligations.

Article 2, paragraph 7(b), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule II of the 1971 Convention. Pursuant to the 1971 Convention, the United States must require licenses for the manufacture, export and import, and distribution of ethylphenidate. This license requirement is accomplished by the CSA's registration requirement as set forth in 21 U.S.C. 822, 823, 957, 958 and in ance with 21 CFR parts 1301 and 1312. In addition, the United States must adhere to specific export and import provisions set forth in the 1971 Convention. This requirement is accomplished by the CSA's export and import provisions established in 21 U.S.C. 952, 953, 957, 958 and in accordance with 21 CFR part 1312. Likewise, under Article 13, paragraphs 1 and 2, of the 1971 Convention, a party to the 1971 Convention may notify through the UN Secretary-General another party that it prohibits the importation of a substance in Schedule II, III, or IV of the 1971 Convention. If such notice is presented to the United States, the United States shall take measures to ensure that the named substance is not exported to the notifying country. This requirement is also accomplished by the CSA's export provisions mentioned above. Under Article 16, paragraph 4, of the 1971 Convention, the United States is required to provide annual statistical reports to the International Narcotics Control Board (INCB). Using INCB Form P, the United States shall provide the following information: (1) in regard to each substance in Schedule I and II of the 1971 Convention, quantities manufactured in, exported to, and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each substance in Schedule II and III of the 1971 Convention, quantities used in the manufacture of exempt preparations; and (3) in regard to each substance in Schedule II–IV of the 1971 Convention, quantities used for the manufacture of non-psychotropic substances or products. Lastly, under Article 2 of the 1971 Convention, the United States must adopt measures in accordance with Article 22 to address violations of any statutes or regulations that are adopted pursuant to its obligations under the 1971 Convention. Persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action; therefore, the United States complies with this provision.

DEA notes that there are differences between the schedules of substances in the 1971 Convention and the CSA. The CSA has five schedules (schedules I–V) with specific criteria set forth for each schedule. Schedule I is the only possible schedule in which a drug or other substance may be placed if it has high potential for abuse and no currently accepted medical use in treatment in the United States. See 21 U.S.C. 812(b). In contrast, the 1971 Convention has four schedules (Schedules I–IV) but does not have specific criteria for each schedule. The 1971 Convention simply defines its four schedules, in Article 1, to mean the correspondingly numbered lists of psychotropic substances annexed to the Convention, and altered in accordance with Article 2.

Proposed Determination To Schedule Ethylphenidate

On April 3, 2019, the Drug Enforcement Administration (DEA) requested that the Department of Health and Human Services (HHS) conduct a scientific and medical evaluation and provide a scheduling recommendation for ethylphenidate. On October 26, 2020, HHS provided DEA a scientific and medical evaluation (dated August 25, 2020) entitled ''Basis for the recommendation to place ethylphenidate in schedule I of the Controlled Substances Act'' and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b), following consideration of the eight-factors and findings related to the substance's abuse potential, legitimate medical use, safety, and dependence liability, HHS recommended that ethylphenidate be controlled in schedule I of the CSA under 21 U.S.C. 812(b). Upon receipt of the scientific and medical evaluation and scheduling recommendation from HHS, DEA reviewed the documents and all other relevant data and conducted its own eight-factor analysis in accordance with 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its proposed scheduling action. Please note that both DEA and HHS eight-factor analyses are available in their entirety under the tab ''Supporting Documents'' of the public docket of this rulemaking action at *http://www.regulations.gov,* under docket number ''DEA–1142.''

1. *The Drug's Actual or Relative Potential for Abuse:* The term ''abuse'' is not defined in the CSA. However, the legislative history of the CSA suggests that DEA consider the following criteria when determining whether a particular drug or substance has a potential for abuse: [7]

(a) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

(b) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or

(c) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to

[6] 21 U.S.C. 811(d)(3).

[7] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

administer such drugs in the course of his professional practice; or

(d) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

Both DEA and HHS eight-factor analyses found that ethylphenidate has abuse potential associated with its abilities to produce psychoactive effects that are similar to those produced by schedule II stimulants such as methylphenidate that have a high potential for abuse. In particular, the responses in humans to ethylphenidate are stimulant-like and include tachycardia, anxiety, hallucinations, impaired thinking, paranoia and hypertension.

Ethylphenidate does not have an approved medical use in the United States. Thus, because this substance is not an approved drug product, a practitioner may not legally prescribe it, and it cannot be dispensed to an individual. DEA and HHS conclude that ethylphenidate is being abused for its psychoactive properties because it is being used without medical advice.

Reports from the public health sector and law enforcement suggest that ethylphenidate is being abused and taken in amounts sufficient to create a hazard to an individual's health. This hazard is evidenced by deaths associated with ethylphenidate use which represents a safety issue for those in the community. Further, ethylphenidate was first reported to the National Forensic Laboratory Information System (NFLIS-Drug) [8] database in 2013; a January 2023 query of this database for ethylphenidate reports indicated a total of 191 such reports through 2022 from 23 states by participating Federal, State, and local forensic laboratories. Consequently, the data indicate that ethylphenidate is being abused, and presents safety hazards to the health of individuals who consume it due to its stimulant properties, making it a hazard to the safety of the community.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* As described by HHS, studies show that ethylphenidate produces pharmacological effects that are similar to those produced by methylphenidate, a schedule II substance. Similar to these schedule II substances, ethylphenidate binds to monoamine transporters for dopamine and norepinephrine and blocks the uptake of these neurotransmitters at their transporters. Functionally, ethylphenidate, similar to methylphenidate and cocaine, inhibits norepinephrine and dopamine uptake. The potency of ethylphenidate in inhibiting norepinephrine uptake is about 6.75-fold less than that of methylphenidate and 1.7-fold less than cocaine. With respect to behavioral data, according to HHS, while ethylphenidate is pharmacodynamically similar to methylphenidate, it is less potent than methylphenidate in the locomotor activity assay. Specifically, ethylphenidate is approximately 80% as effective as methylphenidate in producing locomotor effect. Self-reports by users of ethylphenidate demonstrate that the drug produces typical stimulant-like effects, including euphoria and psychological and psychomotor stimulation. Overall, these data indicate that ethylphenidate produces stimulant-like pharmacological effects and behaviors that are similar to those of schedule II substances methylphenidate and methamphetamine.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Ethylphenidate is structurally similar to the schedule II substance methylphenidate. As stated in the HHS review, ethylphenidate is chemically known as ethyl 2-phenyl-2-piperidin-2-ylacetate, (*RS*)-ethyl 2-phenyl-2-(piperidin-2-yl)acetate and *dl*-ethylphenidate. Another name for ethylphenidate is EPH.

Ethylphenidate user reports suggest that following insufflation, the pharmacokinetics of the drug are relatively rapid, with the onset of effects occurring approximately 13 minutes after administration (with a range of 0 to 35 minutes). Additionally, following oral ingestion, the mean onset of action is 23 minutes (ranging from 5 to 31 minutes). According to published scientific literature, the mean duration of action of ethylphenidate is approximately 2 hours.

As stated by HHS, there are no published clinical or nonclinical toxicology studies using ethylphenidate. Furthermore, the only evidence of the toxicological effects of ethylphenidate come from anecdotal user reports and fatal overdoses that implicated its role in a death.

Neither DEA nor HHS is aware of any currently accepted medical use for ethylphenidate. According to HHS's August 2020 scientific and medical evaluation and scheduling recommendation, the Food and Drug Administration (FDA) has not approved a marketing application for a drug product containing ethylphenidate for any therapeutic indication, nor is HHS aware of any reports of clinical studies or claims of an accepted medical use for ethylphenidate in the United States.

Although there is no evidence to suggest ethylphenidate has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, all of the following must be demonstrated: the drug's chemistry is known and reproducible; there are adequate safety studies; there are adequate and well-controlled studies proving efficacy; the drug is accepted by qualified experts; and the scientific evidence is widely available. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994). Based on this analysis, ethylphenidate has no currently accepted medical use in the United States. Furthermore, DEA has not found any references regarding clinical testing of ethylphenidate in the scientific and medical literature. Taken together with HHS's conclusion, DEA finds that there is no legitimate medical use for ethylphenidate in the United States.

4. *History and Current Pattern of Abuse:* As described by DEA and HHS, ethylphenidate is a stimulant and is structurally and pharmacologically similar to the schedule II substance, methylphenidate. Ethylphenidate has been trafficked and abused in North America and Europe since its first report of abuse in 2011. In addition, ethylphenidate has been identified in law enforcement seizures in the United States since 2013 and has persisted through 2020 (There were no ethylphenidate-related NFLIS-Drug reports in 2021 and 2022). Thus, ethylphenidate abuse occurs worldwide.

[8] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle the nation's drug analysis cases. NFLIS-Drug participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS-Drug, is currently 98.5 percent. NFLIS-Drug includes drug chemistry results from completed analyses only. While NFLIS-Drug data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. See 76 FR 77330, 77332, December 12, 2011. NFLIS data were queried on January 20, 2023.

5. *Scope, Duration and Significance of Abuse:* Forensic laboratories have confirmed the presence of ethylphenidate in drug exhibits received from State, local, and Federal law enforcement agencies. Law enforcement data show that ethylphenidate first appeared in the illicit drug market in 2013 with 10 encounters. Overall, from 2013 through 2022, NFLIS registered 191 reports from Federal, State and local forensic laboratories identifying this substance in drug-related exhibits from 23 states. Thus, ethylphenidate abuse is wide-spread.

6. *What, if Any, Risk There Is to the Public Health:* Based on the review of both HHS and DEA, public health risks of ethylphenidate result from its ability to induce stimulant-like responses, which may lead to adverse events that include psychological and cognitive impairment. Furthermore, risk to the public health is associated with adverse reactions in humans, which include hallucinations, impaired thinking, and paranoia. Nineteen deaths in the United Kingdom involving ethylphenidate have occurred between July 2013 and December 2014. A majority of these deaths involved males from East of Scotland with a history of current or previous heroin abuse. Additionally, according to the 2016 WHO Critical Review, these cases were almost exclusively associated with poly-drug use, with benzodiazepines, methadone, and other opioids being the most commonly detected drugs. Thus, the public health risks associated with ethylphenidate are confirmed by the pharmacological profile along with the fatalities associated with ethylphenidate use.

7. *Its Psychic or Physiological Dependence Liability:* According to HHS, the psychic or physiological dependence liability of ethylphenidate can be inferred based on case reports and from data on substances that have similar pharmacological actions. As noted by HHS, scientific literature of published case reports demonstrate the propensity of ethylphenidate re-dosing by its users. Furthermore, according to self-reports users of ethylphenidate typically experience stimulant-like behavioral effects. In addition, DEA notes that because ethylphenidate shares pharmacological properties with schedule II stimulant substances such as methylphenidate and methamphetamine, ethylphenidate likely has a dependence profile similar to these substances, which are known to cause substance dependence.

In summary, data suggests that ethylphenidate produces behavioral effects in animals and humans similar to those of schedule II stimulants. Although there are no clinical studies evaluating dependence liabilities specific for ethylphenidate, the pharmacological profile of this substance suggests that it possesses dependence liabilities qualitatively similar to schedule II substances such as methylphenidate and methamphetamine.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* Ethylphenidate is not an immediate precursor of any controlled substance under the CSA as defined by 21 U.S.C. 802(23).

Conclusion: After considering the scientific and medical evaluation conducted by HHS, HHS's scheduling recommendation, and DEA's own eight-factor analysis, DEA finds that the facts and all relevant data constitute substantial evidence of the potential for abuse of ethylphenidate. As such, DEA hereby proposes to permanently schedule ethylphenidate as a schedule I controlled substance under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required 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 Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. Ethylphenidate has a high potential for abuse.

Ethylphenidate, similar to the schedule II stimulants methylphenidate and methamphetamine, is a stimulant with a high potential for abuse. In animals, behavioral locomotor studies show that ethylphenidate produces stimulation similar to that of methylphenidate. Additionally, typical stimulant effects such as euphoria, psychomotor stimulation, and anxiety have been described from self-reports of ethylphenidate abusers. These effects are similar to those of schedule II stimulant such as methylphenidate and methamphetamine. These data collectively indicate that ethylphenidate has a high potential for abuse similar to other substances in schedule II such as methylphenidate and methamphetamine.

2. Ethylphenidate currently has no accepted medical use in treatment in the United States.

According to HHS, FDA has not approved a marketing application for a drug product containing ethylphenidate for any therapeutic indication. As HHS states, there are also no clinical studies or petitioners that claim an accepted medical use in the United States. In addition, as discussed above in the Factor 3 analysis, ethylphenidate does not satisfy DEA's five-part test for having a currently accepted medical use in treatment in the United States.

3. There is a lack of accepted safety for use of ethylphenidate under medical supervision.

Currently, ethylphenidate does not have an accepted medical use as noted by HHS. Because ethylphenidate has no approved medical use in treatment in the United States and has not been investigated as a new drug, its safety for use under medical supervision has not been determined. Thus, there is a lack of accepted safety for use of ethylphenidate under medical supervision.

Although the first finding shows ethylphenidate to have similar effects to schedule II substances such as methylphenidate and methamphetamine, it bears reiterating that there is only one possible schedule in the CSA—schedule I—to place ethylphenidate since it has no currently accepted medical use in treatment in the United States. See the background section for additional discussion.

Based on these findings, the Administrator concludes that ethylphenidate (chemical name: ethyl 2-phenyl-2-(piperidin-2-yl)acetate), including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA. 21 U.S.C. 812(b)(1). More precisely, because of its stimulant-like effects, DEA is proposing to place ethylphenidate in 21 CFR 1308.11(f) (the stimulants category of schedule I). As such, the proposed control of ethylphenidate also includes its salts, isomers, and salts of isomers.

Requirements for Handling Ethylphenidate

If this rule is finalized as proposed, ethylphenidate would be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

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) ethylphenidate, or who desires to handle ethylphenidate, is required to be registered 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 as of the effective date of a final scheduling action. Any person who currently handles ethylphenidate, and is not registered with DEA, would need to submit an application for registration and may not continue to handle ethylphenidate as of the effective date of a final scheduling action, 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.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration would be required to surrender all quantities of currently held ethylphenidate or to 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. As of the effective date of a final scheduling action, ethylphenidate would be required to 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 would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b) and in accordance with 21 CFR 1301.71–1301.93 as of the effective date of a final scheduling action. Non-practitioners handling ethylphenidate would also need to 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 would need to be in compliance with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302 as of the effective date of a final scheduling action.

5. *Quota.* Only registered manufacturers would be 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 as of the effective date of a final scheduling action.

6. *Inventory.* Every DEA registrant who possesses any quantity of ethylphenidate on the effective date of a final scheduling action would be required to take an inventory of ethylphenidate on hand at that time, pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who becomes registered with DEA to handle ethylphenidate on or after the effective date of a final scheduling action would be required to have 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 958, 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 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports with respect to ethylphenidate pursuant to 21 U.S.C. 827 and 958(e) and in accordance with 21 CFR parts 1304 and 1312, as of the effective date of a final scheduling action. Manufacturers and distributors would be required to 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, as of the effective date of a final scheduling action.

8. *Order Forms.* Every DEA registrant who distributes ethylphenidate would be required to comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305, as of the effective date of a final scheduling action.

9. *Importation and Exportation.* All importation and exportation of ethylphenidate would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312, as of the effective date of a final scheduling action.

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

Regulatory Analyses

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

In accordance with 21 U.S.C. 811(a), this proposed 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 criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This proposed 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 proposed 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 the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed 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.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA proposes 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. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If 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.

According to HHS, ethylphenidate has a 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, DEA estimates that no United States entity currently handles ethylphenidate and does not expect any United States entity to handle ethylphenidate in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule if finalized. As such, the proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action 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 million 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.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521.

Signing Authority

This document of the Drug Enforcement Administration was signed on September 7, 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**.

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, DEA proposes to amend 21 CFR part 1308 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. Amend § 1308.11 by:
■ a. Redesignating paragraph (f)(6) through (12) as (f)(7) through (13); and
■ b. Adding a new paragraph (f)(6)

The addition reads as follows:

§ 1308.11 Schedule I.

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(f) * * *

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(6) Ethylphenidate (ethyl 2-phenyl-2-(piperidin-2-yl)acetate)						1727
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Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2023–20439 Filed 9–21–23; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2023–0267; FRL–10958–01–R9]

Second 10-Year Maintenance Plan for the 24-Hour PM_{10} Standards; Sacramento County Planning Area, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the ''Second 10-Year PM_{10} Maintenance Plan for Sacramento County'' (''Second 10-Year Maintenance Plan'' or ''Plan'') as a revision to the state implementation plan (SIP) for the State of California (''State''). The Second 10-Year Maintenance Plan includes, among other elements, a base year emissions inventory, a maintenance demonstration, contingency provisions, and motor vehicle emissions budgets for use in transportation conformity determinations, to ensure the continued maintenance of the national ambient air quality standards (NAAQS) for particulate matter of 10 microns or less (PM_{10}). With this proposed rulemaking, the EPA is beginning the adequacy process for the 2024, 2027, and 2033 motor vehicle emissions budgets. Additionally, as part of the technical basis for this approval, the EPA is taking comment on our August 1, 2022 concurrence on the wildfire exceptional events demonstration submitted by the California Air Resources Board (CARB) on April 26, 2021.

DATES: Written comments must arrive on or before October 23, 2023.

ADDRESSES: Submit your comments identified by Docket ID No. EPA–R09–OAR–2023–0267 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effect comments, please visit