Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web page can be found at: *www.regulations.gov/docket/EERE-2021-BT-STD-0018.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9870. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Amelia Whiting, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–2588. Email: *Amelia.Whiting@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: On August 9, 2021, DOE published a RFI undertaking an early assessment review for amended energy conservation standards for pumps to determine whether to amend applicable energy conservation standards. Specifically, DOE is seeking data and information to evaluate whether amended energy conservation standards would result in a significant savings of energy; be technologically feasible; and be economically justified. 86 FR 43430. Interested parties in the matter, Grundfos (on August 10, 2021), HI (on August 12, 2021), Pentair (on August 12, 2021), and CA IOUs (on August 13, 2021), requested an extension of the public comment period for the RFI. (Grundfos, No. 2 at p. 1; HI, No. 3 at p. 1; Pentair., No. 4 at p. 1; CA IOUs, No. 5, at p. 1).[1] Grundos, HI, and Pentair commented that the extension is necessary to allow ample time to provide adequate comments on the issues identified. (Grundfos, No. 2 at p. 1; HI, No. 3 at p. 1; Pentair., No. 4 at p. 1) The CA IOUs noted that a data set of pump performance data was being complied by the Northwest Energy Efficiency Alliance (''NEEA'') and additional time was necessary to analyze and review the NEEA dataset. (CA IOUs, No. 5, at p. 1)

DOE has reviewed the requests and is extending the comment period to allow additional time for interested parties to submit comments. As noted, the RFI was issued as part of an early assessment review to determine whether to amend energy conservation standards for pumps. Based on the information received in response to this RFI, DOE will determine whether to proceed with a rulemaking for a new or amended energy conservation standard. If DOE makes an initial determination that a new or amended energy conservation standard would satisfy the applicable statutory criteria or DOE's analysis is inconclusive, DOE would undertake the preliminary stages of a rulemaking to issue a new or amended energy conservation standard. If DOE makes an initial determination based upon available evidence that a new or amended energy conservation standard would not meet the applicable statutory criteria, DOE will engage in notice and comment rulemaking before issuing a final determination that new or amended energy conservation standards are not warranted. As such, DOE has determined that an extension of 30 days is sufficient for this preliminary stage. Therefore, DOE is extending the comment period until October 8, 2021.

Signing Authority

This document of the Department of Energy was signed on August 27, 2021, by Kelly Speakes-Backman, Principal Deputy Assistant Secretary and Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 27, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–18885 Filed 9–1–21; 8:45 am]

BILLING CODE 6450–01–P

[1] The parenthetical reference provides a reference for information located in DOE's rulemaking docket. (Docket No. EERE–2021–BT–STD–0018, which is maintained at *www.regulations.gov/#!docketDetail;D=EERE-2021-BT-STD-0018*). The references are arranged as follows: (commenter name, comment docket ID number, page of that document).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–737]

Schedules of Controlled Substances: Placement of Methiopropamine in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing *N*-methyl-1-(thiophen-2-yl)propan-2-amine (methiopropamine), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances Act. 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, or possess) or propose to handle methiopropamine.

DATES: Comments must be submitted electronically or postmarked on or before October 4, 2021.

Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). 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.

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 4, 2021.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–737'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *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.

• *Paper comments:* Paper comments that duplicate the electronic submission are not necessary. 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:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. The Drug Enforcement Administration (DEA) will make them 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 it to be made 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 it cannot be redacted effectively, all or part of that comment may not be made available publicly. 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 directed above, 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, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. 21 CFR 1316.47(a). Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

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 DEA using the address information provided above.

Legal Authority

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 adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),[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. 21 U.S.C. 811(d)(3). In the event that the Secretary of HHS (Secretary) did not 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, by rule, may add to such a schedule any drug or other substance, if he finds that such drug or other substance has a potential

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (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 Controlled Substances Act, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

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 is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of DEA. 28 CFR 0.100.

Background

Methiopropamine is a central nervous stimulant and is structurally related to the schedule II stimulants methamphetamine and amphetamine. 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 *N*-methyl-1-(thiophen-2-yl)propan-2-amine (methiopropamine) in Schedule II of the 1971 Convention (CND Dec/60/8). Because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for methiopropamine, 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 methiopropamine. 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 methiopropamine. 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 accordance 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 Methiopropamine

On November 20, 2018, DEA requested HHS conduct a scientific and medical evaluation and recommend whether methiopropamine should be controlled under the CSA. On August 27, 2020 (dated August 25, 2020), HHS provided DEA a scientific and medical evaluation entitled ''Basis for the recommendation to control methiopropamine and its salts in schedule I of the Controlled Substance 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 methiopropamine 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–737.''

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: [2]

(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 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 methiopropamine has abuse potential associated with its abilities to produce psychoactive effects that are similar to those produced by schedule II stimulants such as amphetamine and methamphetamine

[2] 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.

that have a high potential for abuse. In particular, the responses in humans to methiopropamine are stimulant-like and include tachycardia, anxiety, insomnia, perspiration, and hallucination.

Methiopropamine has no approved medical uses in the United States. Because this substance is not an approved drug product, a practitioner may not legally prescribe it, and it cannot be dispensed to an individual. The use of this substance without medical advice leads to the conclusion that this stimulant is being abused for its psychoactive properties.

Reports from public health and law enforcement suggest that this substance is being abused and taken in amounts sufficient to create a hazard to an individual's health. This hazard is evidenced by deaths, representing a safety issue for those in the community. Further, methiopropamine was first identified in the National Forensic Laboratory Information System (NFLIS) [3] database in 2011; a September 29, 2020 query of this database for methiopropamine reports indicated a total of 128 such reports through 2018 from 19 states by participating federal, state, and local forensic laboratories. Consequently, the data indicate that methiopropamine is being abused, and it 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 methiopropamine produces pharmacological effects that are similar to those produced by schedule II substances such as amphetamine and methamphetamine. Similar to these schedule II substances, methiopropamine binds to monoamine transporters for dopamine and norepinephrine and blocks the uptake of these neurotransmitters at their transporters. However, methiopropamine does not have an affinity for serotonin transporters or a significant effect on serotonin transporter activity. Behavioral studies in animals demonstrate that methiopropamine produces locomotor behavior similar to those of amphetamine and methamphetamine. Self-reports by methiopropamine users demonstrate that methiopropamine produces classic stimulant-like effects, including euphoria, psychological and psychomotor stimulation, insomnia, anxiety, panic attacks, and an increased heart rate. Overall, these data indicate that methiopropamine produces pharmacological effects and stimulant-like behaviors that are similar to those of schedule II substances amphetamine and methamphetamine.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Methiopropamine is structurally similar to the schedule II substances methamphetamine and amphetamine. Specifically, methiopropamine is a thiophene analog of methamphetamine.

Self-reports by methiopropamine users in 2020 suggest that the pharmacokinetics of the drug following insufflation are rapid, with the onset of effects occurring five to ten minutes after administration. Methiopropamine reaches its maximum concentration at approximately thirty to sixty minutes later, with a duration of action that can persist for two to four hours. Limited studies identify nor-methiopropamine as the main metabolite found in bodily fluids.

Neither DEA nor HHS is aware of any currently accepted medical use for methiopropamine. 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 methiopropamine for any therapeutic indication, nor is HHS aware of any reports of clinical studies or claims of an accepted medical use for methiopropamine in the United States.

Although no evidence suggests that methiopropamine 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, methiopropamine has no currently accepted medical use in the United States. Furthermore, DEA has not found any references regarding clinical testing of methiopropamine in the scientific and medical literature. Taken together with HHS's conclusion, DEA finds that there is no legitimate medical use for methiopropamine in the United States.

4. *History and Current Pattern of Abuse:* As described by DEA and HHS, methiopropamine is a stimulant and is structurally and pharmacologically similar to the schedule II substances methamphetamine and amphetamine. Methiopropamine has been trafficked and abused in North America and Europe since its first report of abuse in 2011. In addition, methiopropamine has been identified in law enforcement seizures in the United States since 2011 through 2018. Thus, methiopropamine abuse occurs worldwide.

5. *Scope, Duration and Significance of Abuse:* Forensic laboratories have confirmed the presence of methiopropamine in drug exhibits received from state, local, and federal law enforcement agencies. Law enforcement data show that methiopropamine first appeared in the illicit drug market in 2011 with four encounters. Overall, from 2011 through 2018, NFLIS registered 128 reports from federal, state and local forensic laboratories identifying this substance in drug-related exhibits from 19 states. Thus, methiopropamine abuse is widespread.

6. *What, if Any, Risk There Is to the Public Health:* Based on the review of both HHS and DEA, public health risks of methiopropamine result from its ability to induce stimulant-like responses, which may lead to adverse events that include psychological and cognitive impairment. In addition, methiopropamine has been involved, with one or more other substances, in 14 deaths in the United Kingdom from 2012 to 2016, with methiopropamine being the sole contributing substance in one death in Australia in 2015. Thus, the public health risks associated with methiopropamine are confirmed by the pharmacological profile along with the fatalities associated with methiopropamine.

7. *Its Psychic or Physiological Dependence Liability:* According to HHS, the psychic or physiological dependence liability of methiopropamine is demonstrated by its positive abuse-related studies in animals and reported stimulant effects in humans. The results from two behavioral locomotor studies in 2016 demonstrate that methiopropamine produced behavioral effects similar to

[3] NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96% of an estimated 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only. While NFLIS 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, Dec. 12, 2011.

those of substances with stimulant effects such as amphetamine and methamphetamine. Furthermore, according to self-reports of drug users in 2020, methiopropamine has been abused for its stimulant properties. In addition, DEA notes that because methiopropamine shares pharmacological properties with schedule II stimulant substances such as amphetamine and methamphetamine, methiopropamine likely has a dependence profile similar to these substances, which are known to cause substance dependence.

In summary, data suggests that methiopropamine 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 methiopropamine, the pharmacological profile of this substance suggests that it possesses dependence liabilities qualitatively similar to schedule II substances such as amphetamine and methamphetamine.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* Methiopropamine 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 methiopropamine. As such, DEA hereby proposes to permanently schedule methiopropamine 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, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. Methiopropamine Has a High Potential for Abuse

Methiopropamine, similar to the schedule II stimulants amphetamine and methamphetamine, is a stimulant with a high potential for abuse. In animals, behavioral locomotor studies show that methiopropamine produces stimulation similar to that of methamphetamine. As HHS mentions, methiopropamine abuse in humans has been reported in at least 16 countries, including North America and Europe. Additionally, typical stimulant effects such as euphoria, psychomotor stimulation, and anxiety have been described from self-reports of methiopropamine abusers. These effects are similar to those of schedule II stimulant such as methamphetamine and amphetamine. These data collectively indicate that methiopropamine has a high potential for abuse similar to other substances in schedule II such as amphetamine and methamphetamine.

2. Methiopropamine 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 methiopropamine 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, methiopropamine 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 Methiopropamine Under Medical Supervision

Currently, methiopropamine does not have an accepted medical use as noted by HHS. Because methiopropamine 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 methiopropamine under medical supervision.

Although the first finding shows methiopropamine to have similar effects to schedule II substances such as amphetamine and methamphetamine, it bears reiterating that there is only one possible schedule in the CSA—schedule I—to place methiopropamine 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 methiopropamine (chemical name: *N*-methyl-1-(thiophen-2-yl)propan-2-amine), 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 methiopropamine in 21 CFR 1308.11(f) (the stimulants category of schedule I). As such, the proposed control of methiopropamine includes the substance as well as its salts, isomers, and salts of isomers.

Requirements for Handling Methiopropamine

If this rule is finalized as proposed, methiopropamine would become 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 (as of the effective date of the planned final scheduling action):

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) methiopropamine, or who desires to handle methiopropamine, 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 methiopropamine, and is not registered with DEA, would need to submit an application for registration and may not continue to handle methiopropamine 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 methiopropamine or to transfer all quantities of currently held methiopropamine 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, methiopropamine 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.* Methiopropamine 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 methiopropamine 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 methiopropamine 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 methiopropamine 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 methiopropamine on the effective date of a final scheduling action would be required to take an inventory of methiopropamine 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 methiopropamine 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 methiopropamine) 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 methiopropamine) 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 methiopropamine 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 methiopropamine 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 methiopropamine 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 methiopropamine 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 methiopropamine 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 methiopropamine (chemical name: *N*-methyl-1-(thiophen-2-yl)propan-2-amine), 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, methiopropamine.

According to HHS, methiopropamine 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 methiopropamine in the United States. Therefore, DEA estimates that no United States entity currently handles methiopropamine and does not expect any United States entity to handle methiopropamine 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.

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 further amend 21 CFR part 1308, which we proposed to amend on August 11, 2021 at 86 FR 43983, as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR 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 redesignating paragraph (f)(9) through (f)(11) as (f)(10) through (f)(12) and adding new paragraph (f)(9) to read as follows:

§ 1308.1 Schedule I.

* * * * *

(f) * * *

(9) Methiopropamine (*N*-methyl-1-(thiophen-2-yl)propan-2-amine) 1478

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2021–18843 Filed 9–1–21; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 223

[Docket No. 2021–4]

Small Claims Procedures for Library and Archives Opt-Outs and Class Actions

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Copyright Office is issuing a notice of proposed rulemaking regarding the procedures for libraries and archives to opt out of proceedings before the Copyright Claims Board (''CCB'') and the procedures for a party before the CCB with respect to a class action proceeding, under the Copyright Alternative in Small-Claims Enforcement Act of 2020. The Office invites public comments on this proposed rule.

DATES: Comments on the proposed rule must be made in writing and received by the U.S. Copyright Office no later than 11:59 p.m. EDT on October 4, 2021.

ADDRESSES: For reasons of government efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office website at *https://www.copyright.gov/rulemaking/case-act-implementation/library-opt-out.* If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Kevin. R. Amer, Acting General Counsel and Associate Register of Copyrights, by email at *kamer@copyright.gov,* or John R. Riley, Assistant General Counsel, by email at *jril@copyright.gov.* Each can be contacted by telephone at (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

The Copyright Alternative in Small-Claims Enforcement (''CASE'') Act of 2020 [1] directs the Copyright Office to establish the Copyright Claims Board (''CCB'' or ''Board''), a voluntary tribunal within the Office comprised of three Copyright Claims Officers who have the authority to render determinations on certain copyright disputes with a low economic value. This notice of proposed rulemaking is being issued subsequent to a notification of inquiry (''NOI'') published in the **Federal Register** on March 26, 2021, which describes in detail the legislative background and regulatory scope of the present rulemaking proceeding.[2] The Office assumes the reader's familiarity with that document.

[1] Public Law 116–260, sec. 212, 134 Stat. 1182, 2176 (2020).

[2] 86 FR 16156, 16161 (Mar. 26, 2021). Comments received in response to the March 26, 2021 NOI are available at *https://www.regulations.gov/document/COLC-2021-0001-0001/comment.* References to these comments are by party name (abbreviated where appropriate), followed by ''Initial NOI Comments'' or ''Reply NOI Comments,'' as appropriate.

A. Library and Archives Opt Out

The CASE Act directs the Register of Copyrights to ''establish regulations allowing for a library or archives that does not wish to participate in proceedings before the Copyright Claims Board to preemptively opt out of such proceedings.'' [3] The Office must also ''compile and maintain a publicly available list of the libraries and archives that have successfully opted out of proceedings.'' [4] In promulgating these regulations, the Register cannot ''charge a library or archives a fee to preemptively opt out of proceedings'' or ''require a library or archives to renew a decision to preemptively opt out of proceedings.'' [5]

For the purposes of this provision, the statute defines ''library'' and ''archives'' as ''any library or archives, respectively, that qualifies for the limitations on exclusive rights under section 108 [of title 17].'' [6] Section 108 provides exemptions to libraries and archives from liability for infringement for specified uses of copyrighted works.[7] For an institution to qualify for those exemptions, ''the collections of the library or archives [must be] . . . open to the public, or . . . available not only to researchers affiliated with the library or archives or with the institution of which it is a part, but also to other persons doing research in a specialized

[3] 17 U.S.C. 1506(aa)(1).

[4] *Id.* at 1506(aa)(2)(B).

[5] *Id.* at 1506(aa)(3)(A).

[6] *Id.* at 1506(aa)(3)(B). The CASE Act's legislative history does not discuss the library and archives opt-out provision. *See generally* S. Rep. No. 116–105 (2019); H.R. Rep. No. 116–252 (2019). Note, the CASE Act's legislative history cited is for S. 1273, 116th Cong. (2019) and H.R. 2426, 116th Cong. (2019), the CASE Act of 2019, bills largely identical to the CASE Act of 2020, with the notable exception that these earlier bills did not contain the libraries and archives opt-out provision.

[7] 17 U.S.C. 108.