suitability action and the employee authorized to make the final decision regarding such suitability action. The official authorized to make the final decision is prohibited from ex parte communications consistent with the requirements of 5 U.S.C. 557(d).

(b) The decision regarding the final action must be in writing, be dated, and inform the respondent of the reasons for the decision. If the decision requires removal, the employing agency must remove the appointee from the rolls within 5 workdays of the agency's decision.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA1180]

Schedules of Controlled Substances: Placement of 4-Fluoroamphetamine in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing the substance 4-fluoroamphetamine (4–FA; 1-(4-fluorophenyl)propan-2-amine), 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 with, or possess) or propose to handle 4-fluoroamphetamine.

DATES: Comments must be submitted electronically or postmarked on or before July 3, 2025.

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 1316.47 and/or 1316.49, 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 or postmarked on or before July 3, 2025.

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. DEA1180'' 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 *https://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. 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 filed with the DEA Administrator, who will make the determination of whether a hearing will be needed to address such matters of fact and law in the rulemaking. Such requests must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. For informational purposes, a courtesy copy of 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.
- *Paperwork Reduction Act Comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to Docket No. DEA1180.

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

As required by 5 U.S.C. 553(b)(4), a summary of this proposed rule may be found in the docket for this rulemaking at *www.regulations.gov.*

SUPPLEMENTARY INFORMATION: In this proposed rule, the Drug Enforcement Administration (DEA) intends to place 4-fluoroamphetamine (4–FA; 1-(4-fluorophenyl)propan-2-amine), 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 for public inspection online at *https://www.regulations.gov.* Such information includes personal or business identifying information (such as name, address, State or Federal identifiers, etc.) voluntarily submitted by the commenter. All information voluntarily submitted by the commenter, unless clearly marked as Confidential Information in the method described below, will be publicly posted. Comments may be submitted anonymously

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want made publicly available should submit two copies of the comment. One copy must be marked ''CONTAINS CONFIDENTIAL INFORMATION'' and should clearly identify all PII or business information the commenter does not want to be made publicly available, including any supplemental materials. DEA will review this copy, including the claimed PII and confidential business information, in its consideration of comments. The second copy should be marked ''TO BE PUBLICLY POSTED'' and must have all claimed confidential or proprietary business information redacted. DEA will

post only the redacted comment on *https://www.regulations.gov* for public inspection. DEA generally will not redact additional information contained in the comment marked ''TO BE PUBLICLY POSTED.'' The Freedom of Information Act applies to all comments received.

For easy reference, an electronic copy of this document and supplemental information to this proposed rule are available at *https://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), 5 U.S.C. 551–559.[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 regard 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, he will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall 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 4-fluoroamphetamine meets the statutory criteria for placement in schedule I, as proposed in this rulemaking.

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 her own motion, at the request of the Secretary of Health and Human Services (HHS), or on the petition of an interested party.[4] This proposed action is initiated on the Acting Administrator's own motion and supported by, *inter alia,* a recommendation from the then-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. Domestic procedures respecting changes in drug schedules under the 1971 Convention are set forth in 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 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.[6] In the event that the 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) remain available and can be used to meet the United States' international obligations under the Convention.

Pursuant to 21 U.S.C. 811(a)(1) and (2), the Attorney General (as delegated to the Administrator of DEA) may, by rule, and upon the recommendation of the Secretary, add to such a schedule or transfer between such schedules any drug or other substance, if she 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

4-Fluoroamphetamine (4–FA) is a central nervous system stimulant and shares structural and pharmacological similarities with schedule II stimulants, such as amphetamine and methamphetamine, and the schedule I substance 3,4-methylenedioxymethamphetamine. (MDMA). On May 15, 2018, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND), during its 61st session held in March 2018, voted to place 4–FA in Schedule II of the 1971 Convention (CND Dec/61/12).

As a signatory to the 1971 Convention, the United States is required, by scheduling under the CSA, to place appropriate controls on 4–FA to meet the minimum requirements of the treaty. Because the procedures in 21 U.S.C. 811(d)(3) and (4) for consultation and issuance of a temporary order for 4–FA, 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 4–FA. 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 4–FA. This license requirement is accomplished by the CSA's registration requirement as set forth in 21 U.S.C. 822, 823, 957, and 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 with the export and import provisions

[1] 21 CFR 1308.41 through 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 (Mar. 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).

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

established in 21 U.S.C. 952, 953, 957, and 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 U.N. 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, exported to, and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each substance in Schedule III and IV of the 1971 Convention, quantities manufactured, as well as quantities exported and imported; (3) in regard to each substance in Schedule II and III of the 1971 Convention, quantities used in the manufacture of exempt preparations; and (4) 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.[7] 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 4–FA

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on 4–FA and on September 6, 2019, submitted it to the then-Assistant Secretary for Health of HHS with a request for a scientific and medical evaluation of available information and a scheduling recommendation for 4–FA.

On March 2, 2021, HHS provided DEA a scientific and medical evaluation entitled ''Basis for the Recommendation to Place 4-Fluoroamphetamine 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 4–FA 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 the detailed DEA and HHS eight-factor analyses supporting this proposed rule are both available in their entirety under the tab ''Supporting Documents'' of the public docket of this rulemaking action at *https://www.regulations.gov,* under docket number ''DEA1180.''

1. The Drug's Actual or Relative Potential for Abuse

In addition to considering the information HHS provided in its scientific and medical evaluation document for 4–FA, DEA also considered all other relevant data regarding actual or relative potential for abuse of 4–FA. The term ''abuse'' is not defined in the CSA; however, the legislative history of the CSA suggests the following four prongs in determining whether a particular drug or substances has a potential for abuse:[8]

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 of the community; or

b. There is a significant diversion of the drug or 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 4–FA produces pharmacological effects that are similar to those produced by schedule I and II substances, such as amphetamine, methamphetamine, and MDMA. 4–FA produces amphetamine-like features in a number of *in vivo* and *in vitro* assays, including the induction of locomotor activity and associated dopamine release. Data also demonstrate that 4–FA is self-administered and produces discriminative stimulus effects that are similar to those of the schedule II substances methamphetamine and cocaine. These pharmacological characteristics of 4–FA are predictive of substances that have a high potential for abuse.

4–FA does not have an approved medical use in the United States, but evidence indicates that 4–FA is being abused and trafficked 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. However, case reports, coroner/medical examiner reports, and law enforcement data[9] demonstrate that 4–FA is being abused because it is being used without medical advice. 4–FA has been identified during the toxicological screening of human urine or serum samples indicating that it is being

[7] *See* 21 U.S.C. 812(b).

[8] 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.

[9] While law enforcement data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV, 76 FR 77330, 77332 (Dec. 12, 2011).

abused by individuals. In humans, stimulant effects, like that of amphetamine, were observed following the oral administration of 4–FA. Non-fatal intoxications and overdoses have also been associated with the abuse of 4–FA.

Law enforcement data show that 4–FA has been encountered in the United States' illicit drug market. From January 2011 to December 2023, National Forensic Laboratory Information System (NFLIS)-Drug registered 269 reports [10] pertaining to the trafficking, distribution, and abuse of 4–FA. These encounters of 4–FA by law enforcement indicate that this substance is being trafficked and abused by individuals in the United States as a recreational drug of abuse.

Overall, these data demonstrate that 4–FA has a high potential for abuse. Thus, based on these data, it is reasonable to conclude that 4–FA, having no medical use, and thus no therapeutic value, presents a hazard to the health and safety of individuals and the community.

2. Scientific Evidence of the Drug's Pharmacological Effects, if Known

As explained in the 8-factor analyses by HHS and by DEA, the available pharmacology data indicate that 4–FA produces pharmacological effects that are similar to those produced by schedule I and II substances, such as methamphetamine, cocaine, and MDMA. Similar to these schedule I and II stimulants, 4–FA affects monoamine neurotransmission. Briefly, 4–FA promotes the release of dopamine, norepinephrine, and serotonin, and blocks the reuptake of these substances at nerve terminals. Data also demonstrate that 4–FA produces locomotor behavior and discriminative stimulus effects that are similar to those of the schedule I and II substances MDMA, methamphetamine, and cocaine. In a self-administration study, 4–FA produced rewarding properties. Furthermore, in humans, stimulant effects, like that of amphetamine, were observed following the oral administration of 4–FA. Non-fatal intoxications and overdoses have also been associated with the abuse of 4–FA. These pharmacological characteristics of 4–FA are predictive of substances that have a high potential for abuse. Overall, these data indicate that 4–FA produces pharmacological effects and stimulant-like behaviors that are similar to those of the amphetamine and MDMA.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

4–FA is a halogenated amphetamine, which can be produced by a variety of synthetic methods that are commonly utilized for the preparation of amphetamine. After oral ingestion, 4–FA is excreted in the urine mainly as an unchanged drug, but three metabolites, in low concentrations, have also been identified. Available pharmacology data demonstrate that the effects of 4–FA after oral administration, generally, occurred approximately 30 to 60 minutes post-ingestion and lasted for 4 to 8 hours after exposure. In addition, maximum blood concentrations of 4–FA occurred 2 hours after administration of 4–FA with both clinical and recreational uses. Data also show that 4–FA is eliminated from the body approximately 8 to 9 hours with a variation of 5.5 to 16.8 hours after administration. In the HHS report, United States Food and Drug Administration (FDA) concluded that 4–FA has no currently accepted medical use in the United States. Similarly, DEA concludes 4–FA has no currently accepted medical use according to established DEA procedure and case law.[11]

4. History and Current Pattern of Abuse

4–FA is a recreational drug that has been identified in the United States' illicit drug market. Evidence indicates that 4–FA has been substituted for MDMA and amphetamines. Thus, it is highly likely that this substance is abused in the same manner as these stimulant substances. That is, 4–FA, similar to other stimulant substances, is most likely ingested by swallowing capsules or tablets or snorted by nasal insufflation of the powder. Demographic data collected from toxicology analyses suggest that the main users of 4–FA are young adults. In addition, there is evidence that 4–FA being ingested with other substances, including schedule I synthetic cathinones, common cutting agents, or other substances of abuse.

5. Scope, Duration and Significance of Abuse

Evidence shows that 4–FA is a recreational drug of abuse. According to HHS, based on the pharmacological properties of 4–FA, the scope, duration, and significance of abuse of 4–FA would be similar to stimulants that are scheduled under the CSA, including the schedule I substance MDMA, as well as the schedule II stimulants cocaine and methamphetamine, if uncontrolled. Evidence of 4–FA abuse is confirmed by law enforcement encounters of this substance. According to analyses by forensic laboratories, drug exhibits received from State, local, or Federal law enforcement agencies were found to contain 4–FA. Between January 2011 and December 2023, NFLIS registered 269 reports from Federal, State, and local forensic laboratories identifying this substance in drug-related exhibits from 27 States. These encounters of 4–FA by law enforcement indicate that this substance is being trafficked and abused in the United States. Furthermore, evidence also indicate that 4–FA is abused internationally. According to the European Monitoring Centre for Drugs and Drug Addiction, 4–FA has also been seized abroad, indicating it is being abused internationally. Taken together, these data indicate that the abuse of 4–FA is widespread.

[10] NFLIS-Drug is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories in the United States. NFLIS-Drug data were queried on October 15, 2024.

[11] To place a drug or other substance in schedule I under the CSA, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. 21 U.S.C. 812(b)(1)(B). There is no evidence suggesting that 4–FA has a currently accepted medical use in treatment in the United States. To determine whether a drug or other substance has a currently accepted medical use, DEA has traditionally applied a five-part test to a drug that has not been approved by FDA: i. The drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. *Marijuana Scheduling Petition; Denial of Petition; Remand,* 57 FR 10499 (Mar. 26, 1992), pet. for rev. denied, *Alliance for Cannabis Therapeutics* v. *Drug Enforcement Admin.,* 15 F.3d 1131, 1135 (D.C. Cir. 1994). DEA and HHS applied the traditional five-part test for currently accepted medical use in this matter. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care practitioners operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which the part 1 is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently accepted medical use. Office of Legal Counsel, Memorandum for Merrick B. Garland Attorney General Re: Questions Related to the Potential Rescheduling of Marijuana at 3 (April 11, 2024). For purposes of this proposed rule, there is no evidence that health care providers have widespread experience with medical use of 4–FA, or that the use of 4–FA is recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

6. What, if Any, Risk There Is to the Public Health

Available evidence on the overall public health risks associated with the use of 4–FA suggests that 4–FA can cause acute health problems leading to emergency department admissions and death. Indeed, 4–FA has been associated with numerous overdoses and at least five deaths. Acute effects of 4–FA are those typical of sympathomimetic agents (*e.g.,* cocaine, methamphetamine, amphetamine) and include, among other effects, tachycardia, headache, palpitations, agitation, anxiety, mydriasis, tremor, fever or sweating, and hypertension. In addition, products containing 4–FA often do not bear labeling information regarding their ingredients, and if they do, such labels may not contain the expected active ingredient or identify the health risks and potential hazards associated with these products. These factors demonstrate that 4–FA is a serious public health threat.

7. Its Psychic or Physiological Dependence Liability

According to HHS, there is reason to suspect that 4–FA will have psychic dependence liability even though studies have not specifically examined physical dependence with respect to 4–FA. While there may be no studies examining the psychic and physiological dependence of 4–FA, its dependence liability can be inferred by case reports. Self-reports by users of 4–FA indicate that 4–FA produces typical stimulant-like effects, including euphoria, and psychological and psychomotor stimulation. These reports, combined with the pharmacological profile of 4–FA in animals, indicate that 4–FA produces stimulant effects that are similar to those produced by psychomotor stimulants in schedule II, such as amphetamine and methamphetamine. Thus, as HHS notes, it is likely that 4–FA will produce similar psychic dependence to these schedule II psychomotor stimulant drugs.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

4–FA is not an immediate precursor of any substance controlled under the CSA, as defined in 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 4–FA. As such, DEA hereby proposes to permanently schedule 4–FA as a schedule I controlled substance under the CSA. This action would enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances.

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.[12] After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Acting Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. 4–FA Has a High Potential for Abuse

According to HHS, 4–FA is structurally and chemically similar to schedule I and II stimulant substances, such as amphetamine, methamphetamine, and MDMA. An assessment of all available *in vitro* and *in vivo* pharmacology studies (*i.e.,* drug discrimination and intravenous self-administration studies) as well as clinical and human anecdotal data support that the abuse potential of 4–FA is similar to that of schedule I and II stimulant substances. Furthermore, 4–FA has been detected in various drug seizures across the United States and in various European countries; thus, there is significant evidence that individuals are using 4–FA for abuse purposes. Overall, these data provide supportive evidence that 4–FA has a high potential for abuse that is similar to substances in schedule I or II of the CSA.

2. 4–FA Has No Currently Accepted Medical Use in Treatment in the United States

HHS stated that FDA has not approved a marketing application for a drug product containing 4–FA for any indication. Moreover, there are no clinical studies or petitioners, of which HHS is aware, that claim an accepted medical use in the United States. DEA further notes that according to established DEA procedure and case law, 4–FA has no currently accepted medical use. Thus, evidence demonstrates that 4–FA has no currently accepted medical use in treatment in the United States.

[12] 21 U.S.C. 812(b).

3. There Is a Lack of Accepted Safety for Use of 4–FA Under Medical Supervision

Currently, 4–FA does not have an accepted medical use as noted by HHS. Because 4–FA 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 4–FA under medical supervision.

Based on these findings, the Acting Administrator concludes that 4-fluoroamphetamine (4–FA; 1-(4-fluorophenyl)propan-2-amine), including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA. More precisely, because of its stimulant-like effects, DEA is proposing to place 4–FA in 21 CFR 1308.11(f) (the stimulants category of schedule I).

Requirements for Handling 4–FA

If this rulemaking is finalized as proposed, 4–FA 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) 4–FA, or who desires to handle 4–FA, would need 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 4–FA, and is not registered with DEA, would need to submit an application for registration and may not continue to handle 4–FA 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, and 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 4–FA or to transfer all quantities of currently held 4–FA 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, 4–FA 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.* 4–FA would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821, 823, and 871(b), and in accordance with 21 CFR 1301.71 through 1301.76, as of the effective date of a final scheduling action. Non-practitioners handling 4–FA would also need to comply with the employee screening requirements of 21 CFR 1301.90 through 1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 4–FA would need to comply 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 4–FA 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 4–FA on the effective date of a final scheduling action would need to take an inventory of 4–FA 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.

Any person who becomes registered with DEA to handle 4–FA on or after the effective date of a final scheduling action would need to take an initial inventory of all stocks of controlled substances (including 4–FA) 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.

After the initial inventory, every DEA registrant would need to take an inventory of all controlled substances (including 4–FA) 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 need to maintain records and submit reports with respect to 4–FA 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 4–FA to the Automation of Reports and Consolidated Order System (ARCOS) 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 4–FA would need 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 4–FA would need to be comply 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 4–FA 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, 13563, and 14192 (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. DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulation,

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 Acting 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 4-fluoroamphetamine (4–FA, 1-(4-fluorophenyl)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, 4–FA.

According to HHS, 4–FA 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. There appear to be no legitimate sources for 4–FA as a marketed drug in the United States, but DEA notes that this substance is available for purchase from legitimate suppliers for scientific research. There is no evidence of significant diversion of 4–FA from legitimate suppliers. As such, the proposed rule, if finalized, is not expected to result in a significant economic impact 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 proposed rule would not impose a new collection of information under the Paperwork Reduction Act of 1995.[13] Also, this proposed rule would not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this proposed rule would require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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. In § 1308.11:

■ a. Redesignate paragraphs (f)(8) through (13) as (f)(9) through (14); and

■ b. Add a new paragraph (f)(8).

The addition reads as follows:

§ 1308.11 Schedule I.

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(f) * * *

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(8) 4-Fluoroamphetamine (4–FA, 1-(4-fluorophenyl)propan-2-amine)						1476
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Signing Authority

This document of the Drug Enforcement Administration was signed on May 27, 2025, by Acting Administrator Robert J. Murphy. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

[FR Doc. 2025–09988 Filed 6–2–25; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–1189]

Designation of Propionyl Chloride as a List I Chemical

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration is proposing the control of propionyl chloride as a list I chemical under the Controlled Substances Act (CSA). The Drug Enforcement Administration finds that propionyl chloride is used in the illicit manufacture of the controlled substances fentanyl, fentanyl analogues and fentanyl-related substances, and is important to the manufacture of these substances. In the respective synthetic pathways in which it is used to manufacture those substances, it is a replacement for propionic anhydride, which is currently a list I chemical. If finalized, the proposed rule would subject handlers of propionyl chloride to the chemical regulatory provisions of the CSA and its implementing regulations. This proposed rulemaking does not establish a threshold for domestic and international transactions of propionyl chloride. As such, all transactions of propionyl chloride, regardless of size, shall be regulated. In addition, chemical mixtures containing propionyl chloride are not exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of propionyl chloride shall be regulated pursuant to the CSA. Although no automatic exemption is available, manufacturers may submit an application for exemption.

DATES: Comments must be submitted electronically or postmarked on or before July 3, 2025. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–1189'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration 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 electronic submissions 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,

[13] 44 U.S.C. 3501–3521.