effective September 15, 2024. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

In 2003, Congress enacted the Vision 100-Century of Aviation Reauthorization Act (Pub L., 108–176), which established a joint planning and development office in the FAA to manage the work related to the Next Generation Air Transportation System (NextGen). Today, NextGen is an ongoing FAA-led modernization of the nation's air transportation system to make flying safer, more efficient, and more predictable.

In support of NextGen, this proposal is part of an ongoing, large, and comprehensive airway modernization project in the state of Alaska. Part of this project is to transition the Alaskan en route navigation structure away from dependency on NDBs and move to develop and improve the Area Navigation (RNAV) route structure. The FAA is planning to decommission the Evansville, AK, NDB. As a result, the segment of Alaskan Federal Airway V–444 between the Evansville NDB and the Browerville, AK, VOR will become unusable. The mitigation to the loss of this segment of V–444 is RNAV route T–232. T–232 directly overlays the segment of V–444 proposed for removal. Additionally, the segment of Alaskan Federal Airway V–504 between the Evansville NDB and the Deadhorse, AK, VOR/Distance Measuring Equipment (DME) will become unusable. The mitigation to the loss of this segment of V–504 is RNAV route T–240. T–240 directly overlays the segment of V–504 proposed for removal.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend Alaskan VOR Federal Airways V–444 and V–504 in Alaska. The FAA is proposing these actions due to the pending decommissioning of the Evansville, AK, NDB.

V–444: V–444 in Alaska currently extends between the Barrow, AK, VOR/DME and the intersection of the Northway, AK, VOR/Tactical Air Navigation (VORTAC) 120° (M), 138° (T), and the Gulkana, AK, VOR/DME 062° (M), 079° (T) radials. As amended, V–444 would extend between the Bettles, AK, VOR/DME and the intersection of the Northway, AK, VORTAC 120° (M), 138° (T), and the Gulkana, AK, VOR/DME 062° (M), 079° (T) radials.

V–504: V–504 currently extends between the Nenana, AK, VORTAC and the Deadhorse, AK, VOR/DME. As amended, V–504 would extend between the Neana VORTAC and the Bettles, AK, VOR/DME.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

Paragraph 6010(b) Alaskan VOR Federal Airways.

* * * * *

V–444 [Amended]

From Bettles, AK; Fairbanks, AK; Big Delta, AK; Northway, AK; intersection of the Northway 120° (M), 138° (T), and Gulkana 062° (M), 079°(T) radials.

* * * * *

V–504 [Amended]

From Nenana, AK; to Bettles, AK.

Issued in Washington, DC, on December 20, 2024.

Richard Lee Parks,

Manager (A), Airspace Rules and Regulations.

[FR Doc. 2024–31104 Filed 12–27–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1246]

Schedules of Controlled Substances: Placement of 4-Chloromethcathinone 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-chloromethcathinone (4–CMC, 1-(4-chlorophenyl)-2-(methylamino)propan-1-one), 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-chloromethcathinone.

DATES: Comments must be submitted electronically, and written comments must be postmarked or shipped on or before January 29, 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 on or before January 29, 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. DEA–1246'' 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 comment 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. DEA–1246.

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

SUPPLEMENTARY INFORMATION: In this proposed rule, the Drug Enforcement Administration (DEA) proposes to place 4-chloromethcathinone (also known as 4–CMC or 1-(4-chlorophenyl)-2-(methylamino)propan-1-one) including its salts, isomers, and salts of isomers in schedule I of the Controlled Substances Act (CSA).

Posting of Public Comments

Please note that 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 identifiers (such as name, address, state or Federal identifiers, etc.) voluntarily submitted by the commenter. In general, 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 PII and business information already redacted. DEA will post only the redacted comment on *https://www.regulations.gov* for public inspection. 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 scheduling action are available at *https://www.regulations.gov.*

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 regarding to the objections or issues.

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

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above. The decision whether a hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the **Federal Register**.[3] Once the Administrator designates an Administrative Law Judge (ALJ) to preside over the hearing, the ALJ's functions shall commence, 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-chloromethcathinone meets the statutory criteria for placement in schedule I, as proposed in this rule.

[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.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion, 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 Administrator's own motion and supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of HHS.

In addition, the United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), Feb. 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added to a schedule specified in the notification, the Secretary of 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) control. 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 he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

4-Chloromethcathinone (4–CMC) is a central nervous system stimulant that shares structural and pharmacological similarities with schedule I synthetic cathinones such as 4-methylethcathinone (4–MEC), 4-fluoromethcathinone (4–FMC), and 3-fluoromethcathinone (3–FMC), and schedule II stimulants such as amphetamine and methamphetamine. On May 7, 2020, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs (CND) voted to place 4–CMC in Schedule II of the 1971 Convention during its 63rd session held in March 2020 (CND Dec/63/9).

As a signatory to the 1971 Convention, the United States is required, by scheduling under the CSA, to place appropriate controls on 4–CMC 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–CMC, 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–CMC. 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–CMC. 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 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 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, 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.

[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).

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

Proposed Determination to Schedule 4–CMC

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on 4–CMC and on May 12, 2021, submitted it to the Assistant Secretary for Health of HHS with a request for a scientific and medical evaluation of available information and a scheduling recommendation for 4–CMC.

On December 22, 2022, HHS provided DEA a scientific and medical evaluation entitled ''Basis for the Recommendation to Control 4-Chloro-N-methylcathinone (4–CMC) and its Optical Isomers, Salts, and Salts of Optical Isomers, 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–CMC 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. Readers should refer to the full eight-factor analyses prepared by HHS and by DEA in support of this proposal, which are 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 ''DEA–1246.''

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–CMC, DEA also considered all other relevant data regarding actual or relative potential for abuse of 4–CMC. 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 substance 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–CMC produces pharmacological effects that are similar to those of the ten schedule I cathinone stimulants,[9] MDMA, and the schedule II drugs cocaine and methamphetamine. 4–CMC exhibits a typical stimulant-like pharmacological profile in preclinical studies and in human case reports. 4–CMC produces full generalization to the schedule II stimulants, methamphetamine, and cocaine, and to MDMA, and, in humans, 4–CMC caused stimulant-like adverse effects, like that of these schedule I and II stimulants.

4–CMC does not have an approved medical use in the United States, but evidence indicates that 4–CMC 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 [10] demonstrate that 4–CMC is being abused because it is being used without medical advice. 4–CMC has been identified during the toxicological screening of human urine or serum samples indicating that it is being abused by individuals. In humans, stimulant effects, like those of amphetamine, were observed following the oral administration of 4–CMC. Non-fatal intoxications and overdoses have also been associated with the abuse of 4–CMC.

Law enforcement data show that 4–CMC has been encountered in the United States' illicit drug market. From January 2014 to August 2024, the National Forensic Laboratory Information System (NFLIS)-Drug registered 399 reports [11] pertaining to the trafficking, distribution, and abuse of 4–CMC. These encounters of 4–CMC 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–CMC has a high potential for abuse. Thus, based on these data, it is reasonable to conclude that 4–CMC, 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 discussed in the eight-factor analyses prepared by DEA and by HHS, the available pharmacology data indicate that 4–CMC produces pharmacological effects that are similar to those produced by schedule I and II substances, such as mephedrone, 4–FMC, methamphetamine, cocaine, methcathinone, and MDMA. Similar to these schedule I and II stimulants, 4–CMC affects monoamine neurotransmission via action at monoamine transporters. 4–CMC binds to monoamine transporters for dopamine, serotonin, or norepinephrine and promotes the release of these monoamines or blocks their uptake. Actions at these transporters, especially actions that alter dopaminergic neurotransmission, are believed to be involved in the production of the stimulant effects of this class of drugs. Data also demonstrate that 4–CMC produces locomotor behavior and discriminative stimulus effects that are similar to those of the schedule I and II substances methamphetamine and cocaine. Furthermore, in humans, adverse effects of 4–CMC are similar to those reported following the use of

[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, 4601.

[9] Schedules of Controlled Substances: Placement of 10 Synthetic Cathinones Into Schedule I, 82 FR 12171–12177 (Mar. 1, 2017). The ten synthetic cathinones were 4-methethcathinone (4–MEC), 4′–Methyl–α–pyrrolidinopropiophenone (4–MePPP), α–pyrrolidinovalerophenone (α–PVP), butylone, pentedrone, pentylone, 4–fluoromethcathinone (4–FMC), 3–fluoromethcathinone (3–FMC), naphyrone, and α–Pyrrolidinobutiophenone (α–PBP).

[10] 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).

[11] 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 was queried on September 4, 2024.

schedule I synthetic cathinones and schedule II stimulants. These pharmacological characteristics of 4–CMC are predictive of substances that have a high potential for abuse. Overall, these data indicate that 4–CMC produces pharmacology effects and stimulant-like behaviors that are similar to those of methamphetamine and MDMA.

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

4–CMC is a synthetic cathinone that is structurally similar to schedule I substances such as 4–FMC, methcathinone, and mephedrone. Anecdotal information in the record indicates that the effects of 4–CMC can be felt more quickly after insufflation (2–3 minutes) than after oral ingestion (30–60 minutes), but its duration of effect is longer with oral ingestion. In addition, toxicology data show that 4–CMC is rapidly metabolized in the human body. DEA is not aware of any legitimate medical use for 4–CMC. Additionally, there are no therapeutic applications or recorded medical uses of 4–CMC. According to HHS, the Food and Drug Administration (FDA) concluded that 4–CMC has no currently accepted medical use in the United States. Similarly, DEA concludes 4–CMC has no currently accepted medical use according to established DEA procedure and case law.[12]

4. History and Current Pattern of Abuse

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

5. Scope, Duration, and Significance of Abuse

Evidence in the record shows that 4–CMC is a recreational drug of abuse. According to HHS, based on the pharmacological properties of 4–CMC, the scope, duration, and significance of abuse of 4–CMC 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. Law enforcement data is also evidence of the abuse of 4–CMC.

According to HHS, evidence of 4–CMC abuse is confirmed by data from poison control centers (PCC). PCC data is derived from the National Poison Data System (NPDS), a database managed by the American Association of Poison Control Centers (AAPCC).[13] Between 2010 and 2019, there were 13,238 PCC cases involving synthetic cathinones, of which 10,482 were abuse cases. Approximately 7,775 (74 percent) of the synthetic cathinone cases involved a synthetic cathinone as a single drug substance. HHS reported that it is likely that some portion of these cases involved 4–CMC exposure because 4–CMC is a synthetic cathinone. PCC data also showed that the most common category of medical outcome were cases with moderate effects (*i.e.,* symptoms that are prolonged and involved some treatments) (3,746 of 5,654, or 66.3 percent). Of the cases admitted to a health care facility, most (3,039 of 4,720, or 64.4 percent) were admitted to a critical care unit. From these data, HHS concluded that individuals likely seek aid through PCCs or emergency departments (ED) following ingestion of synthetic cathinones because of the known adverse effects of synthetic cathinones.

Evidence of 4–CMC abuse is also confirmed by law enforcement seizure data. According to analyses by forensic laboratories, drug exhibits received from State, local, or Federal law enforcement agencies were found to contain 4–CMC. Between January 2014 and August 2024, NFLIS-Drug registered 399 reports from Federal, State, and local forensic laboratories identifying this substance in drug-related exhibits from 33 states.[14] There is additional evidence that 4–CMC is abused internationally. 4–CMC has been identified in items seized by law enforcement agencies in countries such as China, Czechia, Hungary, Indonesia, and Poland. These encounters of 4–CMC by law enforcement indicate that this substance is being trafficked in the United States and internationally. The abuse of 4–CMC in the United States and internationally indicates that the abuse of 4–CMC is widespread.

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

Available evidence in the record on the overall public health risks associated with the use of 4–CMC suggests that it can cause acute health problems leading to ED admissions and death. Indeed, 4–CMC has been associated with overdoses and deaths of individuals. Acute effects of 4–CMC are those typical of sympathomimetic agents (*e.g.,* cocaine, methamphetamine, amphetamine) and among other effects include euphoria, increased energy, sociability and sexuality, visual and auditory hallucinations, strong empathogenic feelings, bruxism, lightheadedness, dizziness, slurred speech, slowed behavior, mydriasis, increased drive, disorientation as to time, place, and surroundings, tachycardia, agitation, logorrhea, poor light reflex, and difficulty walking and holding items. In addition, products containing 4–CMC 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

[12] 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–CMC 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 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–CMC, or that the use of 4–CMC is recognized by entities that regulate the practice of medicine under either the traditional five-part test or the two-part test.

[13] AAPCC is a nationwide network of PCCs that receive reports from individuals, healthcare professionals, and other interested persons in the general U.S. population regarding exposures to prescription drugs and other substances.

[14] NFLIS-Drug was queried on September 4, 2024.

hazards associated with these products. These factors demonstrate that 4–CMC is a serious public health threat.

7. Its Psychic or Physiological Dependence Liability

According to the HHS eight-factor analysis, the psychic or physiological dependence liability of 4–CMC is demonstrated by animal abuse-related studies. HHS found that the pharmacological data (*e.g.,* locomotor studies) strongly suggest that 4–CMC produces behavioral effects that are similar to those of schedule I and II stimulants. Because 4–CMC shares pharmacological properties with those of the schedule I and II substances that have dependence potential, such as methamphetamine, cocaine, and MDMA, it is probable that 4–CMC has a dependence profile similar to these substances which are known to cause substance dependence. It is also probable that 4–CMC will have rewarding properties similar to those of schedule I and II stimulants and, consequently, psychic dependence of 4–CMC can develop and may contribute to its continued use among individuals who abuse it despite its adverse consequences. Thus, as HHS notes, it is likely that 4–CMC will produce similar psychic dependence to schedule I and II stimulant drugs.

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

4–CMC 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–CMC. As such, DEA hereby proposes to permanently schedule 4–CMC 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.[15] After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all other available data, the Administrator of DEA, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1. 4–CMC Has a High Potential for Abuse

According to HHS, 4–CMC is structurally and pharmacologically similar to schedule I and II stimulant substances, such as schedule I synthetic cathinones, methamphetamine, and MDMA. 4–CMC demonstrated activity as a monoamine reuptake inhibitor at dopamine, serotonin, and norepinephrine transporters. This mechanism of action is similar to the schedule I substances 4–FMC, mephedrone, MDMA, and methcathinone, as well as the schedule II stimulants, cocaine and methamphetamine. In locomotor studies, 4–CMC produced behavioral stimulation similar to that of the schedule II stimulants cocaine and methamphetamine and the schedule I stimulant MDMA. In drug discrimination studies, 4–CMC fully generalized to the discriminative stimulus effects of the schedule II stimulants cocaine and methamphetamine and the schedule I stimulant MDMA. Thus, 4–CMC elicits pharmacological effects similar to cocaine, methamphetamine, MDMA, and methcathinone, illustrating a high potential for abuse that is similar to substances in schedules I and II of the CSA. Overall, these data provide supportive evidence that 4–CMC has a high potential for abuse that is similar to substances in schedule I or II of the CSA.

2. 4–CMC 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–CMC for any indication. Moreover, FDA is not aware of any adequate and well-controlled clinical studies that show 4–CMC is safe and effective for any intended use. DEA further notes that, according to established DEA procedure and case law, 4–CMC has no currently accepted medical use. Thus, evidence demonstrates that 4–CMC has no currently accepted medical use in treatment in the United States.

3. There is a Lack of Accepted Safety for Use of 4–CMC Under Medical Supervision

Currently, 4–CMC does not have an accepted medical use. And because it has not been approved for use by FDA, its safety under medical supervision has not been determined. Thus, there is a lack of accepted safety for use of 4–CMC under medical supervision.

Based on these findings, the Administrator concludes that 4-chloromethcathinone (4–CMC, 1-(4-chlorophenyl)-2-(methylamino)propan-1-one), including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA.

Requirements for Handling 4–CMC

If this rule is finalized as proposed, 4–CMC 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–CMC, or who desires to handle 4–CMC, would be 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 4–CMC, and is not registered with DEA, would need to submit an application for registration and may not continue to handle 4–CMC 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–CMC or to transfer all quantities of currently held 4–CMC 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–CMC 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–CMC 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

[15] 21 U.S.C. 812(b).

1301.71 through 1301.76 as of the effective date of a final scheduling action. Non-practitioners handling 4–CMC 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–CMC 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–CMC 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–CMC on the effective date of a final scheduling action would be required to take an inventory of 4–CMC 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–CMC 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 4–CMC) 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 4–CMC) 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 4–CMC 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–CMC 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–CMC 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 4–CMC would need to 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–CMC 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 14094 (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. E.O. 14094 modernizes the regulatory review process to advance policies that promote the public interest and address national priorities.

Executive Order 12988, Civil Justice Reform

This 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 4-chloromethcathinone (4–CMC, 1-(4-chlorophenyl)-2-(methylamino)propan-1-one), 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–CMC.

The entities affected by this proposed rule include the manufacturers, distributors, importers, exporters, and researchers of 4–CMC. DEA determines the North American Industry Classification System (NAICS) industries that best represent these business activities. Table 1 lists the business activities and corresponding NAICS industries.[16]

[16] Executive Office of the President Office of Management and Budget, North American Industry Classification System, United States, 2022, *https://www.census.gov/naics/reference_files_tools/2022_NAICS_Manual.pdf.* (Accessed 4/2/2024)

TABLE 1—BUSINESS ACTIVITY AND CORRESPONDING NAICS INDUSTRIES

Business activity	NAICS code	NAICS industry description
Manufacturer	325412	Pharmaceutical Preparation Manufacturing.
Distributor, Importer, Exporter	424210	Drugs and Druggists' Sundries Merchant Wholesalers.
	424690	Other Chemical and Allied Products Merchant Wholesalers.
Researcher	541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology).
	611310	Colleges, Universities and Professional Schools.

From Statistics of U.S. Businesses (SUSB) data, DEA determined the number of firms and small firms for each of the affected industries, and by comparing the number of affected small entities to the number of small entities for each industry, DEA determine whether a substantial number of small entities are affected in any of the industries. Table 2 lists the number of firms, small firms, and percent small firms in each affected industry.

TABLE 2—PERCENT AFFECTED SMALL ENTITIES BY INDUSTRY

NAICS industry	Firms [17]	SBA size standard [18]	Small firms [19]	Percent small entities (%)
325412-Pharmaceutical Preparation Manufacturing	1,007	1,300	931	92.4
424210—Drugs and Druggists' Sundries Merchant Wholesalers	6,958	250	6,663	95.8
424690—Other Chemical and Allied Products Merchant Wholesalers	6,069	175	5,781	95.3
541715—Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	8,019	1,000	7,571	94.4
611310—Colleges, Universities and Professional Schools	2,433	$34.5	1,515	62.3

Based on the American Chemical Society's SciFinder database, DEA identified 10 entities supplying 4–CMC across these industries. Suppliers include 325412, 424210, and 424690 industries. Even if all affected suppliers were small entities, they would account for only 0.15 percent of the small entities in those industries, not a substantial number.[20] Additionally, DEA expects the number of researchers working with 4–CMC is small because 4–CMC lacks current marketing approval under a new drug application or an abbreviated new drug application, and is not subject to an investigational new drug application as noted in the HHS review. Also, DEA believes the researchers working with 4–CMC may also work with other controlled substances; hence, they have probably already registered with DEA and are qualified to handle controlled substances. For these reasons, DEA believes the number of affected researchers that are small entities is not a substantial number of small entities in 541715 and 622310 industries.

The primary costs associated with this proposed rule would be the annual registration fee for Schedule I controlled substances ($3,699 for manufacturers, $1,850 for distributors, and $296 for researchers). As mentioned above, DEA has identified 13 domestic suppliers of 4–CMC from the SciFinder database and none of these suppliers has registered with DEA to handle Schedule I controlled substances. However, it is common for suppliers to have items in their catalog while not actually having any material level of sales because FDA has not approved a marketing application for a drug product containing 4–CMC. Therefore, some suppliers may simply remove 4–CMC from their catalog without any impact. Additionally, as discussed above, the researchers working with 4–CMC are likely to work with other controlled substances and hence, must already register with DEA.

In summary, the small entities impacted by this proposed rule are those in 325412-Pharmaceutical Preparation Manufacturing, 424210—Drugs and Druggists' Sundries Merchant Wholesalers, and 424690-Other Chemical and Allied Products Merchant Wholesalers. The affected small entities account for less than 0.15 percent of the small businesses and are not likely to manufacture or carry inventory of 4–CMC. 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 of 1995 (UMRA), 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 $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under the UMRA.

Paperwork Reduction Act of 1995

This proposed rule would not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995.[21] 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,

[17] Statistics of U.S. Businesses, 2021 SUSB Annual Data Tables by Establishment Industry, *https://www.census.gov/data/tables/2021/econ/susb/2021-susb-annual.html.* (Accessed 4/2/2024).

[18] U.S. Small Business Administration, Table of size standards, Version March 2023, Effective: March 17, 2023, *https://www.sba.gov/sites/sbagov/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023_.xlsx.* (Accessed 4/2/2024).

[19] See footnote 17.

[20] 20/(931 + 6,664 + 5,781) = 0.15%.

[21] 44 U.S.C. 3501–3521.

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.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 13, 2024, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Heather Achbach,

Federal Register Liaison Officer, Drug Enforcement Administration.

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 21 CFR 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, add paragraph (d)(105) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

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(105) 4-Chloromethcathinone (4–CMC, 1-(4-chlorophenyl)-2-(methylamino)propan-1-one)	1239
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[FR Doc. 2024–30359 Filed 12–27–24; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1457]

Schedules of Controlled Substances: Placement of Seven Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing seven fentanyl-related substances, as identified in this proposed rule, in schedule I of the Controlled Substances Act. These seven substances fall within the definition of fentanyl-related substances set forth in the February 6, 2018 temporary scheduling order. Through the Temporary Reauthorization and Study of Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023, which extended the order until December 31, 2024. If finalized, this action would make permanent the existing regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle these seven specific controlled substances.

DATES: Comments must be submitted electronically or postmarked on or before January 29, 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, must be received on or before January 29, 2025.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). To ensure proper handling of comments, please reference ''Docket No. DEA–1457'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* The Drug Enforcement Administration (DEA) encourages commenters to submit all 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 to 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 for your comment. Submitted comments are not instantaneously available for public view on *Regulations.gov*. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• *Paper comments:* Paper comments that duplicate 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, 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. DEA–1457.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical