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

Accordingly, pursuant to the authority delegated to me, 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), 106(g); 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 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL WI E5 Mosinee, WI [Amended]

Central Wisconsin Airport, WI
(Lat. 44°46′39″ N, long. 89°40′00″ W)
Central Wisconsin: RWY 35–LOC
(Lat. 44°47′02″ N, long. 89°40′34″ W)
Central Wisconsin: RWY 08–LOC
(Lat. 44°47′07″ N, long. 89°28′30″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Central Wisconsin Airport, and within 1 mile each side of the 170° bearing from the Central Wisconsin: RWY 35–LOC extending from the 7-mile radius of the airport to 11.2 miles south of the airport, and within 1 mile each side of the 257° bearing from the Central Wisconsin: RWY 08–LOC extending from the 7-mile radius of the airport to 11.5 miles west of the airport.

Issued in Fort Worth, Texas, on April 5, 2022.

Martin A. Skinner,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2022–07584 Filed 4–8–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2022–F–0342]

Anitox Corporation; Filing of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Anitox Corporation, proposing that the food additive regulations be amended to provide for the safe use of trans-2-hexenal as a preservative in food for poultry and swine.

DATES: The food additive petition was filed on March 8, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this document into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carissa Adams, Center for Veterinary Medicine (HFV–221), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6283, *Carissa.Adams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 2315), submitted by Anitox Corporation, 1055 Progress Circle, Lawrenceville, GA 30043–4646. The petition proposes to amend 21 CFR part 573—Food Additives Permitted in Feed and Drinking Water of Animals to provide for the safe use of trans-2-hexenal as a preservative in food for poultry and swine.

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(r) because it is of a type that does not individually or cumulatively have a significant effect on the human environment. In addition, the petitioner has stated that, to their knowledge, no extraordinary circumstances exist that may significantly affect the quality of the human environment. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: April 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07683 Filed 4–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA824]

Schedules of Controlled Substances: Placement of 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing two phenethylamine hallucinogens, as identified in this proposed rule, 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 for one of these 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 these two specific controlled substances.

DATES: Comments must be submitted electronically or postmarked on or before June 10, 2022.

Interested persons may file a request for hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for 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 May 11, 2022.

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–824'' on all electronic and written correspondence, including any attachments.

• *Electronic comments:* 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 attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the on-line instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number. 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 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 FR Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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

FOR FURTHER INFORMATION CONTACT: 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 schedule the following two controlled substances in schedule I of the Controlled Substances Act (CSA), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- 2,5-dimethoxy-4-iodoamphetamine (DOI) and
- 2,5-dimethoxy-4-chloroamphetamine (DOC)

Posting of Public Comments

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

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

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

An electronic copy of this document and supplemental information to this proposed rule are available at *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, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and such requests must include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. 21 CFR 1316.47(a). Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for a hearing and waivers of participation, together with a written statement of position on the matters of fact and law involved in such hearing, must be sent to DEA using the address information provided above.

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 on his own motion. 21 U.S.C. 811(a). This proposed action is supported by 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. 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),[1] after

[1] As discussed in a memorandum of understanding entered into by the Food and Drug

consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance. 21 U.S.C. 811(d)(3). In the event that the Secretary did not so consult with the Attorney General, and the Attorney General did not issue a temporary order, as provided under 21 U.S.C. 811(d)(4), the procedures for permanent scheduling set forth in 21 U.S.C. 811(a) and (b) control. Pursuant to 21 U.S.C. 811(a)(1), the Attorney General (as delegated to the Administrator of DEA) may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed.

Background

DOI and DOC belong to the phenethylamine class of drugs with hallucinogenic properties, similar to 2,5-dimethoxy-4-methamphetamine (DOM), a schedule I hallucinogen. DOI and DOC have no approved medical use in the United States.

On September 26, 2018, DEA, in accordance with the provisions of 21 U.S.C. 811(b), requested HHS provide a scientific and medical evaluation as well as a scheduling recommendation for DOI and DOC. Additionally, 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), during its 63rd Session in March 2020, voted to place DOC in Schedule I of the 1971 Convention (CND Dec/63/4). As a signatory to this international treaty, the United States is required, by scheduling under the CSA, to place appropriate controls on DOC to meet the minimum requirements of the treaty.

Article 2, paragraph 7(a), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule I of the 1971 Convention. The United States must adhere to specific export and import provisions that are provided 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. 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, paragraph 7(a)(vi) 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. The United States complies with this provision as persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action.

Proposed Determination To Schedule DOI and DOC

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on DOI and DOC and on September 26, 2018, 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 DOI and DOC. On September 28, 2020, HHS provided to DEA a scientific and medical evaluation entitled ''Basis for the Recommendation to Control 2,5-dimethoxy-4-iodoamphetamine (DOI) and 2,5-dimethoxy-4-chloroamphetamine (DOC) and their Salts in Schedule I of the Controlled Substances Act (CSA)'' and a scheduling recommendation. Following consideration of the eight factors and findings related to these substances' abuse potential, legitimate medical use, and dependence liability, HHS recommended that DOI and DOC and their salts be controlled in schedule I of the CSA under 21 U.S.C. 812(b). In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS and all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA in their respective eight-factor analyses, and as considered by DEA in this proposed scheduling determination. Please note that both DEA and HHS analyses are available in their entirety under ''Supporting Documents'' of the public docket for this proposed rule at *https://www.regulations.gov* under docket number ''DEA–824.''

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 DOI and DOC, DEA also considered all other relevant data regarding actual or relative potential for abuse of DOI and DOC. 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: [2]

a. Individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

b. There is a significant diversion of the drug or other substance from legitimate drug channels; or

c. Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or

d. The drug is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, 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.

DEA reviewed the scientific and medical evaluation provided by HHS

Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., 2nd Sess. (1970) reprinted in 1970 U.S.C.C.A.N. 4566, 4603.

and all other data relevant to the abuse potential of DOI and DOC. These data as presented below demonstrate that DOI and DOC have a high potential for abuse.

a. *There is evidence that individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.*

Data show that DOI and DOC have been encountered by law enforcement in the United States (see Factor 5), indicating DOI and DOC availability for abuse. According to HHS, individuals are using DOI and DOC for their hallucinogenic effects and taking them in amounts sufficient to create a hazard to their health.

b. *There is significant diversion of the drug or substance from legitimate drug channels.*

HHS states that DOI and DOC are not Food and Drug Administration (FDA)-approved drugs for treatment in the United States and is unaware of any country in which their use is legal. DOI and DOC are available for purchase from legitimate chemical synthesis companies because they are used in scientific research. There is no evidence of diversion from these companies.

c. *Individuals are taking the substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substance.*

DOI and DOC are not found in FDA-approved drug products and practitioners may neither legally prescribe nor dispense these substances. Therefore, individuals are taking DOI and DOC on their own initiative, rather than based on medical advice from practitioners licensed by law to administer drugs. This is consistent with the data from law enforcement seizures and case reports indicating that individuals are taking DOI and DOC on their own initiative rather than on the medical advice of licensed practitioners.

d. *The drug is a new drug so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that the drug substance will have the same potential for abuse as such drugs, thus making it reasonable to assume that there may be significant diversion 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.*

Chemically, DOI and DOC are analogs of the schedule I hallucinogen DOM. The effects and pharmacological action of DOI and DOC are similar to those of other schedule I hallucinogens, such as DOM and lysergic acid diethylamide (LSD), which have no accepted medical use and a high abuse potential.

In drug discrimination studies (an *in vivo* test to assess drug abuse liability of test drugs in comparison to known drugs of abuse), DOI and DOC produce full substitution for the discriminative stimulus effects of DOM, LSD, and *N,N*-dimethyltryptamine (DMT, schedule I). In humans, anecdotal reports suggest that DOI and DOC produce classic hallucinogenic effects that are similar to DOM, including visual and auditory hallucinations, fatigue, headache, gastrointestinal distress, insomnia and anxiety. HHS notes that use of DOC in combination with other drugs is associated with emergency department admissions and one death.

Due to the psychological and cognitive disturbances associated with DOI and DOC, as with other schedule I hallucinogens, it is reasonable to assume that DOI and DOC have substantial capability to be a hazard to the health of the user and to the safety of the community.

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

In vitro testing shows that DOI and DOC bind to and act as agonists at serotonin (5-HT) 2A (5-HT_{2A}) receptors. In rats, DOI administration induced an increase in wet dog shakes and back muscle contractions. These effects were attributed to 5-HT_{2A} receptor activation, since pretreatment with a 5-HT_{2A} receptor inverse agonist blocked the effect. Agonism of the 5-HT_{2A} receptor is the primary mechanism of action of typical hallucinogenic responses, suggesting that DOI and DOC have hallucinogenic effects. Additionally, animal testing data in rats show that DOI and DOC fully substitute for DOM, LSD, and DMT discriminative stimulus effects in drug discrimination tests.

In humans, HHS reported that anecdotal reports of hallucinogenic experiences with DOI and DOC are available on online drug forums such as *www.erowid.org,* in which recreational drug users report on their experiences with all classes of substances. In these reports, DOI and DOC are reported to induce hallucinogenic effects, including prominent visual effects.

Additionally, a World Health Organization (WHO) critical review of DOC [3] mentions its hallucinogenic effects reported by those that self-experimented with DOC and notes the duration of action may last 12 to 24 hours. WHO notes that the long duration of effects is shared by other structurally related schedule I hallucinogens including DOI, 2,5-dimethoxy-4-bromoamphetamine (DOB), and DOM. DOI and DOC are commonly administered orally and/or sublingually when encountered in the form of blotters.

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

DOI and DOC are centrally-acting hallucinogens and part of the phenethylamine hallucinogen family and share structural similarities with schedule I phenethylamine hallucinogens such as DOM. DOI (CAS 42203–78–1) has a molecular formula of $C_{11}H_{16}INO_2$ and a molecular weight of 321.16 g/mol. The hydrochloride salt of DOI has a melting point of 201 °C. DOC (CAS 123431–31–2) has a molecular formula of $C_{11}H_{16}ClNO_2$ and a molecular weight of 229.70 g/mol. The hydrochloride salt of DOC has a melting point of 193–194.5 °C. DOI and DOC are white, odorless, and crystalline solids.

4. Its History and Current Pattern of Abuse

The history and current pattern of abuse of DOI and DOC are described in law enforcement reports and anecdotal reports by drug abusers. In the United States, law enforcement entities initially encountered DOI and DOC in 2005, according to the National Forensic Laboratory Information System (NFLIS).[4] See Factor 5 for additional information. DOI and DOC are encountered in various forms (*e.g.,* powder, tablets, capsules, liquid, or on blotter paper).

Anecdotal reports on the internet indicate that individuals are using substances they identified as DOI and DOC for their hallucinogenic effects. Importantly, it is impossible to know if the street drugs sold to an individual as DOI or DOC are actually the substances they are marketed as in the absence of chemical analysis or evaluation of biological fluids following ingestion. However, in animal drug discrimination studies, DOI and DOC produced effects that are similar to the effects elicited by schedule I hallucinogens such as DOM, LSD, and DMT.

A July 2019 report from the European Monitoring Centre for Drugs and Drug Addiction included data from their

[3] World Health Organization (WHO). 2019a. Critical Review Report: DOC (4-Chloro-2,5-dimethoxyamfetamine) Expert Committee on Drug Dependence, Forty-second Meeting. Geneva.

[4] NFLIS 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 data were queried on February 23, 2021.

toxicology portal, and indicated that 16 non-fatal intoxications associated with DOC had been reported internationally between 2008 and 2017. In 2019, the United Nations Office on Drugs and Crime reported three deaths associated with DOC (one each in 2015 and 2018; information about the third is unknown).

5. The Scope, Duration, and Significance of Abuse

Data from NFLIS indicate that DOI and DOC were found in samples starting in 2005, in the United States. Specifically, there were 40 NFLIS reports for DOI from 2005 through February 2021, and 785 NFLIS reports for DOC during the same period. DOI has been encountered in 14 states, whereas DOC has been encountered in 38 states. In response to abuse and safety concerns, DOI has been controlled in Florida.

Abuse of DOI and DOC has been characterized as causing acute public health and safety issues worldwide. WHO reports that DOC has been available in Europe since 2001. Based on available abuse data, public health risk, and drug trafficking data, the WHO recommended to the United Nations (UN) that DOC be controlled internationally. In March 2020, the UN Commission on Narcotic Drugs voted to place DOC into Schedule I of the 1971 Convention.

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

DOI and DOC share similar mechanisms of action with and produce similar physiological and subjective effects (see Factor 2 for more information) as other schedule I hallucinogens, such as DOM, DMT, and LSD. Thus, DOI and DOC pose the same risks to public health as similar hallucinogens. Predominantly, the risks to public health are borne by users (*i.e.,* hallucinogenic effects, sensory distortion, impaired judgement, strange or dangerous behaviors), but they can affect the general public, as with driving under the influence. To date, there are no reports of distressing responses or death associated with DOI in medical literature. There have been three published reports, in 2008, 2014, and 2015, of adverse events associated with DOC including, but not limited to, seizures, agitation, tachycardia, hypertension, and death of one individual. Since DOI is structurally similar to DOC and produces similar effects to DOC, it is likely to produce serious adverse effects similar to DOC. Thus, serious adverse events that may include death represent a risk to the individual drug users and to public health.

7. Its Psychic or Physiological Dependence Liability

According to HHS, the physiological dependence liability of DOI and DOC in animals and humans is not reported in scientific and medical literature. Thus, it is not possible to determine whether DOI and DOC produce physiological dependence following acute or chronic administration.

According to HHS, DOI, DOC, and other related phenethylamine hallucinogens (such as the schedule I substance DOM) are highly abusable substances. Drug discrimination studies in animals indicate that DOI and DOC fully substitute to the discriminative stimulus effects of schedule I hallucinogens DOM, LSD, and DMT. HHS notes that hallucinogens are not usually associated with physical dependence, likely due to the rapid development of tolerance precluding daily administration. Hallucinogen abusers may develop psychological dependence as evidenced by the continued use of these substances despite knowledge of their potential toxic and adverse effects.

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

DOI and DOC are not immediate precursors of any controlled substance of the CSA as defined by 21 U.S.C. 802(23).

Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and on DEA's own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of DOI and DOC. As such, DEA proposes to schedule DOI and DOC as controlled substances under the CSA.

Proposed Determination of Appropriate Schedule

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

(1) DOI and DOC have a high potential for abuse that is comparable to other schedule I substances, such as the phenethylamine hallucinogen DOM;

(2) FDA has not approved a marketing application for a drug product containing DOI or DOC for any therapeutic indication. In addition, DEA and HHS know of no clinical studies or petitioners claiming an accepted medical use in the United States. Therefore, DOI and DOC have no currently accepted medical use in treatment in the United States.[5]

(3) There is a lack of accepted safety for use of DOI and DOC under medical supervision. The use of DOC is associated with serious adverse consequences including deaths. Since DOI is structurally similar to DOC and produces effects similar to DOC, it is likely that DOI may produce serious adverse events similar to DOC. Because DOI and DOC have no approved medical use and have not been investigated as new drugs, their safety for use under medical supervision has not been determined. Therefore, there is a lack of accepted safety for use of DOI and DOC under medical supervision.

Based on these findings, the Administrator of DEA concludes that DOI and DOC warrant control in schedule I of the CSA. More precisely, because of their hallucinogenic effects, and because they may produce hallucinogenic-like tolerance and dependence in humans, DEA proposes to place DOI and DOC, including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical description, in 21 CFR 1308.11(d) (the hallucinogenic substances category of schedule I).

Requirements for Handling DOI and DOC

If this rule is finalized as proposed, DOI and DOC would be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal

[5] Although there is no evidence suggesting that DOI and DOC have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: 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. 57 FR 10499 (1992), *pet. for rev. denied, Alliance for Cannabis Therapeutics* v. *DEA,* 15 F.3d 1131, 1135 (D.C. Cir. 1994).

sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, 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) or desires to handle DOI or DOC would be required to register with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312, as of the effective date of a final scheduling action. Any person who currently handles DOI or DOC and is not registered with DEA would need to submit an application for registration and may not continue to handle DOI and DOC as of the effective date of a final scheduling action unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

2. Disposal of Stocks. Any person unwilling or unable to obtain a schedule I registration would be required to surrender or transfer all quantities of currently held DOI and DOC 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, DOI and DOC 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.* DOI and DOC would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 823 and in accordance with 21 CFR 1301.71–1301.76, as of the effective date of a final scheduling action. Non-practitioners handling DOI and DOC would also need to comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels and packaging for commercial containers of DOI and DOC would need to be in compliance with 21 U.S.C. 825, 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 DOI and DOC in accordance with quotas 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 DOI and DOC on the effective date of the final scheduling action would be required to take an inventory of DOI and DOC on hand at that time, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA on or after the effective date of the final scheduling action would be required to take an initial inventory of all stocks of controlled substances (including DOI and DOC) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant would be required to take a new inventory of all controlled substances (including DOI and DOC) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports for DOI and DOC, or products containing DOI and DOC, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c) and parts 1304, 1312, and 1317, as of the effective date of a final scheduling action. Manufacturers and distributors would need to submit reports regarding DOI and DOC to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312, as of the effective date of a final scheduling action.

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

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

10. *Liability.* Any activity involving DOI and DOC 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 and 13563, Regulatory Planning and Review, and Improving Regulation and Regulatory Review

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

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 on 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.

Paperwork Reduction Act

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

Regulatory Flexibility Act

The Administrator of DEA, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, 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 substances DOI and DOC (chemical names: 2,5-dimethoxy-4-iodoamphetamine [DOI] and 2,5-dimethoxy-4-chloroamphetamine [DOC]), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, in schedule I of the CSA. This action is being taken, in part, to enable the United States to meet its obligations under the 1971 Convention for DOC. 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 DOI and DOC.

According to HHS, and also by DEA's findings in this proposed rule, DOI and DOC have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision. There appear to be no legitimate sources for DOI and DOC as marketed drugs in the United States, but DEA notes that these substances are available for purchase from legitimate suppliers for scientific research. There is no evidence of significant diversion of DOI and DOC from legitimate suppliers. As such, the proposed rule will not, if promulgated, result in a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*) that this proposed 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 UMRA of 1995.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read 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, as proposed to be amended at 86 FR 16553 (March 30, 2021), 86 FR 37719 (July 16, 2021), 86 FR 69187 (December 7, 2021), and 87 FR 2383 (January 14, 2022), add paragraphs (d)(106) and (107) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(106) 2,5-dimethoxy-4-iodoamphetamine (Other name: DOI) 7447
(107) 2,5-dimethoxy-4-chloroamphetamine (Other name: DOC) 7448

* * * * *

Anne Milgram,

Administrator.

[FR Doc. 2022–07648 Filed 4–8–22; 8:45 am]

BILLING CODE 4410–09–P

POSTAL REGULATORY COMMISSION

39 CFR Part 3010

[Docket No. RM2022–4; Order No. 6141]

RIN 3211–AA31

Rules of Practice and Procedure

AGENCY: Postal Regulatory Commission.

ACTION: Proposed rulemaking.

SUMMARY: The Commission is proposing to add rules which revise the Commission's rules of practice and procedure regarding notices, motions, and information requests. The Commission invites public comment on the proposed rules.

DATES: *Comments are due:* May 26, 2022.

ADDRESSES: For additional information, Order No. 6141 can be accessed electronically through the Commission's website at *https://www.prc.gov.* Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Relevant Statutory Requirements

Pursuant to 39 U.S.C. 503, the Commission establishes this rulemaking docket to propose amendments to the Commission's rules of practice and procedure regarding notices, motions, and information requests.

II. Background

The proposed amendments provide rules relating to motions for reconsideration of final Commission orders.[1]

[1] Motions for review of other Commission determinations may be filed in accordance with 39 CFR 3010.160.

III. Basis and Purpose of Proposed Rules

The proposed amendments revise the Commission's rules on notices, motions, and information requests, within its rules of practice and procedure, to provide rules specific to motions for reconsideration. The proposed amendments reflect the Commission's current practice of hearing timely motions for reconsideration of its final orders.

Under the proposed rules, any party may file a motion for reconsideration of a Commission final order within 15 days of the issuance of the order subject to the motion. All motions for reconsideration must briefly and specifically allege material errors of fact or law, and the relief sought, and must be confined to new questions raised by the determination or action ordered and upon which the moving party had no prior opportunity to submit arguments. Finally, no motion for reconsideration shall stay the effect of an order of the Commission unless the Commission orders otherwise.

IV. Proposed Rules

Proposed § 3010.165(a). Proposed § 3010.165(a) is added to explain eligibility among parties for filing motions for reconsideration.