



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA1715]

Schedules of Controlled Substances: Placement of 4-Hydroxy-*N,N*-Diisopropyltryptamine (4-OH-DiPT), 5-Methoxy-*alpha*-Methyltryptamine (5-MeO-AMT), 5-Methoxy-*N*-Methyl-*N*-Isopropyltryptamine (5-MeO-MiPT), 5-Methoxy-*N,N*-Diethyltryptamine (5-MeO-DET), and *N,N*-Diisopropyltryptamine (DiPT) into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes placing five tryptamine hallucinogens, 4-hydroxy-*N,N*-diisopropyltryptamine (other names: 4-OH-DiPT; 3-(2-(diisopropylamino)ethyl)-1*H*-indol-4-ol), 5-methoxy-*alpha*-methyltryptamine (other names: 5-MeO-AMT; 1-(5-methoxy-1*H*-indol-3-yl)propan-2-amine), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (other names: 5-MeO-MiPT; *N*-(2-(5-methoxy-1*H*-indol-3-yl)ethyl)-*N*-methylpropan-2-amine), 5-methoxy-*N,N*-diethyltryptamine (other names: 5-MeO-DET; *N,N*-diethyl-2-(5-methoxy-1*H*-indol-3-yl)ethanamine), and *N,N*-diisopropyltryptamine (other names: DiPT; *N*-(2-(1*H*-indol-3-yl)ethyl)-*N*-isopropylpropan-2-amine), including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. 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 five specific tryptamine hallucinogens.

DATES: Comments must be submitted electronically or postmarked on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Interested persons may file a request for a hearing or waiver of hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.47 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 involved in the hearing, must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may file written comments on this rulemaking in accordance with 21 CFR 1308.43(g). To ensure proper handling of comments, please reference “Docket No. DEA1715” on all 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 webpage or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number 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 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 Morrisette 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 Morrisette 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 Morrisette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

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

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

SUPPLEMENTARY INFORMATION:

The Drug Enforcement Administration (DEA) proposes to schedule the following five 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:

- 4-Hydroxy-*N,N*-diisopropyltryptamine (other names: 4-OH-DiPT; 3-(2-(diisopropylamino)ethyl)-1*H*-indol-4-ol),
- 5-Methoxy-*alpha*-methyltryptamine (other names: 5-MeO-AMT; 1-(5-methoxy-1*H*-indol-3-yl)propan-2-amine),
- *N*-Isopropyl-5-methoxy-*N*-methyltryptamine (other names: 5-MeO-MiPT; *N*-(2-(5-methoxy-1*H*-indol-3-yl)ethyl)-*N*-methylpropan-2-amine),
- *N,N*-Diethyl-5-methoxytryptamine (other names: 5-MeO-DET; *N,N*-diethyl-2-(5-methoxy-1*H*-indol-3-yl)ethanamine), and
- *N,N*-Diisopropyltryptamine (other names: DiPT; *N*-(2-(1*H*-indol-3-yl)ethyl)-*N*-isopropylpropan-2-amine).

Posting of Public Comments

All comments received in response to this docket are considered part of the public record. DEA will make comments available for public inspection online at <https://www.regulations.gov>, unless reasonable cause is given. Such information includes personal or business identifiers (such as name, address, state or federal identifiers, etc.) voluntarily submitted by the commenter.

Commenters submitting comments which include personal identifying information (PII), confidential, or proprietary business information that the commenter does not want to be 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. DEA generally will not redact additional information contained in the comment marked “TO BE PUBLICLY POSTED.” The Freedom of Information Act applies to all comments received.

For easy reference, an electronic copy of this document and supplemental information to this proposed rule are available at <https://www.regulations.gov>.

Request for Hearing or Appearance; Waiver

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

- (1) state with particularity the interest of the person in the proceeding;
- (2) state with particularity the objections or issues concerning which the person desires to be heard; and
- (3) state briefly the position of the person regarding 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

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

² 21 CFR 1316.49.

hearing will be needed to address such matters of fact and law in the rulemaking will be made by the Administrator. If a hearing is needed, DEA will publish a notice of hearing on the proposed rulemaking in the *Federal Register*.³ Further, once the Administrator determines a hearing is needed to address such matters of fact and law in rulemaking, he will then designate an Administrative Law Judge (ALJ) to preside over the hearing. The ALJ's functions shall commence upon designation, as provided in 21 CFR 1316.52.

In accordance with 21 U.S.C. 811 and 812, the purpose of a hearing would be to determine whether 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT meet the statutory criteria for placement in schedule I, as proposed in this rulemaking.

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on 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 the Department of HHS (Assistant Secretary) and an evaluation of all other relevant data by DEA. 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 or propose to handle 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT.

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

³ 21 CFR 1308.44(b), 1316.53.

⁴ 21 U.S.C. 811(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-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT are tryptamine hallucinogens. These five tryptamines have no known medical use in the United States and are not marketed internationally as approved drug products. They have all been reported as drugs of abuse in the United States by law enforcement authorities and have been identified in seizures.

Proposed Determination to Schedule 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT

In response to reports of abuse and trafficking, pursuant to 21 U.S.C. 811(b), DEA gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse and dependence of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT. On December 19, 2008, DEA sent this data review document to the then-Assistant Secretary for Health of the Department of HHS⁵ with a request to provide scientific and medical evaluations and scheduling recommendations for these five tryptamine hallucinogens. On March 29, 2012, May 17, 2012, and August 14, 2012, HHS provided to DEA five separate scientific and medical evaluations and scheduling recommendations for these substances.⁶ Following consideration of the eight factors and findings related to each of

⁵ As discussed in a memorandum of understanding entered into by the U.S. Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. *Memorandum of Understanding with the National Institute on Drug Abuse*, 50 FR 9518 (Mar. 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. *Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513, As Amended; Delegation of Authority*, 58 FR 35460 (July 1, 1993).

⁶ The scientific and medical evaluations were titled: 1) "Basis for the Recommendation to Control 4-Hydroxy-N,N-diisopropyltryptamine (4-OH-DIPT) and its Salts in Schedule I of the Controlled Substances

the substances' abuse potential, lack of legitimate medical use, and lack of accepted safety for use under medical supervision, HHS recommended that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT and their respective salts be controlled in schedule I of the CSA under 21 U.S.C. 812(b).

Based on the scientific and medical evaluations and recommendations that HHS provided to DEA, and all other relevant data, DEA published a Notice of Proposed Rulemaking in the *Federal Register* on January 14, 2022, which proposed to place the five tryptamines in schedule I of the CSA and invited interested persons to submit comments and requests for a hearing.⁷ On July 6, 2022, DEA published an announcement of hearing on the five tryptamines.⁸ Upon further consideration, DEA determined that it was appropriate to submit a new request to HHS for an updated scientific and medical evaluation and scheduling recommendations for these substances. Accordingly, DEA withdrew the proposed rule and notice of hearing.⁹

On November 16, 2023, DEA requested the updated scientific and medical evaluation and scheduling recommendation for the five tryptamines. On April 2, 2026, HHS provided to DEA the scientific and medical evaluation titled "Basis for the Recommendation to Control *N,N*-Diisopropyltryptamine (DiPT), 4-Hydroxy-*N,N*-

Act (CSA);" 2) "Basis for the Recommendation to Control 5-Methoxy-alpha-methyltryptamine (5-MeO-AMT) and its Salts in Schedule I of the Controlled Substances Act (CSA);" 3) "Basis for the Recommendation to Control *N*-Isopropyl-5-Methoxy-*N*-Methyltryptamine (5-MeO-MiPT) and its Salts in Schedule I of the Controlled Substances Act (CSA);" 4) "Basis for the Recommendation to Control *N,N*-Diethyl-5-methoxytryptamine (5-MeO-DET) and its Salts in Schedule I of the Controlled Substances Act (CSA);" and 5) "Basis for the Recommendation to Control *N,N*-Diisopropyltryptamine (DiPT) and its Salts in Schedule I of the Controlled Substances Act (CSA)."

⁷ *Schedules of Controlled Substances: Placement of 4-hydroxy-*N,N*-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-alpha-methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-*N,N*-diethyltryptamine (5-MeO-DET), and *N,N*-diisopropyltryptamine (DiPT) in Schedule I*, 87 FR 2376 (Jan. 14, 2022).

⁸ *Schedules of Controlled Substances: Placement of 4-hydroxy-*N,N*-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-alpha-methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-*N,N*-diethyltryptamine (5-MeO-DET), and *N,N*-diisopropyltryptamine (DiPT) in Schedule I; Announcement of Hearing*, 87 FR 40167 (July 6, 2022).

⁹ *Schedules of Controlled Substances: Placement of 4-hydroxy-*N,N*-diisopropyltryptamine (4-OH-DiPT), 5-methoxy-alpha-methyltryptamine (5-MeO-AMT), 5-methoxy-*N*-methyl-*N*-isopropyltryptamine (5-MeO-MiPT), 5-methoxy-*N,N*-diethyltryptamine (5-MeO-DET), and *N,N*-diisopropyltryptamine (DiPT) in Schedule I; Withdrawal of Proposed Rule and Notice of Hearing*, 87 FR 45076 (July 27, 2022).

Diisopropyltryptamine (4-OH-DiPT), 5-Methoxy-Alpha-Methyltryptamine (5-MeO-AMT), 5-Methoxy-*N*-Methyl-*N*-Isopropyltryptamine (5-MeO-MiPT), and 5-Methoxy-*N,N*-Diethyltryptamine (5-MeO-DET) and Their Salts in Schedule I of the Controlled Substances Act.” As communicated in the April 2, 2026 letter to DEA, following consideration of the eight factors determinative of control under 21 U.S.C. 811(c), HHS recommended that DiPT, 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, and 5-MeO-DET and their respective salts be controlled in schedule I of the CSA under 21 U.S.C. 812(b).

In response to the HHS communications in 2012 and 2026, DEA reviewed the scientific and medical evaluation and scheduling recommendations provided by HHS, and all other relevant data, and completed its own eight-factor analysis in August 2021 and updated in May 2026 in accordance with 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 the DEA and HHS analyses, including the evaluation of the eight factors determinative of control along with their supporting data and citations, are available in their entirety under the tab “Supporting Documents” of the public docket for this proposed rule at <https://www.regulations.gov> under docket number “DEA1715.”

1. Their Actual or Relative Potential for Abuse

In addition to considering the information HHS provided in its scientific and medical evaluation documents for 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT, DEA also considered all other relevant data regarding actual or relative potential for abuse of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT. The term “abuse” is not defined in the CSA; however, the legislative history of the CSA

suggests the consideration of the following four criteria in determining whether a particular drug or substance has a potential for abuse:¹⁰

- 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 significant diversion of the drug or other 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.*

As stated previously, DEA reviewed the scientific and medical evaluation provided by HHS and all other data relevant to the abuse potential of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT. These data as presented below demonstrate that these five tryptamine hallucinogens have a high potential for abuse.

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

Data show that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT have been encountered by law enforcement in the United States (see Factor 5 below, discussing evidence of abuse in the United States), indicating 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT are available for abuse. Further, HHS noted that

¹⁰ 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.

some of the five tryptamines have been found in America's Poison Centers, National Poison Data System (NPDS). In aggregate, there have been 65 exposures to at least one of the five tryptamines between 2000-2021, and the majority of exposures were single-substance cases. Some of the adverse effects reported were tachycardia, hallucinations, agitation, and hypertension. Thus, HHS determined that there is evidence of abuse with "deleterious clinical effects" and further stated that based on available data, these substances have the potential to be consumed in amounts sufficient to create a hazard to the health of individuals who consume them.

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

4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT are not U.S. Food and Drug Administration (FDA)-approved drugs in the United States, and they are not legally marketed in any country. Therefore, legitimate drug channels are limited to research conducted with the drugs, manufacturing facilities, and to the supply chain that produces the drug for legitimate research. However, HHS noted that FDA is not aware of any diversion from research or legitimate manufacturing activities for 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT. Therefore, this characteristic of abuse is not applicable.

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.

4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT are not approved for medical use, are not formulated or available for clinical use, and practitioners may not legally prescribe these substances. Therefore, individuals are taking 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT on their own initiative, rather than based on medical advice from a practitioner licensed by law to administer drugs. This is consistent with the data from law enforcement seizures, the NPDS database, and case

reports indicating that individuals are taking 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT on their own initiative rather than on the medical advice of a licensed practitioner. Therefore, it is assumed that individuals are taking these five substances on their own initiative, rather than based on medical advice from a practitioner licensed by law to administer drugs.

d. The drug or substance 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 the drug or 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.

4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT are structurally related to schedule I hallucinogens of the tryptamine class and produce similar pharmacological effects to other natural and synthetic schedule I hallucinogens. According to HHS, these five tryptamine hallucinogens elicit pharmacological responses similar to the schedule I substances both in *in vitro* and *in vivo* studies as well as anecdotal reports, to include stimulation of the 2A subtype of serotonin (5-HT) receptors (5-HT_{2A}) and substitution in the drug discrimination assay, as well as reports in the NPDS database.

Given the similarities to certain schedule I hallucinogens, the five tryptamine hallucinogens are expected to have clinical effects and risks to the public health similar to that of tryptamines currently controlled in schedule I (e.g., 4-hydroxy-*N,N*-dimethyltryptamine [4-OH-DMT, also known as psilocyn, the active metabolite of psilocybin]; *N,N*-dimethyltryptamine [DMT]; alpha-methyltryptamine [AMT]; 5-methoxy-*N,N*-diisopropyltryptamine [5-MeO-DiPT]; *N,N*-diethyltryptamine [DET]) as well as a phenethylamine hallucinogen (4-methyl-2,5-dimethoxy-amphetamine [DOM])

and an ergotamine hallucinogen (lysergic acid diethylamide [LSD]). The indicators of abuse potential for the five tryptamine hallucinogens suggest that they have a relative potential for abuse that is comparable to other hallucinogenic substances already controlled in schedule I of the CSA.

2. Scientific Evidence of Their Pharmacological Effects, If Known

The five tryptamine hallucinogens are structurally related to and share pharmacological properties with schedule I tryptamine hallucinogens. Based on non-clinical *in vitro* studies, the neurochemical effects of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT mainly involve the serotonergic system in the central nervous system (CNS). Tryptamine hallucinogens are believed to produce their characteristic effects primarily through stimulation of the 5-HT_{2A} receptor. Similar to schedule I hallucinogens that are also mediated by serotonin receptors, such as DMT, DET, DOM, and LSD, the five tryptamine hallucinogens have binding affinity for and act as agonists at the 5-HT_{2A} receptor. There have been reports of partial involvement by activation of the serotonin 1A-subtype (5-HT_{1A}). 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT also bind to and functioned as agonists at 5-HT_{1A} receptors.

Other potential targets include the 5-HT_{2C} receptor subtype and monoamine transporters (serotonin transporter [SERT], norepinephrine [NE] transporter [NET] and dopamine [DA] transporter [DAT]). At the 5-HT_{2C} receptor, 5-MeO-AMT displayed the highest affinity and displayed full agonist activity. All others bound to the 5-HT_{2C} receptor with varying affinities and fully activated the receptor. 5-MeO-AMT, 5-MeO-MiPT, and 5-MeO-DET had weak or no significant affinity for SERT, NET, and DAT and did not induce the release of NE, 5-HT, or DA. However, 4-OH-DiPT and DiPT had greater affinity for SERT, but did not have significant affinity for DAT or NET.

As concluded by HHS and DEA, the complex pharmacology of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT involve multiple serotonin sites, one of which (5-HT_{2A} receptor) is likely to mediate their hallucinogenic effects. All five tryptamine hallucinogens bind to the 5-HT_{2A} receptor and behave as full or partial agonists like DMT and psilocyn. Based on *in vitro* data the five tryptamine hallucinogens are expected to have hallucinogenic properties and potential toxicities, though they may differ by potency.

Non-clinical *in vivo* studies indicate 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT produce similar pharmacological profiles to that of serotonin-mediated hallucinogens controlled in schedule I of the CSA as assessed via drug discrimination, locomotor activity, and head twitch assays.

Clinical studies to evaluate the effects of 4-OH-DiPT, 5-MeO-DET, and DiPT using formal clinical protocols under institutional settings have not been reported in the published scientific literature. However, subjective effects in humans for these three tryptamines have been reported through individual case reports or summaries of anecdotal reports usually on Internet forums. There are limited published clinical studies for 5-MeO-AMT and 5-MeO-DiPT. In humans, the five tryptamines produced changes in mood, cognition, and perceptions. These substances are orally active and may differ in regard to potency, onset of action, duration of effects, and psychoactive and physiological effects. Hence, based on available pharmacology information the five tryptamines are expected to have significant overlap in effects with schedule I hallucinogenic substances such as DMT, psilocybin, and others.

3. The State of Current Scientific Knowledge Regarding the Drugs or Other Substances

4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT are part of the tryptamine family of hallucinogens and share the core tryptamine structure with

substitutions at various positions. All five substances contain an indole ring with a substituted ethylamino sidechain. 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT share structural similarities with schedule I tryptamine hallucinogens such as DMT, DET, AMT, and psilocyn.

Limited metabolism studies have been conducted for 5-MeO-MiPT and other tryptamine hallucinogens. Data indicate that tryptamine hallucinogens undergo metabolism through oxidative deamination, *N*-demethylation, *O*-demethylation, and *N*-oxidation with *N*-oxides as major metabolites. Additionally, various cytochrome P450 and monoamine oxidase enzymes have been reported to play a role in the metabolism. It is expected that these five tryptamine hallucinogens would undergo similar metabolism.

There are no well-controlled clinical studies showing safety or efficacy for these substances. In addition, there is no evidence by qualified experts that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT are accepted as having therapeutic uses. Thus, DEA concludes that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT have no currently accepted medical use in treatment in the United States.

4. Their History and Current Pattern of Abuse

In the United States, law enforcement entities initially encountered 5-MeO-AMT and DiPT in 2003, 5-MeO-MiPT in 2004, 5-MeO-DET in 2006, and 4-OH-DiPT in 2009, according to the National Forensic Laboratory Information System-Drug (NFLIS-Drug).¹¹ Each of these tryptamines is encountered in various forms (e.g., powder, tablets, capsules, liquid, or on blotter paper). The abuser population of these

¹¹ NFLIS-Drug represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS-Drug is a comprehensive information system that includes data from forensic laboratories that handle more than 96 percent of an estimated 1 million distinct annual federal, state, and local drug analysis cases. NFLIS-Drug includes drug chemistry results from completed analyses only. While NFLIS-Drug data are not direct evidence of abuse, these 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). NFLIS-Drug data were queried on April 7, 2026.

substances is commonly comprised of young adults. These substances are generally purchased from Internet-based companies in addition to being purchased from dealers.

4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT do not have a currently accepted medical use in treatment in the United States. Anecdotal reports from users of these substances indicate that these substances produce classical hallucinogenic properties, such as perceptual distortions and pleasurable physical effects. Users report oral administration as the most common route of administration. Other routes of administration such as insufflation, smoking, and rectal administration have been reported. 5-MeO-MiPT has been mentioned to cause a wide range of effects including: euphoria, mood lift, intensification of tactile sensations and smell, sexual interest, emotional opening, relaxation, powerful “rushing” sensation (smoked), immersive experiences (smoked), feelings of body and muscle energy, buzzing, visual distortions, color intensification, disorientation, and sometimes dissociation, tremor, emotional lability, possible stomach discomfort, gas and vomiting, anxious stimulation muscle tension/discomfort, and difficulty sleeping for 4 to 8 hours after peak effects in some people.

5. The Scope, Duration, and Significance of Abuse

According to NFLIS-Drug, in the United States, there has been availability, trafficking, and abuse of a number of tryptamines including 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT. This is evidenced by a cumulative total of 518 encounters of these tryptamines by United States law enforcement in several states and the District of Columbia. Additionally, there have been international encounters of 5-MeO-AMT, 5-MeO-MiPT and 5-MeO-DET between 2006-2017, as well as detection of 4-OH-DiPT in hair samples in China and urine samples in Italy.¹²

¹² Göl E, Çok I. (2019). New psychoactive substances in Turkey: Narcotics cases assessed by the Council of Forensic Medicine between 2016 and 2017 in Ankara, Turkey. *Forensic Sci Int* 294:113-123; Shi Y,

According to HHS' 2026 review, based on data from the America's Poison Centers' NPDS database, there were 65 exposure cases from January 1, 2003, to December 31, 2021, involving one or more of the five tryptamines. Over 61 percent of cases were single-substance cases, 84 percent were classified as "abuse," and healthcare facilities reported over 89 percent of exposure cases. The substances most identified were 5-MeO-AMT (25), 5-MeO-DET (23), and 5-MeO-MiPT (14). Two single-substance cases of intentional abuse were reported for DiPT, whereas there was only one multi-substance case involving 4-OH-DiPT. While most cases resulted in minor to moderate related medical effects, moderate effects were the most frequently reported within single-substance cases. Further, four cases were reported as major medical effect (three of which were caused by 5-MeO-AMT). No single-substance exposure cases involving the five tryptamines resulted in death. As stated by HHS, NPDS only captures a small fraction of exposures resulting in death because drug exposures that result in unattended, or out-of-hospital death are unlikely to be reported to a United States Poison Control Center. See HHS review for further information on the NPDS analysis and potential caveats and limitations related to reporting.

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

Available evidence indicates that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT pose a risk to public health due to their hallucinogenic properties that usually occur quickly after drug administration and may cause impairing effects on the user's judgment and lead to dangerous behavior. The risks could be to the individual user or to the community, especially when the user is operating a motor vehicle. Several

Wang R, Yuan S, Qiang H, Shen M, Shen B, Drummer OH, Yu Z, Zhao Y, Xiang P (2020). UHPLC-MS/MS method for simultaneously detecting 16 tryptamines and their metabolites in human hair and applications to real forensics cases. *J Chromatogr B Analyt Technol Biomed Life Sci* 1159:122392; Pichini S, Pujadas M, Marchei E, Pellegrini M, Fiz J, Pacifici R, Zuccaro P, Farré M, de la Torre R (2008). Liquid chromatography-atmospheric pressure ionization electrospray mass spectrometry determination of "hallucinogenic designer drugs" in urine of consumers. *J Pharm Biomed Anal* 47(2):335-42

adverse effects were reported in animal studies and in humans from Internet forums for all five tryptamine hallucinogens. Published and anecdotal reports have described various adverse effects associated with these five hallucinogens including agitation, confusion, psychological distress, and one death in the case of 5-MeO-AMT in 2004. The toxicology report also reported alcohol and the presence of an antidepressant, bupropion. Some users of 4-OH-DiPT reported that the hallucinations were intense and the psychological and physiological effects were frightening or disturbing. An adolescent non-lethal poisoning was reported in 2005 after ingesting an alleged combination of 5-MeO-MiPT and harmaline, a CNS stimulant.

7. Their Psychic or Physiological Dependence Liability

Assessing psychological dependence potential of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT was limited due to lack of available data. From NPDS data, there is evidence individuals are using these substances. The majority of the cases were classified as “abuse” cases.

Serotonin-mediated hallucinogens are not usually associated with physical dependence and the physiological dependence liability in animals or humans has not been reported in scientific and medical literature for these five substances. At this time, it is not possible to determine whether 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT produce physiological dependence following either acute or chronic administration.

8. Whether the Substances Are an Immediate Precursor of Substances Already Controlled under the CSA

4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT 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 the facts and all relevant data constitute substantial evidence of potential for abuse of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT. As such, DEA hereby proposes to schedule 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT as schedule I 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.¹³ 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 21 U.S.C. 812(b)(1), finds that:

1. The drugs have a high potential for abuse.

4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT elicit pharmacological effects qualitatively similar to those of schedule I hallucinogens, discussed below. These effects are marked by hallucinations and CNS stimulation. Law enforcement reported a number of encounters with these substances. Law enforcement first encountered 5-MeO-AMT and DiPT in 2003, 5-MeO-MiPT in 2004, 5-MeO-DET in 2006, and 4-OH-DiPT in 2009. NPDS data from 2003 to 2021 show sporadic cases of the five tryptamines, mostly classified as abuse with minor to moderate outcomes.

The available data indicate that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT have high potential for abuse that is similar to that of schedule I tryptamine hallucinogens DET (5-MeO-AMT) and DMT (5-MeO-DET, 5-MeO-MiPT, and DiPT), the phenethylamine hallucinogen DOM (4-OH-DiPT, 5-MeO-DET, 5-MeO-

¹³ 21 U.S.C. 812(b).

MiPT, and DiPT), and the ergotamine hallucinogen LSD (5-MeO-AMT, 4-OH-DiPT, 5-MeO-DET, 5-MeO-MiPT).

2. The drugs have no currently accepted medical use in treatment in the United States.

According to HHS, 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT lack FDA-approval for any therapeutic indication. In addition, there are no adequate and well-controlled clinical studies or well-defined dosage forms for any of the five tryptamine hallucinogens. DEA notes that there are no therapeutic applications for these five tryptamine hallucinogens accepted by qualified experts, nor are there adequate and well-controlled studies proving safety or efficacy for any medical use. Thus, there is no evidence that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT have currently accepted medical uses in treatment in the United States.¹⁴

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

Because 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT have no approved medical use and have not been thoroughly investigated as new drugs, their

¹⁴ Pursuant to 21 U.S.C. 812(b)(1)(B), when placing a drug or other substance in schedule I, DEA must consider whether the substance has a currently accepted medical use in treatment in the United States. First, DEA looks to whether the drug or substance has FDA approval. When no FDA approval exists, DEA has traditionally applied a five-part test to determine whether a drug or substance has a currently accepted medical use: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available. *See 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 and concluded the test was not satisfied. In a published letter in a different context, HHS applied a 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' 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-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT, or that the use of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT are recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied.

safety for use under medical supervision is not determined. Thus, there is a lack of accepted safety for use of these substances under medical supervision.

Based on these findings, the Administrator concludes that 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT warrant control in schedule I of the CSA. More precisely, because of their hallucinogenic effects, DEA proposes to place 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT, 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 hallucinogens category of schedule I).

Requirements for Handling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT

If this rule is finalized as proposed, 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT would be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, 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, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT would need to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

Any person who currently handles 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT and is not registered with DEA to conduct research with a schedule I controlled substance must submit an application for registration and may not continue to

handle 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT, 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.

Notwithstanding the foregoing, pursuant to 21 U.S.C. 822(h), if, on the date the final rule is effectuated, a person is conducting research on 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT and is already registered to conduct research with another controlled substance in schedule I, the person may continue to conduct research on 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT if they submit a completed application for registration or modification of existing registration, as applicable, to conduct research with 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT not later than 90 calendar days after the date of effectuation of the final rule. The person may continue to conduct such research until the person withdraws the application or the Administrator serves on the person an order to show cause proposing denial of the application pursuant to 21 U.S.C. 824(c) and in accordance with 21 CFR 1301.37. If the Administrator serves an order to show cause proposing denial of the application or modification, the person may not continue to conduct research with 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT and may not receive or otherwise obtain additional 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT. If an order to show cause is served and the person requests a hearing in accordance with 21 CFR 1301.37(d), the hearing shall be held in accordance with 21 CFR 1301.41-1301.46 on an expedited basis and not later than 45 calendar days after the request is made, except that the hearing may be held at a later time if so requested by the person. If the person sends a copy of the application to a manufacturer or distributor of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT, receipt of the copy by the manufacturer or distributor constitutes sufficient evidence that the person is authorized to receive 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT

pursuant to 21 U.S.C. 822(h)(4). Continuation of research under 21 U.S.C. 822(h) does not authorize any other handling (e.g., distribution) of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT.

Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of a schedule I controlled substance in a manner not authorized by the CSA is unlawful and those in possession of any quantity may be subject to prosecution pursuant to the CSA.

2. *Disposal of Stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender or transfer all quantities of currently held 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT to a person registered with DEA before the effective date of the final scheduling action in accordance with all applicable Federal, State, local, and Tribal laws. 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT must 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-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT would be subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling this substance also would need to comply with the screening requirements of 21 CFR 1301.90-1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT would need to comply with 21 U.S.C. 825 and 958(e) and be in accordance with 21 CFR part 1302.

5. *Quota.* Generally, only registered manufacturers would be permitted to manufacture 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT in

accordance with a quota assigned pursuant to 21 U.S.C. 826, and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who would handle 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT must have an initial inventory of all stocks of controlled substances including 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant would need to take an inventory of all controlled substances (including 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT) on hand every two years, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant would need to maintain records and submit reports with respect to 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT, pursuant to 21 U.S.C. 827, 832(a), and 958(e), and in accordance with 21 CFR 1301.74 and 1301.76, and parts 1304, 1312, and 1317. Manufacturers and distributors would need to submit reports regarding 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT to the Automated Reports and Consolidated Ordering System pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT would need to comply with the order form requirements, pursuant to 21 U.S.C. 828 and 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT would need to comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT 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, 14192, and 14294

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 (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563. DEA scheduling actions promulgated by formal rulemaking are not regulatory actions under E.O. 14192, Unleashing Prosperity Through Deregulation, and are not subject to E.O. 14294, Fighting Overcriminalization in Federal Regulations.

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 rule would require compliance with the following existing OMB collections: 1117-0003, 1117-0004, 1117-0006, 1117-0008, 1117-0009, 1117-0010, 1117-0012, 1117-0014, 1117-0021, 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.

Regulatory Flexibility Act

The Administrator, 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 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT, 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. 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 or propose to handle 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT.

The entities affected by this rule include the manufacturers, distributors, importers, exporters, and researchers of 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT. DEA determined the North American Industry Classification System (NAICS)

industries that best represent these business activities. Table 1 lists the business activities and corresponding NAICS industries.¹⁵

Table 1: Business Activity and Corresponding NAICS Industries.

Business Activity	NAICS Code	NAICS Industry Description
Manufacturer	325412	Pharmaceutical Preparation Manufacturing
Distributor, Importer, Exporter	424210 424690	Drugs and Druggists' Sundries Merchant Wholesalers Other Chemical and Allied Products Merchant Wholesalers
Researcher	541715 611310	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology) 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 determined 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 Small Entities by Industry.

NAICS Industry	Firms ¹⁶	SBA Size Standard ¹⁷	Small Firms ¹⁸	Percent Small Entities (%)
325412-Pharmaceutical Preparation Manufacturing	1,179	1,300 employees	1,099	93.2
424210-Drugs and Druggists' Sundries Merchant Wholesalers	7,012	250 employees	6,703	95.6
424690-Other Chemical and Allied Products Merchant Wholesalers	5,487	175 employees	5,197	94.7
541715-Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	10,042	1,000 employees	9,599	95.6

¹⁵ 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 2/5/2026)

¹⁶ Statistics of U.S. Businesses, 2022 SUSB Annual Data Tables by Establishment Industry, <https://www.census.gov/data/tables/2022/econ/susb/2022-susb-annual.html> (Accessed 2/5/2026)

¹⁷ U.S. Small Business Administration, Table of size standards, Version March 2023, Effective: March 17, 2023, <https://www.sba.gov/document/support-table-size-standards>. (Accessed 2/5/2026) Size standards are based on the number of employees or annual receipts depending on industry.

¹⁸ Based on the estimated number of firms below the SBA size standard for each industry.

611310-Colleges, Universities and Professional Schools	2,494	\$34.5 million	1,515	60.8
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Based on the American Chemical Society’s SciFinder database,¹⁹ DEA identified 25 domestic entities supplying 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT across these industries. Suppliers include NAICS code 325412, 424210, and 424690 industries. Even if all affected suppliers were small entities, they would account for only 0.18 percent of the small entities in those industries, not a substantial number.²⁰ Additionally, DEA expects the number of researchers working with 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT is small because 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT lack 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-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, or DiPT 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 NAICS code 541715 and 611310 industries.

In summary, an insubstantial number of small entities will be affected by this proposed rule. As such, the proposed rule, if finalized, is not expected to result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined and certifies that this proposed action would not result in any Federal mandate that may result “in the expenditure by State, local, and Tribal

¹⁹ SciFinder; Chemical Abstracts Service: Columbus, OH; <https://scifinder.cas.org> (accessed 5/15/2026).

²⁰ $25 / (1,179 + 7,012 + 5,487) = 0.02\%$

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 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:

a. Add new paragraphs (d)(118) to (122) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

* * * * *	
(118) 4-hydroxy- <i>N,N</i> -diisopropyltryptamine (Other names: 4-OH-DiPT; 3-(2-(diisopropylamino)ethyl)-1 <i>H</i> -indol-4-ol)	7516
(119) 5-methoxy- <i>alpha</i> -methyltryptamine (Other names: 5-MeO-AMT; 1-(5-methoxy-1 <i>H</i> -indol-3-yl)propan-2-amine)	7506
(120) 5-methoxy- <i>N</i> -methyl- <i>N</i> -isopropyltryptamine (Other names: 5-MeO-MiPT; <i>N</i> -(2-(5-methoxy-1 <i>H</i> -indol-3-yl)ethyl)- <i>N</i> -methylpropan-2-amine)	7512

(121) 5-methoxy- <i>N,N</i> -diethyltryptamine (Other names: 5-MeO-DET; <i>N,N</i> -diethyl-2-(5-methoxy-1 <i>H</i> -indol-3-yl)ethanamine)	7525
(122) <i>N,N</i> -diisopropyltryptamine (Other names: DiPT; <i>N</i> -(2-(1 <i>H</i> -indol-3-yl)ethyl)- <i>N</i> -isopropylpropan-2-amine)	7522
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SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on September 11, 2026, by DEA Administrator Terrance C. Cole. 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.

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