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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-1641]

Schedules of Controlled Substances: Temporary Placement of *O*-Desmethyltramadol in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Drug Enforcement Administration issues this temporary order to schedule *O*-desmethyltramadol (other names: *O*-DSMT; desmetramadol; 3-[(1*R*,2*R*)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, in schedule I of the Controlled Substances Act. DEA bases this action on a finding that placing *O*-DSMT in schedule I is necessary to avoid an imminent hazard to public safety. This order imposes 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 *O*-DSMT.

DATES: This temporary order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], until August 12, 2028. If this order is extended or made permanent, DEA will publish a document in the *Federal Register*.

ADDRESSES: 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: The Drug Enforcement Administration (DEA) issues a

temporary scheduling order[1] (in the form of a temporary amendment) to add *O*-desmethyltramadol (other names: 3-(2-((dimethylamino)methyl)-1-hydroxycyclohexyl)phenol; *O*-DSMT; desmetramadol), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, to schedule I under the Controlled Substances Act (CSA).

Legal Authority

The CSA provides the Attorney General (as delegated to the Administrator of DEA (Administrator) pursuant to 28 CFR 0.100) with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the evaluation requirements of 21 U.S.C. 811(b), if he finds that such action is necessary to avoid an imminent hazard to the public safety.[2] In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1) while the substance is temporarily controlled under section 811(h), the Attorney General may extend the temporary scheduling for up to one year.[3]

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355.[4]

Background

The CSA requires the Administrator of DEA (Administrator) to notify the Secretary of Health and Human Services (HHS) of an intent to temporarily place a substance in schedule I of the CSA (i.e., to issue a temporary scheduling order).[5] By letter dated May 27, 2025, the previous Acting Administrator transmitted the required notice to place *O*-DSMT in schedule I on a temporary basis to the then-Acting Assistant Secretary for HHS (Assistant Secretary).[6] On June 11, 2025, the previous Acting

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[1] Though DEA has used the term "final order" with respect to temporary scheduling orders in the past, this action adheres to the statutory language of 21 U.S.C. 811(h), which refers to a "temporary scheduling order." No substantive change is intended.
[2] 21 U.S.C. 811(h)(1).
[3] 21 U.S.C. 811(h)(2).
[4] 21 U.S.C. 811(h)(1); 21 CFR part 1308.
[5] 21 U.S.C. 811(h)(4).
[6] 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).

Assistant Secretary responded to this notice and advised DEA that, based on a review by the Food and Drug Administration (FDA), there were currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for *O*-DSMT. The previous Assistant Secretary also stated that HHS had no objection to the temporary placement of *O*-DSMT in schedule I of the CSA. *O*-DSMT is not currently listed in any schedule under the CSA.

DEA has taken into consideration the Acting Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). DEA has found the control of *O*-DSMT in schedule I on a temporary basis is necessary to avoid an imminent hazard to public safety.

To find that temporarily placing a substance in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors set forth in 21 U.S.C. 811(c): the substance's history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health.[7] Consideration of these factors includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of *O*-DSMT.[8]

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.[9] Substances in schedule I have high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use of the drug under medical supervision.[10]

As required by 21 U.S.C. 811(h)(1)(A), DEA published a notice of intent (NOI) to temporarily schedule *O*-DSMT in the *Federal Register* on June 24, 2026.[11] That NOI discussed findings from DEA's Three-factor analysis dated May 2026, which DEA made available on *www.regulations.gov*.

_O_-Desmethyltramadol (_O_-DSMT)

O-DSMT is a mu-opioid agonist that is being abused for its psychoactive effects. *O*-DSMT is

[7] 21 U.S.C. 811(c)(4)-6), (h)(3).
[8] 21 U.S.C. 811(h)(3).
[9] 21 U.S.C. 811(h)(1).
[10] 21 U.S.C. 812(b)(1).
[11] *Schedules of Controlled Substances: Temporary Placement of O-DSMT in Schedule I*, 91 FR 37822 (June 24, 2026).

one of two metabolites produced by liver enzymes following the ingestion of the parent compound tramadol. Tramadol is active as a norepinephrine and serotonergic reuptake inhibitor, in addition to being a weak mu-opioid receptor agonist. *O*-DSMT is an active metabolite of tramadol with a strong affinity for the mu-opioid receptor and is responsible for the majority of the opioidergic effects following the ingestion of tramadol.

In the United States, since tramadol is only approved as a pill formulation, a user must ingest tramadol orally, thus allowing the drug to be metabolized via the liver, to experience the analgesic effects. In the absence of any approved medical product or identified lawful commercial source of *O*-DSMT in the United States, understanding the metabolism of tramadol and its opioidergic metabolite *O*-DSMT has resulted in the clandestine production of *O*-DSMT. Data has demonstrated that *O*-DSMT has a significantly higher affinity for opioid receptors (K_i – 3.4 nM) than the parent drug tramadol (K_i – 2400 nM) and is more potent in producing analgesia. In addition, overdoses and deaths, both internationally and within the United States, have been documented involving *O*-DSMT. With no approved medical use and limited safety or toxicological information, *O*-DSMT has emerged in the designer drug market, and the abuse of this substance is a significant public health concern in the United States.

Available data and information for *O*-DSMT, summarized below, indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States,[12] and a

[12] When finding schedule I placement on a temporary basis is necessary to avoid imminent hazard to the public, 21 U.S.C 811(h) does not require DEA to consider whether the substance has a currently accepted medical use in treatment in the United States. Nonetheless, there is no evidence suggesting that *O*-DSMT has a currently accepted medical use in treatment in the United States. First, DEA looks to whether the drug or substance has FDA approval for marketing in interstate commerce. When no FDA approval exists, DEA has traditionally applied a five-part test to determine whether a drug or substances 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 applied the traditional five-part test and concluded the test was not satisfied. In a recent published letter in a different context, HHS applied an additional two-part test to determine currently accepted medical use for substances that do not satisfy the five-part test: (1) whether there exists widespread, current experience with medical use of the substance by licensed health care providers operating in accordance with implemented jurisdiction-authorized programs, where medical use is recognized by entities that regulate the practice of medicine, and, if so, (2) whether there exists some credible scientific support for at least one of the medical conditions for which part (1) is satisfied. On April 11, 2024, the Department of Justice's Office of Legal Counsel (OLC) issued an opinion, which, among other things, concluded that HHS's two-part test would be sufficient to establish that a drug has a currently

lack of accepted safety for use under medical supervision. DEA's Three-factor analysis is available in its entirety under "Supporting and Related Material" of the public docket for this action at *www.regulations.gov* under Docket Number DEA-1641.

Factor 4. Its history and current pattern of abuse

As described previously, *O*-DSMT is a major metabolite of tramadol. *O*-Demethylation of the parent drug tramadol results in the formation of *O*-DSMT, which is primarily catalyzed by the cytochrome P450 liver enzyme 2D6 (CYP2D6). Individuals of various backgrounds have been identified as either ultrarapid metabolizers, normal metabolizers, intermediate metabolizers, or poor metabolizers of tramadol based upon genotyping of CYP2D6. The current Clinical Pharmacogenetics Implementation Consortium guidelines recommend avoiding tramadol in CYP2D6 ultrarapid metabolizers (due to possible toxicity from increased formation of *O*-DSMT) and CYP2D6 poor metabolizers (due to possible lack of efficacy from decreased formation of *O*-DSMT). Ultrarapid metabolizers have approximately 40 percent greater serum concentration of *O*-DSMT and subsequently experience a stronger opioid response compared with poor metabolizers.

O-DSMT has been encountered in various forms, including as a solid powder, pressed into pills or tablets, in a capsule, as a semi-solid paste/slurry, and in liquid formulations. Direct ingestion of *O*-DSMT avoids the need for metabolic activation via liver enzymes, resulting in a compound that is pharmacologically active at the mu-opioid receptor. Injection or insufflation by drug abusers of tramadol would be devoid of most immediate opioid activity due to the parent compound having little affinity for the opioid receptors. As further described in Factor 5, drug seizures have demonstrated *O*-DSMT both alone and in combination with multiple other drugs. In a randomized, double-blind, placebo and active comparator-controlled trial, the pharmacokinetics and analgesic properties of *O*-

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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 notice of intent, there is no evidence that health care providers have widespread experience with medical use of *O*-DSMT or that the use of *O*-DSMT is recognized by entities that regulate the practice of medicine, so the two-part test also is not satisfied. By letter dated June 11, 2025, DEA has been advised by HHS that there are currently no approved new drug applications or investigational new drug applications for *O*-DSMT. Additionally, HHS communicated no objections to the temporary placement of *O*-DSMT into Schedule I of the CSA.

DSMT, as compared to tramadol, in 103 healthy participants were investigated. The study also investigated CYP2D6 inhibition on the ability of both tramadol and *O*-DSMT to influence analgesia. The results showed that 20 mg of *O*-DSMT was equivalent in its analgesic potency as compared to 50 mg of tramadol following chronic dosing at steady state, whereby both were significantly greater than placebo (*see* Three-Factor analysis).

Factor 5. The scope, duration, and significance of abuse

With the first encounters appearing in 2011, law enforcement continues to report seizures of *O*-DSMT. The threat of serious injury to the individual and the imminent threat to public safety following the ingestion of *O*-DSMT persists. DEA's National Forensic Laboratory Information System (NFLIS)[13] has reported 147 encounters of *O*-DSMT across 30 states.[14] Because not every forensic laboratory has the capacity to test for *O*-DSMT, it is likely that these encounters are underreported.

O-DSMT has been encountered in various forms, including as a solid powder, pressed into pills or tablets, in a capsule, as a semi-solid paste/slurry, and in liquid formulations. Among these various reports, *O*-DSMT has been found as the only drug in a majority of these encounters (*n*=118 of 147, 80.2 percent), or mixed with various other substances to include mitragynine (kratom alkaloid), heroin, isopropyl-U-47700 (synthetic opioid), methamphetamine, fentanyl, acetyl fentanyl, 5F-AEB (synthetic cannabinoid), methoxyacetyl fentanyl, *N*-benzylfuranylfentanyl, 3-OH-PCE (synthetic hallucinogen), tramadol, bromazolam (designer benzodiazepine), *para*-fluorofentanyl, dipentylone (synthetic cathinone), and/or cocaine, among others. *O*-DSMT has also been identified in conjunction with other substances, as evidenced by toxicology reports (*see* Factor 6). *O*-DSMT was found to be mixed with the

[13] NFLIS is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state, local, and federal forensic laboratories in the United States. NFLIS represents an important resource in monitoring illicit drug trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle more than 96 percent of an estimated 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only. While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV,* 76 FR 77330, 77332 (Dec. 12, 2011).

[14] NFLIS query date: May 11, 2026; 2025 and 2026 data are still being reported.

kratom plant as determined by testing of the packaging material and the confirmation of both *O*-DSMT and mitragynine in toxicology results of individuals.

Factor 6. What, if any, risk there is to the public health

Public health risks associated with *O*-DSMT abuse relates to its pharmacological similarities with known opioids such as morphine, oxycodone, and fentanyl. The ingestion of *O*-DSMT has resulted in serious adverse effects including lung congestion, brain edema, and death. The following four examples discussed briefly below can be found in their entirety in DEA's Three-factor analysis at *www.regulations.gov* under Docket Number DEA-1641.

In 2009, reports in Sweden described nine deaths due to intoxication with *O*-DSMT combined with mitragynine and confirmed via forensic autopsies. Occurring between October 2009 and October 2010, ten forensic medical investigations found concomitant use of *O*-DSMT and mitragynine in the blood of these deceased individuals. It was noted that in nine of these cases, the death was explained by intoxication with *O*-DSMT. Other substances were identified, but it was stated that these substances were not at toxic levels. Ages of the individuals ranged between 22-35 years old, concentrations of *O*-DSMT ranged between 0.4 and 4.3 μg/g in blood, and all the individuals died before arriving at a hospital. Deaths for all individuals were noted to be accidental. Additional information in the reports detailed significant lung congestion and edema following use of "Krypton" (a mix of kratom and *O*-DSMT).

Around the same time as the deaths were reported in Sweden, a group in Germany in 2010 were asked to analyze urine samples for "Krypton" in a former opiate-addicted woman. The woman's clinical picture included miosis, itchiness, agitation, and moderate euphoria following three months of use. Both immunoassays and liquid chromatography-tandem mass spectrometry (LC–MS/MS) were conducted on the samples. Results were negative for tramadol or its metabolites using the immunoassays. LC–MS/MS detected the kratom alkaloids mitragynine, speciociliatine, speciogynine, mitraciliatine, and paynantheine and approximately 9 mg/L *O*-DSMT, but no tramadol nor *N*-desmethyltramadol. Once confronted with these results, the woman admitted to having drunk "3-4 infusions of Krypton" during

the past week. The researchers ruled out the use of tramadol because both tramadol and *N*-desmethyltramadol were not detectable. It was concluded that the most likely source of the *O*-DSMT was the "Krypton" product, containing both kratom alkaloids and *O*-DSMT.

In 2021 in Portugal, a 25-year-old male was found dead in his room at a boarding house where he lived. He was a chemistry student who, according to relatives, was "trying to find a cure to his illness using chemical products bought by himself." Drug paraphernalia found at the scene included a spoon, a syringe, and six different plastic bags found with powders inside. It was noted that all six bags were labeled with the supposed name of the compounds. Further testing confirmed that the labels were accurate for each substance, including *O*-DSMT. His past medical history included schizophrenia and bipolar disorder. In addition, needle puncture marks in the victim's arms, indicative of drug abuse, were noted during autopsy.

In 2021 in Kansas City, Kansas, a 19-year-old male with a history of anxiety and depression was last observed by a roommate lying on his bed and reported to be "snoring and sweaty." The autopsy did not reveal any significant anatomical abnormalities. Drug evidence at the scene was noted to be labeled as clonazolam, flubromazolam, *O*-desmethyltramadol (*O*-DSMT), and 2-methyl-AP-237. Toxicological analysis of whole blood from autopsy identified the following: 2-methyl AP-237 (379 ng/mL), detla-9 THC (56.8 ng/mL), 11-nor-9-carboxy-delta-9-THC (141 ng/mL), 8-aminoclonazolam (4.6 ng/mL), *O*-DSMT (10.9 ng/mL), and mitragynine (2.7 ng/mL). 7-Amino clonazepam, diphenhydramine, fluoxetine, norfluoxetine, trazodone, and propranolol were also identified but not quantified.

As noted in Factor 5, counterfeit pills pressed to resemble tramadol may contain *O*-DSMT either alone or in combination with other substances. Clandestine manufacturers will commonly use legitimate markings when producing counterfeit pills. Should a user ingest a pill marked as tramadol that was surreptitiously produced with *O*-DSMT, the individual might experience serious adverse effects due to the stronger analgesic potential of *O*-DSMT as compared to tramadol.

As users obtain these drugs through unknown sources, the identity and purity of these substances is uncertain and inconsistent, thus posing significant adverse health risks to users. *O*-DSMT is being

encountered on the illicit drug market in the United States, has no accepted medical use in the United States, and continues to be available and abused for its psychoactive properties. In summary, *O*-DSMT has been reported to cause serious adverse effects, including death, following its use.

Finding of Necessity of Schedule I Placement to Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the available data and information summarized above, the uncontrolled manufacture, distribution, reverse distribution, importation, exportation, conduct of research and chemical analysis, possession, and abuse of *O*-DSMT poses an imminent hazard to public safety. *O*-DSMT has not been approved by the FDA and has not been marketed in the United States, and DEA is not aware of any currently accepted medical uses for *O*-DSMT in the United States. A substance meeting the statutory requirements for temporary scheduling, found in 21 U.S.C. 811(h)(1), may only be placed in schedule I. Substances in schedule I must have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for *O*-DSMT indicate that this substance meets the three statutory criteria.

As required by 21 U.S.C. 811(h)(4), in a letter dated May 27, 2025, the previous Acting Administrator notified the previous Acting Assistant Secretary of DEA's intention to temporarily place *O*-DSMT in schedule I. In a letter dated June 11, 2025, the previous Acting Assistant Secretary did not object to the temporary placement of *O*-DSMT in schedule I. DEA subsequently published a NOI in the *Federal Register* on June 24, 2026.[15]

Conclusion

In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule *O*-DSMT in schedule I of the CSA, and finds that placement of this substance in schedule I is necessary to avoid an imminent hazard to the public's safety.

The temporary placement of *O*-DSMT in schedule I of the CSA will take effect on the date the

[15] *Schedules of Controlled Substances: Temporary Placement of O-DSMT in Schedule I*, 91 FR 37822 (June 24, 2026).

order is published in the *Federal Register* and will remain in effect for two years, with a possible extension of one year, pending completion of the regular (permanent) scheduling process.[16]

The CSA sets forth specific criteria for scheduling drugs or other substances. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557.[17] The permanent scheduling process of formal rulemaking affords interested parties appropriate process and the government any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review.[18] Temporary scheduling orders are not subject to judicial review.[19]

Requirements for Handling

Upon the effective date of this temporary order, *O*-DSMT will be subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, possession of, and engagement in research and conduct of instructional activities or chemical analysis with, schedule I controlled substances, including but not limited to the following:

1. *Registration.* Any person who handles (possesses, manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with) or desires to handle, *O*-DSMT must be registered with DEA to conduct such activities, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Any person who currently handles *O*-DSMT and is not registered with DEA must submit an application for registration and may not continue to handle *O*-DSMT as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823,

[16] 21 U.S.C. 811(h)(1) and (2).
[17] 21 U.S.C. 811.
[18] 21 U.S.C. 877.
[19] 21 U.S.C. 811(h)(6).

957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

Notwithstanding the foregoing, pursuant to 21 U.S.C. 822(h), if, on [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], a person is conducting research on *O*-DSMT and is already registered to conduct research with another controlled substance in schedule I, the person may continue to conduct research on *O*-DSMT if they submit a completed application for registration or modification of existing registration, as applicable, to conduct research with *O*-DSMT not later than 90 calendar days after [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. 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 *O*-DSMT and may not receive or otherwise obtain additional *O*-DSMT. 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 *O*-DSMT, receipt of the copy by the manufacturer or distributor constitutes sufficient evidence that the person is authorized to receive *O*-DSMT 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 *O*-DSMT.

Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of *O*-DSMT in a manner not authorized by the CSA on or after [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] is unlawful, and those in possession of any quantity of *O*-DSMT may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is unable to obtain a schedule I registration to handle *O*-DSMT must surrender all currently held quantities of this substance.

3. *Security*. *O*-DSMT is subject to schedule I security requirements and must be handled in

accordance with 21 CFR 1301.71-1301.93, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

4. *Labeling and Packaging*. All labels, labeling, and packaging for commercial containers of *O*-DSMT must comply with 21 U.S.C. 825 and 958(e) and 21 CFR part 1302. Current DEA registrants will have 30 calendar days from [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER] to comply with all labeling and packaging requirements.

5. *Inventory*. Every DEA registrant who possesses any quantity of *O*-DSMT on the effective date of this order must take an inventory of all stocks of this substance on hand pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants will have 30 calendar days from the effective date of this order to comply with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including *O*-DSMT) on hand on a biennial basis pursuant to 21 U.S.C. 827 and 958 and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records*. All DEA registrants must maintain records with respect to *O*-DSMT pursuant to 21 U.S.C. 827 and 958(e) and in accordance with 21 CFR parts 1304, 1312, and 1317, and section 1307.11. Current DEA registrants authorized to handle *O*-DSMT shall have 30 calendar days from the effective date of this order to comply with all recordkeeping requirements.

7. *Reports.* All DEA registrants must submit reports with respect to *O*-DSMT pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, 1312, and 1317, and sections 1301.74(c) and 1301.76(b), as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER]. Manufacturers and distributors must also submit reports regarding *O*-DSMT 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.

8. *Order Forms*. All DEA registrants who distribute *O*-DSMT must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

9. *Importation and Exportation*. All importation and exportation of *O*-DSMT must be in

compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

10. *Quota.* Only DEA-registered manufacturers may manufacture *O*-DSMT in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303, as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER].

11. *Liability*. Any activity involving *O*-DSMT not authorized by or in violation of the CSA, occurring as of [INSERT DATE OF PUBLICATION IN FEDERAL REGISTER], is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

The CSA provides for expedited temporary scheduling actions where necessary to avoid an imminent hazard to public safety. Under 21 U.S.C. 811(h)(1), the Administrator, as delegated by the Attorney General, may, by order, temporarily place substances in schedule I. Such orders may not be issued before the expiration of 30 days from: (1) the publication of a notice in the *Federal Register* of the intent to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary, as delegated by the Secretary of HHS.[20]

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order (as distinct from a rule) and sets forth the procedures by which such orders are to be issued, DEA believes the notice-and-comment requirements the Administrative Procedure Act (APA) at 5 U.S.C. 553, which are applicable to rulemaking, do not apply to this temporary scheduling order. The APA expressly differentiates between orders and rules, as it defines an "order" to mean a "final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency *in a matter other than rule making*."[21] This contrasts with permanent scheduling actions, which are subject to formal rulemaking procedures done "on the record after opportunity for a hearing," and final decisions that conclude the

[20] 21 U.S.C. 811(h)(1).
[21] 5 U.S.C. 551(6) (emphasis added).

scheduling process and are subject to judicial review.[22] The specific language chosen by Congress indicates its intent that DEA issue *orders* instead of proceeding by rulemaking when temporarily scheduling substances. Given that Congress specifically requires the Administrator (as delegated by the Attorney General) to follow rulemaking procedures for *other* kinds of scheduling actions,[23] it is noteworthy that, in section 811(h)(1), Congress authorized the issuance of temporary scheduling actions by order rather than by rule.

Even assuming that this action is subject to the notice-and-comment requirements of the APA, the Administrator finds that there is good cause to forgo these requirements pursuant to 5 U.S.C. 553(b)(B), as any further delays in the process for issuing temporary scheduling orders would be impracticable and contrary to the public interest given the manifest urgency to avoid an imminent hazard to public safety.

Although DEA believes this temporary scheduling order is not subject to the notice-and-comment requirements of the APA, DEA notes that in accordance with 21 U.S.C. 811(h)(4), the Administrator took into consideration comments submitted by the Acting Assistant Secretary in response to the notices that DEA transmitted to the Acting Assistant Secretary pursuant to such subsection.

Further, DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act (RFA). The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking. Therefore, in this instance, since DEA believes this temporary scheduling action is not a "rule," it is not subject to the requirements of the RFA when issuing this temporary action.

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not

[22] 21 U.S.C. 811(a) and 877.
[23] *See* 21 U.S.C. 811(a).

a significant regulatory action. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866, sec. 3(f), provides the definition of a "significant regulatory action," requiring review by the Office of Management and Budget. Because this is not a rulemaking action, this is not a significant regulatory action as defined in Section 3(f) of E.O. 12866. In addition, DEA scheduling actions are not subject to either E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

This action will 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. Therefore, in accordance with E.O. 13132, it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

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

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

2. In § 1308.11:

a. Remove and reserve paragraph (h)(65); and

b. Add paragraph (h)(88).

The addition reads as follows:

§ 1308.11 Schedule I

* * * * *

(h) * * *

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(88) *O*-Desmethyltramadol (other names: *O*-DSMT; desmetramadol; 3-[(1*R*,2*R*)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol)	9667

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SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on August 6, 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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