



## 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:** Proposed amendment; notice of intent.

**SUMMARY:** The Administrator of the Drug Enforcement Administration is issuing this notice of intent to publish a temporary order to schedule *O*-desmethyltramadol (other names: *O*-DSMT; desmetramadol; 3-[(1R,2R)-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. When it is issued, the temporary scheduling order will 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 *O*-DSMT.

**DATES:** [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** 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; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3249.

**SUPPLEMENTARY INFORMATION:** The notice of intent contained in this document is issued pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The Drug

Enforcement Administration (DEA) intends to issue a temporary scheduling order<sup>1</sup> (in the form of a temporary amendment) to add *O*-desmethyiltramadol (other names: *O*-DSMT; desmetramadol), its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, to schedule I under the Controlled Substances Act (CSA). The temporary scheduling order will be published in the *Federal Register* on or after [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

### **Legal Authority**

The CSA provides the Attorney General with the authority to temporarily place a substance in schedule I of the CSA for two years without regard to the 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.<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup> The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of DEA (Administrator).<sup>5</sup>

### **Background**

The CSA requires the 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).<sup>6</sup> By letter dated May 27, 2025, the previous Acting

---

<sup>1</sup> Though DEA has used the term “final order” with respect to temporary scheduling orders in the past, this notice of intent adheres to the statutory language of 21 U.S.C. 811(h), which refers to a “temporary scheduling order.” No substantive change is intended.

<sup>2</sup> 21 U.S.C. 811(h)(1).

<sup>3</sup> 21 U.S.C. 811(h)(2).

<sup>4</sup> 21 U.S.C. 811(h)(1); 21 CFR part 1308.

<sup>5</sup> 28 CFR 0.100.

<sup>6</sup> 21 U.S.C. 811(h)(4).

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).<sup>7</sup> On June 11, 2025, the previous Acting 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.

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.<sup>8</sup> This consideration includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of *O*-DSMT.<sup>9</sup>

Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I.<sup>10</sup> 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.<sup>11</sup>

### ***O*-Desmethyltramadol (*O*-DSMT)**

*O*-DSMT is a mu-opioid agonist that is being abused for its psychoactive effects. *O*-DSMT is one of two metabolites produced by liver enzymes following the ingestion of the parent compound tramadol. Tramadol, in and of itself, prior to being metabolized, is active as a

---

<sup>7</sup> 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).

<sup>8</sup> 21 U.S.C. 811(c)(4)-6), (h)(3).

<sup>9</sup> 21 U.S.C. 811(h)(3).

<sup>10</sup> 21 U.S.C. 811(h)(1).

<sup>11</sup> 21 U.S.C. 812(b)(1).

norepinephrine and serotonergic reuptake inhibitor, in addition to being a weak mu-opioid receptor agonist. While the second metabolite, *N*-DSMT, is inactive, *O*-DSMT is an active metabolite of tramadol with a strong affinity for the mu-opioid receptor. *O*-DSMT is responsible for the majority of the opioidergic effects following the ingestion of the parent compound 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 due to its lack of accepted medical use, understanding of the metabolism of tramadol and its opioidergic metabolite 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 uses in treatment in the United States,<sup>12</sup> and a lack of accepted safety for use under medical supervision. DEA's Three-

---

<sup>12</sup> 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. 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

Factor analysis is available in its entirety under “Supporting and Related Material” of the public docket for this action at [www.regulations.gov](http://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 liver enzyme 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 the cytochrome P450 enzyme 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

---

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 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.

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*-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)<sup>13</sup> has reported 148 encounters of *O*-DSMT across 30 states to date.<sup>14</sup> Because not every forensic laboratory has the capacity to test for *O*-DSMT, it is likely that encounters of *O*-DSMT are underreported.

Among these various reports, *O*-DSMT has been found as the only drug in a majority of these encounters (n=118 of 148, 79.7 percent), or co-reported 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,

---

<sup>13</sup> NFLIS-Drug 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-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 1.0 million distinct annual State and local drug analysis cases. NFLIS-Drug 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).

<sup>14</sup> NFLIS-Drug query date: May 22, 2026. Reports to NFLIS-Drug are still pending for 2025 and 2026.

*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 kratom plant as determined by 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](http://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 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 clonazepam, flubromazepam, *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), delta-9 THC (56.8 ng/mL), 11-nor-9-carboxy-delta-9-THC (141 ng/mL), 8-aminoclonazepam (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.

## **Conclusion**

This notice of intent provides the 30-day notice pursuant to 21 U.S.C. 811(h)(1) of DEA's intent to issue a temporary scheduling order. 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 safety.

The temporary placement of *O*-DSMT in schedule I of the CSA will take effect upon publication of a temporary scheduling order in the *Federal Register*, which will not be issued before [INSERT DATE 30 DAYS AFTER PUBLICATION OF THIS NOTICE IN THE FEDERAL REGISTER]. Because the Administrator hereby finds this temporary scheduling order necessary to avoid an imminent hazard to the public safety, it will take effect on the date the order is published in the *Federal Register* and it will remain in effect for two years, with a possible extension of an additional year, pending completion of the regular (permanent) scheduling process.<sup>15</sup> The Administrator intends to issue a temporary scheduling order as soon as possible after the expiration of 30 days from the date of publication of this document. Upon the temporary order's publication, *O*-DSMT will then be subject to the CSA's schedule I regulatory controls and to administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, research, conduct of instructional activities and chemical analysis, and possession.

The CSA sets forth specific criteria for scheduling drugs or other substances. Regular 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

---

<sup>15</sup> 21 U.S.C. 811(h)(1) and (2).

of 5 U.S.C. 556 and 557.<sup>16</sup> The regular 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 regular scheduling process of formal rulemaking are subject to judicial review.<sup>17</sup> Temporary scheduling orders are not subject to judicial review.<sup>18</sup>

## **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 schedule 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.<sup>19</sup>

Inasmuch as section 811(h) directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, including the requirement to publish in the *Federal Register* a notice of intent, the notice-and-comment requirements of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this notice of intent. The APA expressly differentiates between an order and a rule, 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*.”<sup>20</sup> 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 scheduling process and are subject to judicial review.<sup>21</sup> The specific language chosen by Congress indicates its intent that DEA issue *orders*

---

<sup>16</sup> 21 U.S.C. 811.

<sup>17</sup> 21 U.S.C. 877.

<sup>18</sup> 21 U.S.C. 811(h)(6).

<sup>19</sup> 21 U.S.C. 811(h)(1).

<sup>20</sup> 5 U.S.C. 551(6) (emphasis added).

<sup>21</sup> 21 U.S.C. 811(a) and 877.

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,<sup>22</sup> 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 notice of intent is subject to the notice-and-comment requirements of the APA, the Administrator finds that there is good cause to forgo the notice-and-comment 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 notice of intent to issue a 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 previous Acting Assistant Secretary in response to the notice that DEA transmitted to the previous 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. As discussed above, DEA is issuing this notice of intent pursuant to DEA’s authority to issue a temporary scheduling order.<sup>23</sup> 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.

---

<sup>22</sup> See 21 U.S.C. 811(a).

<sup>23</sup> 21 U.S.C. 811(h)(1).

In accordance with the principles of Executive Orders (E.O.) 12866 and 13563, this action is not 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. 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 proposes to amend 21 CFR part 1308 as follows:

#### **PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

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

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

2. In § 1308.11, add paragraph (h)(88) to read as follows:

##### **§ 1308.11 Schedule I**

\* \* \* \* \*

(h) \* \* \*

|                                                                                                                                                    |      |
|----------------------------------------------------------------------------------------------------------------------------------------------------|------|
| * * * * *                                                                                                                                          |      |
| (88) <i>O</i> -Desmethyltramadol (other names: <i>O</i> -DSMT; desmetramadol; 3-<br>[(1R,2R)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol) | 9677 |
| * * * * *                                                                                                                                          |      |

### SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on June 16, 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.*

[FR Doc. 2026-12654 Filed: 6/23/2026 8:45 am; Publication Date: 6/24/2026]