

(b) *Classification*. Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include the following:

(i) Evaluation of the effect of confounding variables, like skin pigmentation, on performance;

(ii) Demonstration of the consistency of the output and representativeness of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment; and

(iii) Evaluation of all adverse events, including skin irritation.

(2) Software verification, validation, and hazard analysis must be performed. Documentation must include:

(i) Technical specifications of the software, including software algorithm(s) and its inputs and outputs; and

(ii) Specification of acceptable incoming sensor data quality control measures.

(3) Non-clinical performance testing must demonstrate the ability of the device to detect adequate photoplethysmography signal quality and validate any alarms.

(4) The skin-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance testing must support the electrical safety and electromagnetic compatibility of the electrical components of the device.

(6) Human factors and usability testing must demonstrate the following:

(i) The caregiver can correctly use the device based solely on reading the device labeling; and

(ii) The caregiver can correctly interpret the device outputs and understand next steps to take based on the outputs.

(7) Labeling must include:

(i) Instructions for identifying the intended use population of the device,

including populations where the device should not be used, and conditions of monitoring;

(ii) A description of what the device measures and outputs to the caregiver, including instructions for the interpretation of results and appropriate actions;

(iii) Situations in which the device may not operate at an expected performance level; and

(iv) Instructions for cleaning the device and cleaning frequency.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1641]

Schedules of Controlled Substances: Placement of O-Desmethyltramadol in Schedule I; Correction

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Correcting amendment.

SUMMARY: On August 12, 2026, the Drug Enforcement Administration (DEA) published a temporary order placing *O*-desmethyltramadol (other names: *O*-DSMT; desmetramadol; 3-[(1*R*,2*R*)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers are possible, in schedule I of the Controlled Substances Act. DEA published this temporary order that specifically noted in the summary that the control of *O*-desmethyltramadol included its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers are possible, however

inadvertently omitted the correct language that should have been included. This document corrects that error, adding the correct language.

DATES: This correcting amendment is effective October 9, 2026, until August 12, 2028, and applicable beginning August 12, 2026.

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

SUPPLEMENTARY INFORMATION: The placement of *O*-desmethyltramadol under schedule I was effective on August 12, 2026.¹ After publication of the temporary scheduling order, DEA inadvertently omitted the correct language that should have been included in 21 CFR part 1308. This document corrects the language in 21 CFR part 1308 to include the isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible of *O*-desmethyltramadol.

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 corrects 21 CFR part 1308 with the following correcting amendment:

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, revise paragraph (h)(88) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(88) *O*-desmethyltramadol, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other names: *O*-DSMT; desmetramadol; 3-[(1*R*,2*R*)-2-[(dimethylamino)methyl]-1-hydroxycyclohexyl]phenol)

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¹ Schedules of Controlled Substances: Temporary Placement of *O*-desmethyltramadol in Schedule I, 91 FR 52013 (Aug. 12, 2026).

Signing Authority

This document of the Drug Enforcement Administration was signed on October 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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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1664]

RIN 1117–ZA08

Schedules of Controlled Substances; Removal of Exemption Status for Inactive Butalbital Products

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final determination.

SUMMARY: The Drug Enforcement Administration (DEA) is revoking the exempted status for certain nonnarcotic prescription products that are currently on DEA's Table of Exempted Prescription Products, but whose National Drug Codes (NDC) are inactive because they are no longer available and/or the company that applied for the exemption no longer exists. These products will be removed from DEA's Table of Exempted Prescription Products and will no longer be considered exempt prescription products under the Controlled Substances Act. This action does not impact exempted prescription products with active NDC numbers.

DATES: This final determination is effective on November 9, 2026.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Ph.D., Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Controlled Substances Act (CSA) authorizes the Attorney General, by regulation, to exempt from certain provisions of the CSA any compound, mixture, or preparation containing certain nonnarcotic controlled substances if he finds that it is both (1) approved for prescription use, and (2) contains one or more other active ingredients which are not listed in any schedule and which are included in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.¹ The Attorney General has delegated this authority to the Administrator of DEA (Administrator).² The Administrator may also revoke a previously granted exemption by following the same procedures that are used to evaluate an application for exemption—namely, by publishing in the **Federal Register** a general notice of the proposed rulemaking (NPRM) for revoking the exemption, permitting interested persons to file written comments on or objections to the proposed revocation, considering any comments submitted, and publishing a final order in the **Federal Register** that sets forth the findings of fact and conclusions of law upon which the order is based.³

This final determination revokes the exemption status for certain prescription products previously granted exemption because the National Drug Codes (NDC) of these products are no longer active and/or the companies that originally filed for their exemption no longer exist. This action revokes the exemption status for a number of products and removes them from DEA's Table of Exempted Prescription Products. While this action revokes the exemption status, this action will have no effect on these products because they are no longer marketed.

Background: Exempted Prescription Products

DEA has exempted prescription drug products from certain parts of the CSA when the products meet the requirements for exemption, including the requirement to contain active ingredients believed to vitiate the potential for abuse. The current table of products that have been granted exempted prescription product status, pursuant to 21 CFR 1308.31 and

1308.32, can be found on the DEA Diversion Control Division website.⁴

Butalbital is classified as an intermediate acting barbiturate. Butalbital is a schedule III nonnarcotic controlled substance that falls under DEA Controlled Substances Code Number 2100, as it is a derivative of barbituric acid.⁵ Originally, some butalbital prescription products were exempted by the Bureau of Drug Abuse Control (BDAC) of the Food and Drug Administration (FDA), the predecessor to the Bureau of Narcotics and Dangerous Drugs and later DEA. A panel of public health physicians and FDA medical officers developed the criteria used to exempt butalbital prescription products by BDAC in 1967. These criteria were based upon the expectation that combining the controlled substance with an amount of counteractive drug sufficient to cause early deterrent side effects would vitiate the potential for abuse. For products containing long or intermediate acting barbiturates in combination with analgesics, the criteria provided that an exemption would be granted if, for every 15 mg of barbiturate, the product contained at least (1) 188 mg aspirin; (2) 375 mg salicylamide; or (3) 70 mg phenacetin, acetanilid, or acetaminophen.

Following the establishment of the criteria, DEA approved subsequent applications by new manufacturers based upon the same criteria, whereby the inclusion of these other active ingredients was thought to be in sufficient quantities to vitiate the potential for abuse. The criteria developed in 1967 was originally found to meet the standard for exemption currently described in 21 U.S.C. 811(g)(3)(A), such that if a prescription drug was found to meet the 1967 criteria for exemption, then it also met the test to contain an ingredient that vitiated the potential for abuse under the CSA standard.

Currently, there are 189 butalbital products listed by their NDC on DEA's Table of Exempted Prescription Products. Using the FDA's National Drug Code Directory⁶ and the U.S.

⁴ Available at https://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list.pdf.

⁵ 21 CFR 1308.13(c)(3).

⁶ FDA's NDC directory contains information about finished, unfinished (e.g., active pharmaceutical ingredients) and compounded drugs. The NDC Directory contains product listing data submitted for all finished drugs including prescription and over-the-counter drugs, approved and unapproved drugs as well as repackaged and relabeled drugs. Drug establishments are required to provide FDA with a current list of all drugs, including active pharmaceutical ingredients manufactured, prepared, propagated, compounded,

¹ 21 U.S.C. 811(g)(3)(A); 21 CFR 1308.31, 1308.32.

² 28 CFR 0.100.

³ See 21 CFR 1308.31(c), (d).