Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure under 5 U.S.C. 553(a)(1). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

Executive Order 12866

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the 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). CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 because it pertains to a foreign affairs function of the United States, as described above, and therefore is specifically exempted by section 3(d)(2) of Executive Order 12866.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

Signing Authority

In accordance with Treasury Order 100–20, the Secretary of the Treasury has delegated to the Secretary of Homeland Security the authority related to the customs revenue functions vested in the Secretary of the Treasury as set forth in 6 U.S.C. 212 and 215, subject to certain exceptions. This regulation is being issued in accordance with Department of Homeland Security Delegation 07010.3, Revision 03.2, which delegates to the Commissioner of CBP the authority to prescribe and approve regulations related to cultural property import restrictions.

Rodney S. Scott, Commissioner, having reviewed and approved this document, has delegated the authority to electronically sign this document to Susan S. Thomas, the Executive Assistant Commissioner, Office of Trade, for purposes of publication in the **Federal Register**.

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise, and Reporting and recordkeeping requirements.

Amendment to the CBP Regulations

For the reasons set forth above, part 12 of title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g, the table in paragraph (a) is amended by adding Nepal to the list in alphabetical order to read as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

* * * * *

(a) * * *

State party	Cultural property	Decision No.
*	*	*
Nepal	Archaeological material of Nepal ranging in date from 32,000 B.C.E. through 1770 C.E., and ethnological material of Nepal ranging in date from the 13th century C.E. through 1950 C.E..	CBP Dec. 26–16
*	*	*

* * * * *

Susan S. Thomas,

Executive Assistant Commissioner, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2026–16432 Filed 8–11–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2018–D–3583]

Guide To Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Guide to Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce.'' This guidance supersedes a previous guidance, entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables,'' issued in 2008, and is a final guidance to the draft guidance for industry entitled ''Guide to Minimize Food Safety Hazards of Fresh-Cut Produce'' issued in 2018. The guidance is intended to help manufacturers or processors of ready-to-eat fresh-cut produce that is not a low-moisture food comply with applicable requirements in our regulations on current good manufacturing practices for hazard analysis and risk-based preventive controls for human food.

DATES: The announcement of the guidance is published in the **Federal Register** on August 12, 2026.

ADDRESSES: You may submit either electronic or written comments on FDA guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–3583 for ''Guide to Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Microbiological Food Safety's Office of Produce Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Adam Baker, Office of Microbiological Food Safety, Office of Produce Safety, or Marla Hallacy, Office of Policy and International Engagement, Office of Policy Initiatives and Projects, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301–796–5528.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Guide to Minimize Biological Hazards in Ready-to-Eat Fresh-Cut Produce.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of October 22, 2018 (83 FR 53197), we made available a draft guidance for industry entitled ''Guide to Minimize Food Safety Hazards of Fresh-Cut Produce'' and gave interested parties an opportunity to submit comments by April 22, 2019, for us to consider before beginning work on a final guidance. We received several comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include clarifying that the guidance applies only to ready-to-eat fresh-cut produce with a water activity above 0.85; adding another example of an antimicrobial substance that can be used as a process control in the production of fresh-cut produce; providing additional examples of a supply chain program to control pathogens in a fresh-cut processing facility; and providing additional recommendations on time/temperature controls. To further improve clarity, we made editorial and organizational changes throughout the guidance. The guidance announced in this notice finalizes the draft guidance dated October 2018. This guidance supersedes a previous guidance, entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables,'' issued in 2008.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 117 have been approved under OMB control number 0910–0751.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous

sentence to find the most current version of the guidance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16420 Filed 8–11–26; 8:45 am]

BILLING CODE 4164–01–P

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 August 12, 2026, 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 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 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

[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).

[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).