TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR EXTERNAL MECHANICAL STIMULATORS FOR THE RELIEF OF CONGESTION—Continued

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Ineffective treatment leading to worsening congestion	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for external mechanical stimulators for the relief of congestion. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 874.6010 to subpart F to read as follows:

§ 874.6010 External mechanical stimulator for the relief of congestion.

(a) *Identification.* An external mechanical stimulator for the relief of congestion delivers vibrations to the sinus and nasal areas to relieve congestion.

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

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including verification of specified mechanical stimulation parameters.

(2) Performance data must demonstrate the electromagnetic compatibility, battery safety, and electrical safety of the device.

(3) Software verification, validation, and hazard analysis must be performed.

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

(5) Human factors testing must demonstrate that users can successfully use the device in the intended use environment based solely on its labeling and instructions for use.

(6) Labeling must include the following:

(i) Device specifications, including the frequency range, maximum output power, and power source; and

(ii) Explanation of the user interface.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22657 Filed 11–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1768]

Specific Listing for 3-Chloromethcathinone, A Currently Controlled Schedule I Substance

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is establishing a specific listing and DEA Controlled Substances Code Number (drug code) for 1-(3-chlorophenyl)-2-(methylamino)propan-1-one (3-chloromethcathinone; 3–CMC) in schedule I of the Controlled Substances Act (CSA). Although 3-chloromethcathinone is not specifically listed in schedule I of the CSA with its own unique drug code, it is a schedule I controlled substances in the United States because it is a positional isomer of 4-chloromethcathinone, which is a schedule I hallucinogen. Therefore, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include 3-chloromethcathinone.

DATES: Effective November 6, 2026.

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

SUPPLEMENTARY INFORMATION:

3-Chloromethcathinone Control

3-Chloromethcathinone (also known as, 1-(3-chlorophenyl)-2-(methylamino)propan-1-one; and 3–CMC) is a chemical substance that is structurally related to 4-chloromethcathinone (also known as, 1-

(4-chlorophenyl)-2-(methylamino)propan-1-one; and 4–CMC). 4-Chloromethcathinone is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(106). As stated in subsection 21 CFR 1308.11(d), a listed hallucinogenic substance includes ''any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation,'' and the term ''isomer'' includes the ''optical, position[al], and geometric isomers.''

When compared to the chemical structure of 4-chloromethcathinone, 3-chloromethcathinone meets the definition of a ''positional isomer'' in 21 CFR 1300.01(b), which cross-references the term ''positional isomer'' in 21 CFR 1308.11(d). Both 4-chloromethcathinone and 3-chloromethcathinone possess the same molecular formula and core structure, and they have the same functional groups. 4-Chlorometh cathinone and 3-chloromethcathinone differ from one another by the position of the chloride atom on the same functional group (phenyl ring). This does not create new chemical functionalities or destroy existing chemical functionalities. Accordingly, under 21 CFR 1308.11(d), 3-chloro methcathinone, as a positional isomer of 4-chloromethcathinone, has been and continues to be a schedule I controlled substance.[1]

Legal Authority

This rule is prompted by a letter dated June 6, 2024, in which the Secretariat of the United Nations informed the United States government that 3-chlorometh cathinone have been added to Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. This letter was prompted by decisions at the 67th Session of the Commission on Narcotic Drugs (CND) in March 2024 to schedule 3-chloromethcathinone under Schedule II of the 1971 Convention (CND Decision 67/2). Preceding these decisions, the Food and Drug Administration (FDA), on behalf of the Secretary of Health and Human Services and pursuant to 21 U.S.C. 811(d)(2), published two notices in the **Federal Register** with an opportunity to submit domestic information and opportunity to comment on this action.[2]

As discussed above in this final rule, 3-chloromethcathinone, by virtue of being a positional isomer of 4-chloro methcathinone, has been controlled in schedule I of the CSA since December 17, 2025.[3] Therefore, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to 3-chloro methcathinone. Drugs controlled in schedule I of the CSA satisfy and exceed the required domestic controls of Schedule II under Article 2 of the 1971 Convention.

Effect of Action

As discussed above, this rule does not affect the continuing status of 3-chloromethcathinone as a schedule I controlled substances in any way. This action, as an administrative matter, merely establishes a separate, specific listing for 3-chloromethcathinone in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for this substance. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of 3-chlorometh cathinone, who had previously been granted individual quotas for such purposes under the drug code for 4-chloromethcathinone.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest.[4]

Pursuant to 5 U.S.C. 553(b)(B), DEA finds that notice-and-comment rulemaking is unnecessary, and that good cause exists to dispense with these procedures, as 3-chloromethcathinone is currently controlled in schedule I as a positional isomer of 4-chlorometh cathinone. The addition of a separate listing for 3-chloromethcathinone and its DEA controlled substances code number in the list of schedule I substances in 21 CFR 1308.11(d) makes no substantive difference in the status of this drug as a schedule I controlled substance, but instead is ''a minor or merely technical amendment in which the public is not particularly interested.''[5] This rule is a ''technical amendment'' to 21 CFR 1308.11(d) as it is ''insignificant in nature and impact, and inconsequential to the industry and public.'' Therefore, DEA finds that publishing a notice of proposed rulemaking and soliciting public comment are unnecessary and good cause exists to dispense with these procedures.

In addition, DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of 3-chloromethcathinone. With 3-chloro methcathinone currently controlled under schedule I as a positional isomer, and with no additional requirements being imposed through this action, DEA finds good cause exists to make this rule effective immediately upon publication in accordance with 5 U.S.C. 553(d)(3).

Executive Orders 12866, 13563, 14192, and 14294 (Regulatory Review).

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14192. This rule is not a significant regulatory action under section 3(f) of E.O. 12866. 3-Chloro methcathinone is already a controlled substance in the United States under schedule I, as it is a positional isomer of the schedule I hallucinogen 4-chloromethcathinone. In this final rule, DEA is merely making an administrative change by amending its regulations to separately list 3-chloromethcathinone in schedule I and to assign a DEA controlled substances code number to this substance. A separate listing for 3-chloromethcathinone and its DEA controlled substances code number will not alter the status of this substance as a schedule I controlled substance. DEA scheduling actions are not subject to E.O. 14192, Unleashing Prosperity Through Deregulation, or E.O. 14294, Fighting Overcriminalization in Federal Regulations.

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[1] 4-Chloromethcathinone (and its isomers) has been subject to schedule I controls since December 17, 2025. *See Schedules of Controlled Substances: Placement of 4-Chloromethcathinone in Schedule I,* 90 FR 51102 (Nov. 11, 2025).

[2] *See International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Bromazolam; Flubromazepam; Butonitazene; 3-Chloromethcathinone (3–CMC); Dipentylone; 2-Fluorodeschloroketamine (2–FDCK); Nitrous Oxide (N2O); Carisoprodol; Request for Comments,* 88 FR 52179 (Aug. 7, 2023)*; International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; World Health Organization; Scheduling Recommendations; Butonitazene; 3-Chloromethcathinone; Dipentylone; 2-Fluorodesch loroketamine; Bromazolam; Request for Comments,* 89 FR 8683 (Feb. 8, 2024).

[3] *Schedules of Controlled Substances: Placement of 4-Chloromethcathinone in Schedule I,* 90 FR 51102 (Nov. 17, 2025).

[4] 5 U.S.C. 553(b)(B).

[5] *National Nutritional Foods Ass'n* v. *Kennedy,* 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79–752, at 200 (1945)). *See also Utility Solid Waste Activities Group* v. *E.P.A.,* 236 F.3d 749, 755 (D.C. Cir. 2001) (the ''unnecessary'' prong ''is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and public'') (internal quotations and citation omitted).

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) applies to rules that are subject to the notice-and-comment requirements under the APA or other laws.[6] As noted in the above section regarding the applicability of the APA, DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995.[7] This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year . . . .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

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. Amend § 1308.11 by adding the new paragraph (d)(118) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

*	*	*	*	*	*	*
(118) 3-Chloromethcathinone (3-CMC, 1-(3-chlorophenyl)-2-(methylamino)propan-1-one)						1241
*	*	*	*	*	*	*

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Signing Authority

This document of the Drug Enforcement Administration was signed on November 2, 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. 2026–22717 Filed 11–5–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2026–0562]

RIN 1625–AA09

Drawbridge Operation Regulation; Wishkah River, Aberdeen, WA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the operating schedule that governs the Puget Sound and Pacific railroad bridge (PS&P) across the Wishkah River, mile 0.1 in Aberdeen, WA. This rule will change the PS&P railroad bridge draw position to the fully closed-to-navigation position. Furthermore, this rule requires 24-hour notice for all drawbridge openings and a bridge operator will no longer be required to be on site.

DATES: This rule is effective December 7, 2026.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov.* Type the docket number (USCG–2026–0562) in the ''SEARCH'' box and click ''SEARCH''. In

[6] 5 U.S.C. 601–612.

[7] 44 U.S.C. 3501–3521.