not limited to, the remedies provided under 19 U.S.C. 1641.

* * * * *

Susan S. Thomas,

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

[FR Doc. 2026–22735 Filed 11–5–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 571

[Docket No. FDA–2026–F–4956]

Food Additive Petitions; Change of Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is amending the regulations for food additive petitions (FAPs) to update addresses and simplify notification procedures. These technical amendments are being made to improve the accuracy of the Agency's regulations and are non-substantive.

DATES: This technical amendment is effective November 6, 2026.

FOR FURTHER INFORMATION CONTACT: Isabel Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–5877, *Isabel.Pocurull@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal food and drug regulations for food additive petitions (FAPs) at 21 CFR 571.1 to update addresses and Agency notification procedure. This technical amendment is being made to improve the accuracy of the Agency's regulations and is non-substantive.

Publication of this document constitutes final action on the changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical or non-substantive, ministerial changes to update addresses and Agency notification procedure.

List of Subjects in 21 CFR Part 571

Administrative practice and procedure, Animal feeds, Animal food additives, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 571 is amended as follows:

PART 571—FOOD ADDITIVE PETITIONS

■ 1. The authority citation for part 571 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371; 42 U.S.C. 241.

■ 2. Amend § 571.1 by:
■ a. Revising paragraph (a);
■ b. In paragraph (c), revising the undesignated text above item A; and
■ c. Revising paragraph (d).

The revisions read as follows:

§ 571.1 Petitions.

(a) Petitions to be filed under the provisions of section 409(b) of the Federal Food, Drug, and Cosmetic Act (the Act) can be submitted using both CVM's eSubmitter program, *https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-programs,* to generate the submission and FDA's electronic submission gateway to submit, *https://www.fda.gov/industry/electronic-submissions-gateway-next-generation-esg-nextgen,* or on compact disk with paper cover letter. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state petitioner's mailing address and email address to which published notices or orders issued or objections filed pursuant to section 409 of the Act may be sent.

* * * * *

(c) * * *

(Date) _____

Name of petitioner _____

Post office address _____

Date _____

Name of food additive and proposed use _____

Food and Drug Administration, Center for Veterinary Medicine, *Director,* Division of Animal Food Ingredients, 5001 Campus Dr., College Park, MD 20740–3835

The undersigned, _____, submits this petition pursuant to section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act with respect to _____ (Name of the food additive and proposed use)

Attached and constituting a part of this petition, are the following:

* * * * *

(d) The petitioner will be notified of the date on which the petition is filed or if an incomplete petition, it will usually be retained but not filed as a petition under section 409 of the Act. The petitioner will be notified in what respects the petition is incomplete.

* * * * *

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–22663 Filed 11–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA–2026–N–12125]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the External Mechanical Stimulator for the Relief of Congestion

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the external mechanical stimulator for the relief of congestion into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the external mechanical stimulator for the relief of congestion. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective November 6, 2026. The classification was applicable on December 4, 2023.

FOR FURTHER INFORMATION CONTACT: Payton Lin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1212, Silver Spring, MD 20993–0002, 240–402–6580, *Payton.Lin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the external mechanical stimulator for the relief of congestion into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the

device. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 16, 2023, FDA received Sound Health Systems, Inc.'s request for De Novo classification of the Sonu device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 4, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 874.6010.[1] We have named the generic type of device ''external mechanical stimulator for the relief of congestion,'' and it is identified as a device that delivers vibrations to the sinus and nasal areas to relieve congestion.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

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

Identified risks to health	Mitigation measures
Injury from mechanical overstimulation on the face causing one or more of the following: • Skin irritation or redness • Pain • Discomfort • Headache • Vertigo • Hearing loss • Tinnitus	Non-clinical performance testing; Human factors testing; Software verification, validation, and hazard analysis; Electrical safety testing; Electromagnetic compatibility testing; Battery safety testing; and Labeling.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

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-