

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 § 874.3410 to subpart D to read as follows:

§ 874.3410 Combined acoustic and electrical external stimulation device for the relief of tinnitus.

(a) *Identification.* A combined acoustic and electrical external stimulation device for the relief of tinnitus is a device that provides acoustic stimulation in the ear and external, electrical stimulation of sensory nerves to relieve tinnitus.

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

(1) Clinical performance testing must demonstrate performance as intended under anticipated conditions for use including the following:

(i) Evaluation of tinnitus symptoms using a validated method; and

(ii) Evaluation of all adverse events.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Verification of specified electrical stimulation parameters; and

(ii) Verification of specified acoustic stimulation parameters, including maximum output limits, distortion levels, and frequency response.

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

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

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

(6) 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.

(7) Labeling must include the following:

(i) A statement that the device is intended to be prescribed by a healthcare professional with expertise in the evaluation and management of tinnitus;

(ii) Information regarding emotional, psychological, and physical considerations for patient selection; and

(iii) Device specifications, including the materials of patient-contacting components of the device, electrical output waveform, stimulation peak voltage and current, pulse duration, frequency, maximum current density, maximum phase charge, and power source.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–11589 Filed 6–9–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 528

Publication of International Criminal Court-Related Sanctions Regulations Web General License 11

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of a web general license.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing a general license (GL) issued pursuant to the International Criminal Court-Related Sanctions Regulations: GL 11. This GL was previously made available on OFAC's website.

DATES: GL 11 was issued on December 18, 2025. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Regulatory Affairs, 202–622–4855; or <https://ofac.treasury.gov/contact-ofac>.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are

available on OFAC's website: <https://ofac.treasury.gov>.

Background

On December 18, 2025, OFAC issued GL 11 to authorize certain transactions otherwise prohibited by the International Criminal Court-Related Sanctions Regulations, 31 CFR part 528. This GL expired on January 17, 2026. This GL was made available on OFAC's website (<https://ofac.treasury.gov>) when it was issued. The text of this GL is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

International Criminal Court-Related Sanctions Regulations

31 CFR Part 528

GENERAL LICENSE NO. 11

Authorizing the Wind Down of Transactions Involving Certain Persons Blocked on December 18, 2025

(a) Except as provided in paragraph (b) of this general license, all transactions prohibited by the International Criminal Court-Related Sanctions Regulations (ICCSR), 31 CFR part 528, that are ordinarily incident and necessary to the wind down of any transaction involving one or more of the following blocked persons are authorized through 12:01 a.m. eastern standard time, January 17, 2026, provided that any payment to a blocked person is made into a blocked interest-bearing account located in the United States, in accordance with the ICCSR:

(1) Gocha Lordkipanidze;

(2) Erdenebalsuren Damdin; or

(3) Any entity in which one or more of the above persons own, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest.

(b) This general license does not authorize any transactions otherwise prohibited by the ICCSR, including transactions involving any person blocked pursuant to the ICCSR other than the blocked persons described in paragraph (a) of this general license, unless separately authorized.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

Dated: December 18, 2025.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2026–11601 Filed 6–9–26; 8:45 am]

BILLING CODE 4810–AL–P