

TABLE 1—ELECTRICAL TONGUE NERVE STIMULATOR TO TREAT MOTOR DEFICITS RISKS AND MITIGATION MEASURES—Continued

Identified risks to health	Mitigation measures
Thermal, electrical, or mechanical fault, or system malfunction resulting in tissue damage due to overstimulation or thermal injury (e.g., burn/shock) to user.	Electrical, mechanical, and thermal safety testing; Electromagnetic compatibility testing; Battery safety testing; Non-clinical performance testing; Software validation, verification and hazard analysis; and Labeling.
Use error that may result in user discomfort or injury	Labeling.
Device contamination resulting in patient illness	Labeling.
Adverse events involving the mouth, tongue, or gums such as irritation and discomfort.	Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. 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) (21 U.S.C. 360(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). At this time FDA has not made this determination for electrical tongue nerve stimulators to treat motor deficits. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, the electrical tongue nerve stimulator to treat motor deficits is for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively 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 system regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

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 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

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

■ 2. Add § 882.5889 to subpart F to read as follows:

§ 882.5889 Electrical tongue nerve stimulator to treat motor deficits.

(a) *Identification.* An electrical tongue nerve stimulator to treat motor deficits is a prescription device that consists of a non-implantable apparatus to generate electrical pulses for stimulation of the nerves in the tongue to provide treatment of motor deficits.

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

(1) Performance data must demonstrate that all patient-contacting components of the device are biocompatible.

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

(3) Non-clinical performance testing must characterize the electrical stimulation parameters of the device.

(4) Software verification, validation, and hazard analysis must be performed. Software documentation must include an assessment of the impact of threats and vulnerabilities on device functionality and end users as part of cybersecurity review.

(5) Labeling must include:

- (i) A detailed summary of the device's technical parameters;
- (ii) Instructions for use;
- (iii) Cleaning, storage, and charging instructions; and
- (iv) Disposal instructions.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 58

[TD 10037]

RIN 1545–BQ59

Excise Tax on Repurchase of Corporate Stock; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final rule; correction and correcting amendments.

SUMMARY: This document includes corrections to Treasury Decision 10037 published in the **Federal Register** on Monday, November 24, 2025. Treasury

Decision 10037 contains final regulations that provide guidance regarding the application of the excise tax on repurchases of corporate stock made after December 31, 2022.

DATES:

Effective date: These corrections are effective on December 19, 2025.

Applicability date: For dates of applicability, see §§ 1.1275–6(f)(12)(iii)(B), 58.4501–6, 58.4501–7(r), and 58.6011–1(d).

FOR FURTHER INFORMATION CONTACT:

Concerning § 58.4501–7, Brittany N. Dobi of the Office of Associate Chief Counsel (International) at (202) 317–5469 (not a toll-free number). For all other issues, Kailee H. Hock of the Office of Associate Chief Counsel (Corporate) at (202) 317–3181 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 10037) subject to these corrections are issued under sections 1275, 4501, and 6011 of the Internal Revenue Code (Code).

Correction of Publication

Accordingly, FR Doc. 2025–20721 (TD 10037), appearing on page 53144 in the **Federal Register** on Monday, November 24, 2025, is corrected as follows:

1. On page 53150, in the second column, in the first full paragraph, the sixth line from the top of the paragraph is corrected to read “purposes. See § 1.368–2(m)(3)(iii)”.

2. On page 53150, in the third column, in the second full paragraph, the sixth line from the top of the paragraph is corrected to read “§ 1.368–2(m)(3)(iii)), and because such a”.

List of Subjects in 26 CFR Part 58

Excise taxes, Stocks, Reporting and recordkeeping requirements.

Correction to the Regulations

Accordingly, 26 CFR part 58 is corrected by making the following correcting amendments:

PART 58—STOCK REPURCHASE EXCISE TAX

■ **Paragraph 1.** The authority citation for part 58 continues to read in part as follows:

Authority: 26 U.S.C. 4501(f) and 7805.

■ **Par. 2.** Section 58.4501–5 is amended by removing the first two sentences of paragraph (b)(11)(ii) and revising the last sentence of paragraph (b)(11)(iii) to read as follows:

§ 58.4501–5 Examples.

* * * * *

(b) * * *
(11) * * *
(iii) * * * Consequently, Corporation X’s stock repurchase excise tax base for its 2025 taxable year is \$20x (\$100x – \$80x).

* * * * *

Oluwafunmilayo A. Taylor,

Chief, Publications and Regulations Section, Associate Chief Counsel. (Procedure and Administration)

[FR Doc. 2025–23460 Filed 12–18–25; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2025–1099]

RIN 1625–AA00

Safety Zone; Fireworks Display, Ohio River Mile Marker 73 to 74, Wellsburg, WV

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Ohio River from Mile Marker 73 to Mile Marker 74 in Wellsburg, WV. This action is necessary to provide for the safety of life on these navigable waters from potential hazards during the Wellsburg New Years Eve Celebration Fireworks Display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Pittsburgh or a designated representative.

DATES: This rule is effective from 11 p.m. on December 31, 2025, until 1 a.m. on January 1, 2026.

ADDRESSES: To view available documents, go to <https://www.regulations.gov> and search for USCG–2025–1099.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact Petty Officer Brett Lanzel, MSU Pittsburgh, U.S. Coast Guard; telephone 206–815–6624, or email Brett.J.Lanzel@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking

§ Section
U.S.C. United States Code

II. Background and Authority

The Coast Guard received notification that fireworks will be launched from a vessel on the Ohio River near Wellsburg, WV. Hazards from fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port (COTP) Pittsburgh has determined that potential hazards associated with fireworks are a safety concern for anyone on the Ohio River within a one mile area of the fireworks display. Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.

The Coast Guard is issuing this rule without prior notice and comment. As is authorized by 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. The Coast Guard was not provided notice of this event with sufficient time to publish an NPRM and consider public comments before the safety zone must be established on December 31, 2025.

For the same reasons, the Coast Guard finds that under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Discussion of the Rule

This rule establishes a safety zone from 11 p.m. on December 31, 2025 until 1 a.m. on January 1, 2026. The safety zone will cover all navigable waters within the one-mile area between Mile Markers 73 and 74 on the Ohio River, near Wellsburg, WV. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or their designated representative.

IV. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders.

A. Impact on Small Entities

The regulatory flexibility analysis provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to rules that are not subject to notice and comment. Because the Coast Guard has, for good cause, waived the