

with “The device, when it is solely intended for use as a drink to test glucose tolerance, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.”

2. FDA is revising § 862.1775 by replacing “The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9” with “The device, when it is solely intended for use as an acid reduction of ferric ion test, a phosphotungstate reduction test, a gasometric uricase test, an ultraviolet uricase test, or an oxygen rate uricase test, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.”

3. FDA is revising § 866.2900 by replacing “The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9” with “The device, when solely intended for use in the collection of concentrated parasites from specimens and transport, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.”

III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (APA) (5 U.S.C. 553). Section 553 of the APA exempts “rules of agency organization, procedure, or practice” from proposed rulemaking (*i.e.*, notice and comment rulemaking). 5 U.S.C. 553(b)(3)(A). Rules are also exempt when an Agency finds “good cause” that notice and comment rulemaking procedures would be “impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. 553(b)(3)(B).

FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (b)(3)(B). FDA’s revisions make technical or non-substantive changes that pertain solely to ensuring that the regulations accurately reflect the exemptions made by the **Federal Register** notices and do not alter any substantive standard. FDA does not believe public comment is necessary for these minor revisions.

The APA allows an effective date less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do

not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects

21 CFR Part 862

Medical devices.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 862 and 866 are amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

- 1. The authority citation for part 862 continues to read as follows:

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

- 2. In § 862.1345, revise paragraph (b) to read as follows:

§ 862.1345 Glucose test system.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is solely intended for use as a drink to test glucose tolerance, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

- 3. In § 862.1775, revise paragraph (b) to read as follows:

§ 862.1775 Uric acid test system.

* * * * *

(b) *Classification.* Class I (general controls). The device, when it is solely intended for use as an acid reduction of ferric ion test, a phosphotungstate reduction test, a gasometric uricase test, an ultraviolet uricase test, or an oxygen rate uricase test, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

- 4. The authority citation for part 866 continues to read as follows:

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

- 5. In § 866.2900, revise paragraph (b) to read as follows:

§ 866.2900 Microbiological specimen collection and transport device.

* * * * *

(b) *Classification.* Class I (general controls). The device, when solely

intended for use in the collection of concentrated parasites from specimens and transport, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

Dated: March 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF STATE

22 CFR Parts 121, 123, 124, 126, and 129

[Public Notice 11078]

International Traffic in Arms Regulations: U.S. Munitions List Categories; Preliminary Injunction Ordered by a Federal District Court

AGENCY: Department of State.

ACTION: Notification of preliminary injunction.

SUMMARY: The U.S. Department of State (the Department) is issuing this document to inform the public of a preliminary injunction ordered by a Federal district court on March 6, 2020, affecting the Department.

DATES: The court order was effective March 6, 2020.

FOR FURTHER INFORMATION CONTACT: For technical questions only: Sarah Heidema, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663-2809; email DDTCPublicComments@state.gov.

SUPPLEMENTARY INFORMATION: On January 23, 2020, the Department published a final rule in the **Federal Register** at 85 FR 3819 that amends the International Traffic in Arms Regulations (ITAR) to revise Categories I, II, and III of the U.S. Munitions List (USML) and removes certain items that no longer warrant control. On the same date, the Department of Commerce published a companion final rule in the **Federal Register** at 85 FR 4136 that makes conforming changes to the Export Administration Regulations (EAR) to control the items removed from the USML. The final rules were to be effective March 9, 2020.

On January 23, 2020, several U.S. States filed a lawsuit in the United States District Court for the Western District of Washington (Civil Action No. 2:20-cv-00111) seeking a court order to prohibit the Departments of State and Commerce from implementing or enforcing the final rules described

above. Plaintiff States subsequently filed a motion for a preliminary injunction.

On March 6, 2020, the District Court issued an “Order Granting in Part Plaintiff States’ Motion for Preliminary Injunction.” This order states that the Department of State is enjoined “from implementing or enforcing the regulation entitled International Traffic in Arms Regulations: U.S. Munitions List Categories I, II, and III, 85 FR 3819 (Jan. 23, 2020) insofar as it alters the status quo restrictions on technical data and software directly related to the production of firearms or firearm parts using a 3D-printer or similar equipment.”

The Department of State is complying with the terms of this order. All persons engaged in manufacturing, exporting, temporarily importing, brokering, or furnishing defense services related to “technical data and software directly related to the production of firearms or firearm parts using a 3D-printer or similar equipment” must continue to treat such technical data and software as subject to control on the USML. All other items addressed in the final rules were transferred from the jurisdiction of the Department and the USML to the Department of Commerce and the Commerce Control List (CCL) on March 9, 2020.

Any further guidance and updates regarding the subject litigation will be posted on the DDTTC website (pmddtc.state.gov) on an ongoing basis.

Michael F. Miller,

Deputy Assistant Secretary of State for Defense Trade Controls.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2020-0058]

RIN 1625-AA00

Safety Zone; Monongahela River Mile 23.8 to Mile 26.0, Pittsburgh, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters of the Monongahela River from mile 23.8 to mile 26.0. This action is necessary to protect persons, vessels, and the marine environment from potential hazards associated with

power line work across the river near Elrama Power Plant, Pittsburgh, PA, during an electrical conductor pull from March 23, 2020 through April 6, 2020. Entry of persons or vessels into this zone is prohibited unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

DATES: This action is effective without actual notice from March 23, 2020 until April 2, 2020. For purposes of enforcement, actual notice will be used from April 2, 2020 until April 6, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2020-0058 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST2 Trevor Vannatta, Waterways Management U.S. Coast Guard; telephone 412-221-0807, email Trevor.J.Vannatta@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Marine Safety Unit Pittsburgh
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On November 12, 2019, the Duquesne Light Company notified the Coast Guard that it will be conducting an electrical conductor pull on March 23, 2020, in order to replace existing electrical conductor with new higher ampacity electrical conductor. The conductor pull will take place between mile 23.8 and mile 26 on the Elrama Power Plant side of the Monongahela River. In response, on February 3, 2020, the Coast Guard published a notice of proposed rulemaking (NPRM) titled USCG-2020-0058_NPRM_D8 (85 FR 5909). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this conductor pull project. During the comment period that ended March 4, 2020, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Pittsburgh (COTP) has determined that potential hazards

from the conductor pull include danger to the navigability of the waterway due to obstruction by equipment. The Captain of the Port (COTP) Marine Safety Unit Pittsburgh has determined that potential hazards associated with ongoing work would be a safety concern for anyone transiting the river during the maintenance activity. Possible hazards include risks of injury or death from near or actual contact among working vessels and mariners traversing through the safety zone.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published February 3, 2020. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone from March 23, 2020 through April 6, 2020. The safety zone would cover all navigable waters from mile 23.8 to mile 26.0 on the Monongahela River near Pittsburgh, PA. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after a scheduled maintenance activity at the Elrama Power Plant. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Marine Safety Unit Pittsburgh. They may be contacted on VHF-FM Channel 16 or by telephone at (412) 221-0807. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful instructions of the COTP or a designated representative. Breaks in the conductor pull will occur during the enforcement periods, which will allow vessels to pass through the safety zone. The COTP or a designated representative will inform the public of the enforcement period for the safety zone as well as any changes in the schedule through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

V. 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, and we discuss First Amendment rights of protestors.