appeals decision, at the following address: Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality Standards, Attn: Facility Accreditation Review Committee, 10903 New Hampshire Ave., Bldg. 66, Rm. 3621, Silver Spring, MD 20993–0002.

* * * * *

■ 37. In § 900.18, revise paragraph (c) introductory text to read as follows:

§ 900.18 Alternative requirements for § 900.12 quality standards.

* * * * *

(c) *Applications for approval of an alternative standard.* An application for approval of an alternative standard or for an amendment or extension of the alternative standard shall be submitted in an original and two copies to the Food and Drug Administration, Center for Devices and Radiological Health, Director, Division of Mammography Quality Standards, 10903 New Hampshire Ave., Bldg. 66, Rm. 3621, Silver Spring, MD 20993–0002. The application for approval of an alternative standard shall include the following information:

* * * * *

■ 38. In § 900.21, revise paragraph (b)(1) to read as follows:

§ 900.21 Application for approval as a certification agency.

* * * * *

(b) * * * (1) An applicant seeking FDA approval as a certification agency shall inform the Food and Drug Administration, Center for Devices and Radiological Health, Director, Division of Mammography Quality Standards, Attn: Program Management Branch, 10903 New Hampshire Ave., Bldg. 66, Rm. 3621, Silver Spring, MD 20993–0002, in writing, of its desire to be approved as a certification agency.

* * * * *

PART 1002—RECORDS AND REPORTS

■ 39. The authority citation for part 1002 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374.

■ 40. In § 1002.50, revise paragraph (c)(3) to read as follows:

§ 1002.50 Special exemptions.

* * * * *

(c) * * *

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality Standards, 10903 New Hampshire Ave., Bldg. 66, Rm. 3621, Silver Spring, MD 20993–0002.

* * * * *

Dated: March 23, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06354 Filed 4–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862 and 866

[Docket No. FDA–2020–N–0011]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending certain medical device regulations to accurately reflect the devices exempted from premarket notification (510(k)) as indicated in the lists published on April 13, 2017, and July 11, 2017. FDA published a final amendment, final order in the **Federal Register** of December 30, 2019 (''Final Order'') codifying the two **Federal Register** notices. The present revisions are necessary to correct editorial errors to ensure that the codified is consistent with the exemptions in the **Federal Register** notices. The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective April 1, 2020.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 240–402–6357.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 510(l)(2) and 510(m)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(l)(2) and 360(m)(1)(A)), FDA issued two separate notices of final determination exempting a list of class I and II devices from section 510(k) of the FD&C Act, respectively, subject to certain limitations published in the **Federal Register** April 13, 2017 (82 FR 17841) and July 11, 2017 (82 FR 31976). The devices included in these lists were exempt upon publication of the final determination notices in the **Federal Register** notices (see sections 510(l)(2)(A) and 510(m)(3) of the FD&C Act). On December 30, 2019 (84 FR 71794), FDA issued an amendment, final order, which amended the codified for the classification regulations implicated in the **Federal Register** notices to reflect the exemptions and limitations on exemptions in those notices. This Final Order incorrectly amended the codified for three device types such that the exemption in the current codified is inconsistent with the scope of the device exemptions described in the **Federal Register** notices. Specifically, for the three implicated device types, FDA indicated in the **Federal Register** notices that a device with a particular intended use was exempt from the premarket notification requirements in section 510(k) of the FD&C Act; however, the codified currently indicates that the entire device type is exempt from section 510(k) of the FD&C Act, which is not the case.

As such, FDA is amending the codified for §§ 862.1345, 862.1775, and 866.2900 (21 CFR 862.1345, 862.1775, and 866.2900) to be consistent with the exemptions as stated in the **Federal Register** notices. These amendments are not substantive changes because the **Federal Register** notices exempted the affected devices from the section 510(k) of the FD&C Act, but are intended to correct the codified and to clarify which devices under those classification regulations are exempt from the premarket notification requirements in section 510(k) of the FD&C Act and which device types remain subject to such requirements.

II. Description of the Technical Amendments

The regulations specified in this rule have been revised to correct and clarify the codified language of the regulations specified in this technical amendment, specifically §§ 862.1345, 862.1775, and 866.2900, to be consistent with the exemptions as stated in the **Federal Register** notices. FDA is making no substantive changes to the following regulations:

1. FDA is revising § 862.1345(b) 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 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 TOXIOLOGY DEVICES

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

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

[FR Doc. 2020–06278 Filed 4–1–20; 8:45 am]

BILLING CODE 4164–01–P

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