determined this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, this rule will not have federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this rule under Executive Order 13211. The agency has determined it is not a ''significant energy action'' under the executive order and will not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609 promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609 and has determined that this action will have no effect on international regulatory cooperation.

X. Additional Information

A. Electronic Access

Except for classified and controlled unclassified material not authorized for public release, all documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the internet through the docket for this rulemaking.

Those documents may be viewed online at *https://www.regulations.gov* using the docket number listed above. A copy of this rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *https://www.federalregister.gov* and the Government Publishing Office's website at *https://www.govinfo.gov*. A copy may also be found at the FAA's Regulations and Policies website at *https://www.faa.gov/regulations_policies*.

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket or notice number of this rulemaking.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121) (set forth as a note to 5 U.S.C. 601) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the persons listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *http://www.faa.gov/regulations_policies/rulemaking/sbre_act/*.

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Freight, Libya.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations, as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 1. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 2. Amend § 91.1603 by revising the section heading and paragraphs (b), (c), and (e) to read as follows:

§ 91.1603 Special Federal Aviation Regulation No. 112—Prohibition Against Certain Flights in the Territory and Airspace of Libya.

* * * * *

(b) *Flight prohibition.* Except as provided in paragraphs (c) and (d) of this section, no person described in paragraph (a) of this section may conduct flight operations in the territory and airspace of Libya.

(c) *Permitted operations.* This section does not prohibit persons described in paragraph (a) of this section from conducting flight operations in the territory and airspace of Libya, provided that such flight operations occur under a contract, grant, or cooperative agreement with a department, agency, or instrumentality of the U.S. Government (or under a subcontract between the prime contractor of the department, agency, or instrumentality and the person described in paragraph (a) of this section), with the approval of the FAA, or under an exemption issued by the FAA. The FAA will consider requests for approval or exemption in a timely manner, with the order of preference being: First, for those operations in support of U.S. Government-sponsored activities; second, for those operations in support of government-sponsored activities of a foreign country with the support of a U.S. Government department, agency, or instrumentality; and third, for all other operations.

* * * * *

(e) *Expiration.* This SFAR will remain in effect until March 20, 2025. The FAA may amend, rescind, or extend this SFAR, as necessary.

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f) and (g), 40101(d)(1), 40105(b)(1)(A), and 44701(a)(5), on or about March 13, 2023.

Billy Nolen,

Acting Administrator.

[FR Doc. 2023–05390 Filed 3–17–23; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 803, 812, and 822

[Docket No. FDA–2021–N–0246]

Medical Devices; Technical Amendments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending certain medical device regulations to update mailing address and docket number and conform the regulatory provisions to the Federal Food, Drug, and Cosmetics Act (FD&C Act). The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature to correct errors and to ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective March 21, 2023.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of Policy, Center for Devices and

Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993–0002, 301–796–5837.

SUPPLEMENTARY INFORMATION:

I. Background

As a part of this technical amendment, the FDA Center for Devices and Radiological Health (CDRH) is making changes to 21 CFR parts 10, 803, 812, and 822 to revise contact addresses, correct docket numbers, and conform the regulatory provisions to the FD&C Act to ensure accuracy and clarity in the Agency's medical device regulations. The changes published in this notice are non-substantive and editorial in nature.

II. Description of the Technical Amendments

The regulation, 21 CFR 10.80(h), is being revised to make a non-substantive editorial change to update a citation that was moved from title 42 to title 21. In § 803.19(b), we are removing the address and replacing it with a website link. We are correcting the docket number in the regulations §§ 812.38 and 812.47 with the docket number specified in the codified of this rulemaking. For §§ 822.1 and 822.4, we are adding the criterion from section 522(a)(1)(A)(ii) of the FD&C Act (21 U.S.C. 360l(a)(1)(A)(ii)) to these provisions for consistency with the statutory language. Similarly, we are amending § 822.24 for consistency with section 522(b)(1) of the FD&C Act. We are amending § 822.7(a)(1) by removing the name of an office that is now obsolete due to CDRH's reorganization. The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action under the Administrative Procedure Act (APA) (5 U.S.C. 553). The APA generally exempts ''rules of agency organization, procedure, or practice'' from the requirements of notice and comment rulemaking (5 U.S.C. 553(b)(A)). Rules are also generally exempt from such requirements when an agency ''for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(B)).

FDA has determined that this rulemaking meets the APA's notice and comment exemption requirements. The revisions in this rule make technical or non-substantive changes. Some of these revisions pertain to the CDRH reorganization, and constitute ''rules of agency organization, procedure, or practice'' not subject to the requirements of notice and comment under 5 U.S.C. 553(b)(A). The balance of these revisions updates the omitted language from the statute or the citation and docket number. Such technical, non-substantive changes are ''a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'' *Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012) (quotation marks and citation omitted). FDA accordingly for good cause finds that notice and public procedure thereon are unnecessary for these amendments.

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)). An effective date 30 or more days from the date of publication is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties, and affected parties do not need time to ''adjust to the new regulation'' before the rule takes effect. *Am. Federation of Government Emp., AFL–CIO* v. *Block,* 655 F.2d 1153, 1156 (D.C. Cir. 1981). 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 10

Administrative practice and procedure, News media.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 822

Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 10, 803, 812, and 822 are amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

■ 1. The authority citations for part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

■ 2. In § 10.80:

■ a. Remove the headings from paragraphs (b) and (d); and

■ b. Revise paragraph (h).

The revision reads as follows:

§ 10.80 Dissemination of draft Federal Register notices and regulations.

* * * * *

(h) In accordance with section 534 of the Federal Food, Drug, and Cosmetic Act, the Commissioner shall consult with interested persons and with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) before prescribing any performance standard for an electronic product. Accordingly, the Commissioner shall publish in the **Federal Register** an announcement when a proposed or final performance standard, including any amendment, is being considered for an electronic product, and any draft of any proposed or final standard will be furnished to an interested person upon request and may be discussed in detail.

* * * * *

PART 803—MEDICAL DEVICE REPORTING

■ 3. The authority citation for part 803 continues to read as follows:

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

■ 4. In § 803.19, revise paragraph (b) to read as follows:

§ 803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

* * * * *

(b) If you are a manufacturer, importer, or user facility, you may request an exemption or variance from any or all of the reporting requirements in this part, including the requirements of § 803.12. You must submit the request to the Center for Devices and Radiological Health (CDRH) in writing at *MDRPolicy@fda.hhs.gov*. Your request must include information necessary to identify you and the device; a complete statement of the request for exemption, variance, or alternative reporting; and an explanation why your request is justified. If you are requesting an exemption from the requirement to submit reports to FDA in electronic format under § 803.12(a), your request should indicate for how long you will require this exemption.

* * * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 5. The authority citation for part 812 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360bbb–8b, 371, 372, 374, 379e, 379k–1, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 6. In § 812.38, revise paragraph (b)(4) to read as follows:

§ 812.38 Confidentiality of data and information.

* * * * *

(b) * * *

(4) Notwithstanding paragraph (b)(2) of this section, FDA will make available to the public, upon request, the information in the IDE that was required to be filed in Docket Number FDA–1995–S–0036 in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, for investigations involving an exception from informed consent under § 50.24 of this chapter. Persons wishing to request this information shall submit a request under the Freedom of Information Act.

* * * * *

■ 7. In § 812.47, revise paragraph (a) to read as follows:

§ 812.47 Emergency research under § 50.24 of this chapter.

(a) The sponsor shall monitor the progress of all investigations involving an exception from informed consent under § 50.24 of this chapter. When the sponsor receives from the IRB information concerning the public disclosures under § 50.24(a)(7)(ii) and (iii) of this chapter, the sponsor shall promptly submit to the IDE file and to Docket Number FDA–1995–S–0036 in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, copies of the information that was disclosed, identified by the IDE number.

* * * * *

PART 822—POSTMARKET SURVEILLANCE

■ 8. The authority citation for part 822 continues to read as follows:

Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

■ 9. In § 822.1, revise the introductory text and paragraphs (b) and (c) and add paragraph (d) to read as follows:

§ 822.1 What does this part cover?

This part implements section 522 of the Federal Food, Drug, and Cosmetic Act by providing procedures and requirements for postmarket surveillance of class II and class III devices that meet any of the following criteria:

* * * * *

(b) The device is intended to be implanted in the human body for more than 1 year;

(c) The device is intended to be used outside a user facility to support or sustain life. If you fail to comply with requirements that we order under section 522 of the Federal Food, Drug, and Cosmetic Act and this part, your device is considered misbranded under section 502(t)(3) of the Federal Food, Drug, and Cosmetic Act and you are in violation of section 301(q)(1)(C) of the Federal Food, Drug, and Cosmetic Act; or

(d) The device is expected to have significant use in pediatric populations.

■ 10. In § 822.4, revise the introductory text and paragraphs (b) and (c) and add paragraph (d) to read as follows:

§ 822.4 Does this part apply to me?

If we have ordered you to conduct postmarket surveillance of a medical device under section 522 of the Federal Food, Drug, and Cosmetic Act, this part applies to you. We have the authority to order postmarket surveillance of any class II or class III medical device, including a device reviewed under the licensing provisions of section 351 of the Public Health Service Act, that meets any of the following criteria:

* * * * *

(b) The device is intended to be implanted in the human body for more than 1 year;

(c) The device is intended to be used to support or sustain life and to be used outside a user facility; or

(d) The device is expected to have significant use in pediatric populations.

■ 11. In § 822.7, revise paragraph (a)(1) to read as follows:

§ 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

(a) * * *

(1) Requesting a meeting with the Director of the Office that issued the order for postmarket surveillance;

* * * * *

■ 12. Revise § 822.24 to read as follows:

§ 822.24 What are my responsibilities once I am notified that I am required to conduct postmarket surveillance?

You must submit your plan to conduct postmarket surveillance to us within 30 days from receipt of the order (letter) notifying you that you are required to conduct postmarket surveillance of a device. The manufacturer shall commence surveillance not later than 15 months after the day the order was issued.

Dated: March 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05657 Filed 3–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

Maine State Plan for State and Local Government Employees; Approval of Plan Supplements and Certification of Completion of Developmental Steps

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notification of certification of the State Plan.

SUMMARY: The Maine Department of Labor, Bureau of Labor Standards submitted documentation attesting to the completion of all structural and developmental aspects of its State Plan for State and Local Government Employees as approved by OSHA. After extensive review of the submissions and opportunity for correction, the Maine State Plan (MEOSH) submitted updated and revised documents. OSHA is approving the revised State Plan, which documents the satisfactory completion of all structural and developmental aspects of Maine's approved State Plan, and is certifying this completion. This certification attests to the fact that the Maine State Plan now has in place those structural components necessary for an effective State Plan for State and Local Government Employees. (Enforcement of occupational safety and health standards with regard to private sector employers and employees in the State of Maine remains the responsibility of the U.S. Department of Labor, OSHA.)

DATES: Effective March 21, 2023.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Contact Frank Meilinger, OSHA Office of Communications, U.S. Department of Labor; telephone (202) 693–1999; email *meilinger.francis2@dol.gov.*

For general and technical information: Contact Douglas J. Kalinowski, Director, OSHA Directorate of Cooperative and State Programs, U.S. Department of Labor; telephone (202) 693–2200; email: *kalinowski.doug@dol.gov.*