4164-01-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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 statue 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.

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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.

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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.

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