

(c) To ensure PMAs include readily available information concerning actual and potential pediatric uses of medical devices.

■ 4. In § 814.20, revise paragraph (b)(3)(i) to read as follows:

§ 814.20 Application.

* * * * *

(b) * * *

(3) * * *

(i) *Indications for use.* (A) A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

(B) Information concerning uses in pediatric patients who are 21 years of age or younger: The application must include the following information, if readily available:

(1) A description of any pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(2) The number of affected pediatric patients.

* * * * *

■ 5. In § 814.37, revise the section heading and paragraph (b) to read as follows:

§ 814.37 PMA amendments and resubmitted PMAs.

* * * * *

(b)(1) FDA may request the applicant to amend a PMA or PMA supplement with any information regarding the device that is necessary for FDA or the appropriate advisory committee to complete the review of the PMA or PMA supplement.

(2) FDA may request the applicant to amend a PMA or PMA supplement with information concerning pediatric uses as required under § 814.20(b)(3)(i).

* * * * *

■ 6. In § 814.39, add paragraph (h) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(h) The application must include the following information, if readily available:

(1) A description of any pediatric subpopulations (neonates, infants, children, adolescents) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and

(2) The number of affected pediatric patients who are 21 years of age or younger.

(3) If information concerning the device that is the subject of the

supplement was previously submitted under § 814.20(b)(3)(i), that information may be incorporated by reference to the application or submission that contains the information. However, if additional information required under § 814.20(b)(3)(i) has become readily available to the applicant since the previous submission, the applicant must submit that information as part of the supplement.

■ 7. In § 814.44, redesignate paragraphs (e)(1)(ii) through (e)(1)(iv) as paragraphs (e)(1)(iii) through (e)(1)(v), respectively, and add new paragraph (e)(1)(ii) to read as follows:

§ 814.44 Procedures for review of a PMA.

* * * * *

(e) * * *

(1) * * *

(ii) The submission of additional information concerning potential pediatric uses required by § 814.20(b)(3)(i) that is readily available to the applicant;

* * * * *

■ 8. Amend § 814.100 as follows:

■ a. Redesignate paragraphs (b) through (e) as paragraphs (d) through (g), respectively;

■ b. Redesignate paragraph (a) as paragraph (b), and remove the first sentence of newly redesignated paragraph (b); and

■ c. Add new paragraphs (a) and (c) to read as follows:

§ 814.100 Purpose and scope.

(a) This subpart H implements sections 515A and 520(m) of the act.

* * * * *

(c) Section 515A of the act is intended to ensure the submission of readily available information concerning actual and potential pediatric uses of medical devices.

* * * * *

■ 9. Amend § 814.104 as follows:

■ a. Revise the last sentence of paragraph (b)(4)(ii);

■ b. Revise the last sentence of paragraph (b)(5); and

■ c. Add paragraph (b)(6) to read as follows:

§ 814.104 Original applications.

* * * * *

(b) * * *

(4) * * *

(ii) * * * The effectiveness of this device for this use has not been demonstrated.

(5) * * * If the amount charged is \$250 or less, the requirement for a report by an independent certified public accountant or an attestation by a responsible individual of the organization is waived; and

(6) Readily available information concerning actual and potential pediatric uses of the device, as required by § 814.20(b)(3)(i).

* * * * *

■ 10. In § 814.116, redesignate paragraphs (c)(2) through (c)(4) as paragraphs (c)(3) through (c)(5), respectively, and add new paragraph (c)(2) to read as follows:

§ 814.116 Procedures for review of an HDE.

* * * * *

(c) * * *

(2) The submission of additional information concerning potential pediatric uses required by § 814.20(b)(3)(i) that is readily available to the applicant;

* * * * *

Dated: March 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-7193 Filed 3-31-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1002, 1003, 1004, 1005, 1010, 1020, 1030, 1040, and 1050

[Docket No. FDA-2010-N-0010]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending certain medical device regulations to correct statutory and regulatory references to ensure accuracy, consistency, and clarity in the agency's regulations.

DATES: This rule is effective April 1, 2010.

FOR FURTHER INFORMATION CONTACT:

Bernice E. Noland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4430, Silver Spring, MD 20993-0002, 301-796-5742.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations at part 1002 (21 CFR part 1002) to correct a regulatory reference. FDA is revising § 1002.30(b) by deleting "paragraph (c) of § 1002.61" and replacing it with "table 1 of § 1002.1." FDA updated

§ 1002.30(a) to reflect this change, but inadvertently retained the reference to “paragraph (c) of § 1002.61” in § 1002.30(b). With this technical amendment, the entirety of the regulation at § 1002.30 accurately references “table 1 of § 1002.1,” which is the former paragraph (c) of § 1002.61.

In addition, FDA is amending its regulations at part 1002 and parts 1005 and 1010 (21 CFR parts 1005 and 1010) to correct statutory references. These parts intermittently cite sections of the Radiation Control for Health and Safety Act of 1968 (Radiation Control Act) (Public Law 90–602). However, “Act” is defined in 21 CFR 1000.3(b), and applicable throughout 21 CFR parts 1000 to 1050, subchapter J, to mean the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 360hh–360ss). The Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), transferred the Radiation Control Act to the FFDCA. With these technical amendments, FDA is replacing citations to the Radiation Control Act with citations to the corresponding sections of the FFDCA. FDA is revising §§ 1002.41(a)(1) and 1002.42 by replacing section “359” of the act with section “535.” FDA is revising § 1005.25(c) by replacing section “360(d)” of the act with section “536(d).” FDA is revising § 1010.4(c)(3) by replacing section “360A(e)” of the act with section “537(e).”

Finally, FDA is amending its authority citations in parts 1003, 1004, 1005, 1010, 1020, 1030, 1040, and 1050 to correct statutory citations. These parts cite to the Public Health Service Act, which codified the Radiation Control Act at 42 U.S.C. 263b–263n, until the SMDA transferred the Radiation Control Act to the FFDCA. Section 19(a)(3) of the SMDA also repealed section 354 of the Radiation Control Act, codified at 42 U.S.C. 263b, which contained Congress’s declaration of purpose in enacting the program of electronic product radiation controls. The SMDA redesignated and transferred the remaining sections to the FFDCA at 21 U.S.C. 360hh–360ss. The authority citations in parts 1003, 1004, 1005, 1010, 1020, 1030, 1040, and 1050 to 42 U.S.C. 263b–263n were not correspondingly updated to reflect the transfer of the Radiation Control Act from the Public Health Service Act to the FFDCA. With these technical amendments, FDA is replacing citations to the Public Health Service Act with citations to the corresponding sections of the FFDCA. Thus, FDA is revising parts 1003, 1004, 1010, 1030, 1040, and 1050 by replacing the authority citation of “42 U.S.C. 263b–263n” with “21

U.S.C. 360hh–360ss.” FDA is similarly revising part 1005 by replacing the authority citation of “42 U.S.C. 263d, 263h” with “21 U.S.C. 360ii, 360mm.” FDA is also revising part 1020 by deleting the authority citation to 21 U.S.C. 360gg. Although section 354 of the Radiation Control Act would have been designated as 21 U.S.C. 360gg had the provision been transferred to the FFDCA, the SMDA repealed that section. As a result, the citation to 21 U.S.C. 360gg in part 1020 is an inadvertent error that this technical amendment will correct by deleting that part of the authority citation.

Publication of this document constitutes final action on the change under the Administrative Procedure Act (5 U.S.C. 553). These technical amendments correct regulatory and statutory references in the Code of Federal Regulations. FDA therefore, for good cause, has determined that notice and public comment are unnecessary, under 5 U.S.C. 553(b)(3)(B). Further, this rule places no burden on affected parties for which such parties would need a reasonable time to prepare for the effective date of the rule. Accordingly, FDA, for good cause, had determined this technical amendment to be exempt under 5 U.S.C. 553(d)(3) from the 30-day effective date from publication.

FDA has determined under 21 CFR 25.30(i) that this final rule 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. In addition, FDA has determined that this final rule contains no collections of information. Therefore, clearance by the Office Management and Budget under the Paperwork Reduction Act of 1995 is not required.

For the effective date of this final rule, see the **DATES** section of this document.

List of Subjects

21 CFR Part 1002

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

21 CFR Part 1003

Administrative practice and procedure, Electronic products, Radiation protection.

21 CFR Part 1004

Electronic products, Radiation protection.

21 CFR Part 1005

Administrative practice and procedure, Electronic products, Imports, Radiation protection, Surety bonds.

21 CFR Part 1010

Administrative practice and procedure, Electronic products, Exports, Radiation protection.

21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

21 CFR Part 1030

Electronic products, Microwave ovens, Radiation protection.

21 CFR Part 1040

Electronic products, Labeling, Lasers, Medical devices, Radiation protection, Reporting and recordkeeping requirements.

21 CFR Part 1050

Electronic products, Medical devices, Radiation protection.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter I is amended as follows:

PART 1002—RECORDS AND REPORTS

■ 1. The authority citation for 21 CFR part 1002 continues to read as follows:

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

■ 2. In § 1002.30, paragraph (b) introductory text is revised to read as follows:

§ 1002.30 Records to be maintained by manufacturers.

* * * * *

(b) In addition to the records required by paragraph (a) of this section, manufacturers of products listed in table 1 of § 1002.1 shall establish and maintain the following records with respect to such products:

* * * * *

■ 3. In 1002.41, paragraph (a)(1) is revised to read as follows:

§ 1002.41 Disposition of records obtained by dealers and distributors.

(a) * * *

(1) The dealer or distributor elects to hold and preserve such information and to immediately furnish it to the manufacturer when advised by the manufacturer or the Director, Center for Devices and Radiological Health, that

such information is required for purposes of section 535 of the Act; and

* * * * *

- 4. Section 1002.42 is revised to read as follows:

§ 1002.42 Confidentiality of records furnished by dealers and distributors.

All information furnished to manufacturers by dealers and distributors pursuant to this part shall be treated by such manufacturers as confidential information which may be used only as necessary to notify persons pursuant to section 535 of the Act.

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

- 5. The authority citation for 21 CFR part 1003 is revised to read as follows:

Authority: 21 U.S.C. 360hh–360ss.

PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS

- 6. The authority citation for 21 CFR part 1004 is revised to read as follows:

Authority: 21 U.S.C. 360hh–360ss.

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

- 7. The authority citation for 21 CFR part 1005 is revised to read as follows:

Authority: 21 U.S.C. 360ii, 360mm.

- 8. In 1005.25, paragraph (c) is revised to read as follows:

§ 1005.25 Service of process on manufacturers.

* * * * *

(c) Service of any process, notice, order, requirement, or decision specified in section 536(d) of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) (21 U.S.C. 360mm(d)) may be made by registered or certified mail addressed to the agent with return receipt requested, or in any other manner authorized by law. In the absence of such a designation or if for any reason service on the designated agent cannot be effected, service may be made as provided in section 536(d) by posting such process, notice, order, requirement, or decision in the Office of the Director, Center for Devices and Radiological Health and publishing a notice that such service was made in the **Federal Register**.

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

- 9. The authority citation for 21 CFR part 1010 is revised to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381.

- 10. In 1010.4, paragraph (c)(3) is revised to read as follows:

§ 1010.4 Variances.

* * * * *

(c) * * *

(3) All applications for variances and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications will be available for public disclosure in the office of the Division of Dockets Management, except for information regarded as confidential under section 537(e) of the act.

* * * * *

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

- 11. The authority citation for 21 CFR part 1020 is revised to read as follows:

Authority: 21 U.S.C. 351, 352, 360e–360j, 360hh–360ss, 371, 381.

PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

- 12. The authority citation for 21 CFR part 1030 is revised to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381.

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

- 13. The authority citation for 21 CFR part 1040 is revised to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381.

PART 1050—PERFORMANCE STANDARDS FOR SONIC, INFRASONIC, AND ULTRASONIC RADIATION-EMITTING PRODUCTS

- 14. The authority citation for 21 CFR part 1050 is revised to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 360hh–360ss, 371, 381.

Dated: March 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-7288 Filed 3-31-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2010-N-0148]

Revision of Organization and Conforming Changes to Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to amend the regulations to reflect organization change in the agency and to make other conforming changes. 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, 2010.

FOR FURTHER INFORMATION CONTACT: Vanessa Starks, Office of Management Programs (HFA-410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4654; or Sharon Burgess, Division of Human Capital Management (HFA-410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2065.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this final rule to amend its regulations by updating the organizational information in part 5 (21 CFR part 5).

The agency has updated the references to part 5, subpart M.

The portion of this final rule updating the organizational information in part 5, subpart M is a rule of agency organization, procedure, or practice. FDA is issuing these provisions as a final rule without publishing a general notice of proposed rulemaking because such notice is not required for rules of agency organization, procedure, or practice under 5 U.S.C. 553(b)(3)(A). For the conforming changes to the other regulations, the agency finds good cause under 5 U.S.C. 553(b)(3)(B) to dispense with prior notice and comment, and good cause under 5 U.S.C. 553(d)(3) to make these conforming changes effective less than 30 days after publication because such notice and comment and delayed effective date are unnecessary and contrary to the public interest. These conforming changes merely update the footnotes in part 5, subpart M. These changes do not result