21 CFR Part 897

Advertising, Cigarettes, Labeling, Sale and distribution, Smokeless tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801, 803, 807, and 820 are amended and part 897 is removed as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

§ 801.126 [Removed]

2. Remove § 801.126.

PART 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR part 803 continues to read as follows:

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

4. Amend § 803.19 by removing paragraphs (f) and (g).

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL DISTRIBUTORS OF DEVICES

5. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360e, 360c, 360i, 360j, 371, 374.

6. Amend § 807.65 by removing paragraph (j).

PART 820—QUALITY SYSTEM REGULATION

7. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: 351, 352, 360, 360c, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

8. Amend § 820.1 by removing paragraphs (e) and (f).

PART 897—[REMOVED]

9. Remove part 897.

Dated: March 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7960 Filed 3–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803, 807, 812, 814, 860, 1005, 1010, 1020, and 1040

[Docket No. 00N–0784]

Medical Devices; Information Processing Procedures; Obtaining, Submitting, Executing, and Filing of Forms: Change of Addresses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending procedural regulations that pertain to obtaining, submitting, executing, and filing certain documents to reflect new addresses in the agency. All filings and other documents subject to these regulations must be directed to the new address. This action is being taken to ensure the accuracy of FDA's regulations.

DATES: This rule is effective March 31, 2000.

FOR FURTHER INFORMATION CONTACT: Domini H. Cassis, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2964.

SUPPLEMENTARY INFORMATION: This rule reflects the relocation of certain component offices within the agency that are responsible for processing documents relating to medical devices. This administrative action is limited to changing specific addresses for obtaining, submitting, executing, and filing certain documents, but it makes no other changes in filing requirements.

This document is published as a final rule with the effective date shown above. Because the final rule is an administrative action to update addresses for certain agency offices, FDA has determined that it has no substantive impact on the public. It imposes no costs, and merely updates a list of addresses included in the Code of Federal Regulations (CFR) for the convenience of the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary and that this rule may take effect upon publication.

List of Subjects

21 CFR Part 803

Imports, Medical devices, Recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

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

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

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 1040

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

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 803, 807, 812, 814, 860, 1005, 1010, 1020, and 1040 are amended as follows:

PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for 21 CFR part 803 continues to read as follows:

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

2. Section 803.11 is revised to read as follows:

§ 803.11 Obtaining the forms.

User facilities and manufacturers must submit all reports of individual adverse events on FDA Form 3500A (MEDWATCH form) or in an electronic equivalent as approved under § 803.14. This form and all other forms referenced in this section can also be obtained from the Consolidated Forms and Publications Office, Washington

Commerce Center, 3222 Hubbard Rd., Landover, MD 20875; from the Food and Drug Administration, MEDWATCH (HF–2), 5600 Fishers Lane, Rockville, MD 20857, 301–827–7240; from the Division of Small Manufacturers Assistance, Office of Health and Industry Programs, Center for Devices and Radiological Health (HFZ–220), 1350 Piccard Dr. Rockville, MD 20850, FAX 301–443–8818; or from http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html on the Internet.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

3. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

4. Section 807.90 is amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

§ 807.90 Format of a premarket notification submission.

* * * * *

(a)(1) For devices regulated by the Center for Devices and Radiological Health, be addressed to the Food and Drug Administration, Center for Devices and Radiological Health (HFZ–401), 9200 Corporate Blvd., Rockville, MD 20850.

(2) For devices regulated by the Center for Biologics Evaluation and Research, be addressed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Room (HFM–99), 1401 Rockville Pike, Rockville, MD 20852–1448. Information about devices regulated by the Center for Biologics Evaluation and Research is available at http://www.fda.gov/cber/dap/devlst.htm on the Internet.

* * * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

5. The authority citation for 21 CFR part 812 continues to read as follows:

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

6. Section 812.19 is revised to read as follows:

§ 812.19 Address for IDE correspondence.

If you are sending an application, supplemental application, report, request for waiver, request for import or export approval, or other correspondence relating to matters covered by this part, you must address it to the Center for Devices and Radiological Health, Document Mail Center (HFZ–401), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850. You must state on the outside wrapper of each submission what the submission is, for example, an ''IDE application,'' a ''supplemental IDE application,'' or a ''correspondence concerning an IDE (or an IDE application).''

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

7. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

8. Section 814.20 is amended by revising paragraphs (g) and (h) to read as follows:

§ 814.20 Application.

* * * * *

(g) FDA has issued a PMA guideline to assist the applicant in the arrangement and content of a PMA. This guideline is available upon request from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr. Rockville, MD 20850, FAX 301–443–8818.

(h) If you are sending a PMA, PMA amendment, PMA supplement, or correspondence with respect to a PMA, you must send it to the Document Mail Center (HFZ–401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

9. The authority citation for 21 CFR part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

10. Section 860.123 is amended by revising paragraph (b)(1) to read as follows:

§ 860.123 Reclassification petition: Content and form.

* * * * *

(b) * * *

(1) Addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Regulations Staff (HFZ–215), 1350 Piccard Dr., Rockville, MD 20850;

* * * * *

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

11. The authority citation for 21 CFR part 1005 continues to read as follows:

Authority: 42 U.S.C. 263d, 263h.

12. Section 1005.25 is amended by revising paragraph (b) to read as follows:

§ 1005.25 Service of process on manufacturers.

* * * * *

(b) A manufacturer designating an agent must address the designation to the Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850. It must be in writing and dated; all signatures must be in ink. The designation must be made in the legal form required to make it valid and binding on the manufacturer under the laws, corporate bylaws, or other requirements governing the making of the designation by the manufacturer at the place and time where it is made, and the persons or person signing the designation shall certify that it is so made. The designation must disclose the manufacturer's full legal name and the name(s) under which the manufacturer conducts the business, if applicable, the principal place of business, and mailing address. If any of the products of the manufacturer do not bear his legal name, the designation must identify the marks, trade names, or other designations of origin which these products bear. The designation must provide that it will remain in effect until withdrawn or replaced by the manufacturer and shall bear a declaration of acceptance duly signed by the designated agent. The full legal name and mailing address of the agent must be stated. Until rejected by the Secretary, designations are binding on the manufacturer even when not in compliance with all the requirements of this section. The designated agent may not assign performance of his function under the designation to another.

* * * * *

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

13. The authority citation for 21 CFR part 1010 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 371, 381; 42 U.S.C. 263b–263n.

14. Section 1010.4 is amended by revising paragraph (b) to read as follows:

§ 1010.4 Variances.

* * * * *

(b) *Applications for variances.* If you are submitting an application for variances or for amendments or

extensions thereof, you must submit an original and two copies to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

* * * * *

15. Section 1010.5 is amended by revising paragraph (c) to read as follows:

§ 1010.5 Exemptions for products intended for United States Government use.

* * * * *

(c) *Application for exemption.* If you are submitting an application for exemption, or for amendment or extension thereof, you must submit an original and two copies to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For an exemption under the criteria prescribed in paragraph (a)(1) of this section, the application shall include the information prescribed in paragraphs (c)(1) through (c)(13) of this section. For an exemption under the criteria prescribed in paragraph (a)(2) of this section, the application shall include the information prescribed in paragraphs (c)(3) through (c)(13) of this section. An application for exemption, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure in the Dockets Management Branch, except for confidential or proprietary information submitted in accordance with part 20 of this chapter. Information classified for reasons of national security shall not be included in the application. Except as indicated in this paragraph, the application for exemption shall include the following:

* * * * *

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

16. The authority citation for 21 CFR part 1020 continues to read as follows:

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

17. Section 1020.30 is amended by revising paragraph (d)(1) to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

* * * * *

(d) * * *

(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§ 1020.30 through 1020.33. All assembler reports must be on a form prescribed by and available from the Director, Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

* * * * *

PART 1040—PERFORMANCE STANDARDS FOR LIGHT–EMITTING PRODUCTS

18. The authority citation for 21 CFR part 1040 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e–360j, 371, 381; 42 U.S.C. 263b–263n.

19. Section 1040.10 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 1040.10 Laser products.

(a) * * *

(3) * * *

(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number, and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Director, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, 2094 Gaither Rd., Rockville, MD 20850.

* * * * *

Dated: March 22, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–8038 Filed 3–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864, 866, 870, 872, 874, 876, 878, 884, 886, and 888

[Docket No. 99N–0035]

Medical Devices; Reclassification of 28 Preamendments Class III Devices into Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying 28 preamendments devices from class III (premarket approval) into class II (special controls). FDA is also identifying the special controls that the agency believes will reasonably ensure the safety and effectiveness of the devices. This reclassification is being undertaken on the agency's own initiative based on new information under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 and the FDA Modernization Act of 1997. The agency is also revising the identification of six of the devices subject to this rule to more accurately reflect the characteristics of devices actually being marketed. FDA is withholding action on 11 devices, which the agency proposed to reclassify, pending further action.

DATES: This rule is effective May 1, 2000.

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices. FDA invited interested persons to comment on the proposed rule by June 14, 1999.

FDA received one request to reopen the comment period for six devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through FDA's Good Guidance Practices (GGP's). The request further said that it was impossible to comment on the