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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16, 610, 640, 812, 814, 822, and 860

Display Date

8-22-08

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8-25-08

Certifier

A. Corbin

[Docket No. FDA-2008-N-0423]

FDA Regulations; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a regulatory hearing process regulation to correct an inaccurate citation, and regulations pertaining to biological products to correct two typographical errors. FDA is also amending certain medical device regulations to include references to and mailing address information for the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH). This action is being taken to ensure the accuracy of FDA's regulations.

DATES: This rule is effective [*Insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Denise Sánchez, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is amending 21 CFR 16.1 to correct an inaccurate citation and is amending 21 CFR 610.51 and 21 CFR 640.53 to correct typographical errors.

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FDA is also amending its medical device regulations in 21 CFR 812, 814, and 860 to include references to and mailing addresses for CBER and CDER, and 21 CFR 822.8 to correct an inadvertent omission of the mailing address for CDRH. Submissions regarding a medical device must be sent to the address of the appropriate center that has regulatory responsibility for the medical device. Therefore, FDA is updating these regulations to include address information for all appropriate centers.

Publication of this document constitutes final action under the Administrative Procedures Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to correct an inaccurate citation and typographical errors, and to update mailing addresses and other information, and is nonsubstantive.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 640

Blood, Labeling, 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 822

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16, 610, 640, 812, 814, 822, and 860 are amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

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

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

§ 16.1 [Amended]

■ 2. Section 16.1 is amended in paragraph (b)(2), by removing “§ 1270.15(e)” and adding in its place “§ 1270.43(e)”.

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

■ 3. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 610.53 [Amended]

- 4. Section 610.53 is amended in paragraph (c) in the table, under column A, by removing the words “Cryoprecipitated AFH” and adding in their place “Cryoprecipitated AHF.”

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

- 5. The authority citation for 21 CFR part 640 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

§ 640.51 [Amended]

- 6. Section 640.51 is amended in paragraph (b) by removing the word “Plasmaphersis” and adding in its place “Plasmapheresis.”

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

- 7. 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.

- 8. Section 812.20 is amended by revising paragraph (d) to read as follows:

§ 812.20 Application.

* * * * *

(d) *Information previously submitted.* Information previously submitted to the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, or the Center for Drug Evaluation and Research, as applicable, in accordance with this chapter ordinarily need not be resubmitted, but may be incorporated by reference.

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 9. 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.

■ 10. Section 814.42 is amended by revising the fourth sentence of paragraph (d)(2) to read as follows:

§ 814.42 Filing a PMA.

* * * * *

(d) * * *

(2) * * * If FDA does not reverse its decision not to file the PMA, the applicant may request reconsideration of the decision from the Director of the Center for Devices and Radiological Health, the Director of the Center for Biologics Evaluation and Research, or the Director of the Center for Drug Evaluation and Research, as applicable. * * *

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■ 11. Section 814.100 is amended by revising paragraph (c)(2) to read as follows:

§ 814.100 Purpose and scope.

* * * * *

(c) * * *

(2) Submitting an HDE to the Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), or the Center for Drug Evaluation and Research (CDER), as applicable.

* * * * *

■ 12. Section 814.104 is amended by revising paragraph (d) to read as follows:

§ 814.104 Original applications.

* * * * *

(d) *Address for submissions and correspondence.* Copies of all original HDEs amendments and supplements, as well as any correspondence relating to an HDE, must be sent or delivered to the following:

(1) For devices regulated by the Center for Devices and Radiological Health, send this information to the Document Mail Center (HFZ-401), Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

(2) For devices regulated by the Center for Biologics Evaluation and Research, send this information to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

(3) For devices regulated by the Center for Drug Evaluation and Research, send this information to the Central Document Control Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266.

PART 822—POSTMARKET SURVEILLANCE

■ 13. The authority citation for 21 CFR part 822 continues to read as follows:

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

■ 14. Section 822.8 is amended by adding a sentence after the first sentence to read as follows:

§ 822.8 When, where, and how must I submit my postmarket surveillance plan?

* * * For devices regulated by the Center for Devices and Radiological Health, send three copies of your submission to the Postmarket Surveillance

Document Center (HFZ-541), Epidemiology Branch, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. * * *

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

- 15. 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.

- 16. Section 860.7 is amended by revising paragraph (g)(4) to read as follows:

§ 860.7 Determination of safety and effectiveness.

* * * * *

(g) * * *

(4) Required information that has been submitted previously to the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, or the Center for Drug Evaluation and Research, as applicable, need not be resubmitted, but may be incorporated by reference.

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

§ 860.123 Reclassification petition: Content and form.

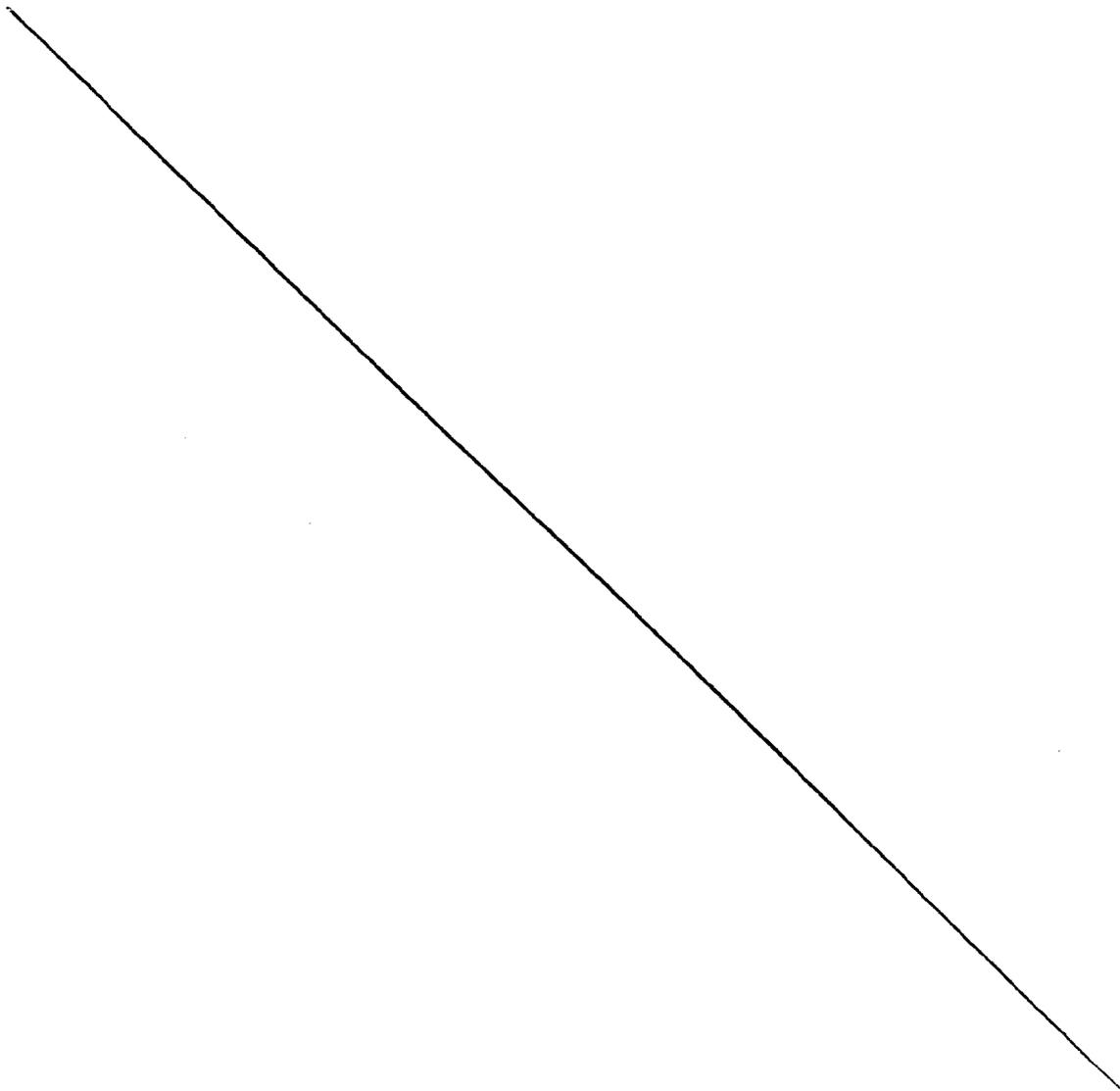
* * * * *

(b) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Regulations Staff (HFZ-215), 1350 Piccard Dr., Rockville, MD 20857; for devices regulated by the Center for Biologics Evaluation and Research, addressed to the Document Control Center (HFM-99), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448;

for devices regulated by the Center for Drug Evaluation and Research,
addressed to the Central Document Control Room, Center for Drug Evaluation
and Research, Food and Drug Administration, 5901-B Ammendale Rd.,
Beltsville, MD 20705-1266, as applicable.

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Dated: 8/18/08

August 18, 2008.

Jeffrey Shuren

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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[Signature]