**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 812 and 814**

**[Docket No. 2006N–0284]**

## Medical Device Regulations; Addresses; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending certain device regulations to include address information for the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research. These regulations pertain to the submission of certain documents to FDA. Currently, only address information for the Center for Devices and Radiological Health is listed in these regulations. This action is being taken to ensure the accuracy of FDA's regulations.

**DATES:** This rule is effective July 25, 2006.

**FOR FURTHER INFORMATION CONTACT:** Stephen M. Ripley, 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:** FDA is amending its regulations in 21 CFR parts 812 and 814 to include address information for the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research. These regulations pertain to the investigational device exemptions (IDEs) and premarket approval (PMA) of medical devices. Currently, only the address information for the Center for Devices and Radiological Health is listed in these regulations for the various submissions associated with IDE applications and PMA applications. IDEs and PMAs, and their associated submissions, must be sent to the address of the appropriate Center that has regulatory responsibility for the medical device. Therefore, FDA is updating its regulations to include this address information.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only a technical change to update addresses in the Code of Federal Regulations, and is nonsubstantive.

**List of Subjects**

*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, and Reporting and recordkeeping requirements.

■ 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 812 and 814 are amended as follows:

## PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 1. 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.

■ 2. Section 812.19 is revised to read as follows:

### § 812.19 Address for IDE correspondence.

(a) 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 send the submission to the appropriate address as follows:

(1) For devices regulated by the Center for Devices and Radiological Health, 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.

(2) For devices regulated by the Center for Biologics Evaluation and Research, send it 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 it to Central Document Control Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266.

(b) 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

■ 3. 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.

■ 4. Section 814.20 is amended by revising paragraph (h) to read as follows:

### § 814.20 Application.

* * * * *

(h) If you are sending a PMA, PMA amendment, PMA supplement, or correspondence with respect to a PMA, you must send the submission to the appropriate address as follows:

(1) For devices regulated by the Center for Devices and Radiological Health, send it to: Document Mail Center (HFZ–401), 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 it to: 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 it to: Central Document Control Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901–B Ammendale Rd., Beltsville, MD 20705–1266.

Dated: July 17, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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