

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 812

[Docket No. 2006N-0494]

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Certifier L. CLAWSON
DDM

**Medical Device Regulations; Disqualification of a Clinical Investigator;
Technical Amendment**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a medical device regulation to include references to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). This regulation pertains to the disqualification of a clinical investigator. Currently, only a reference to the Center for Devices and Radiological Health is listed in this regulation. 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: 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:

I. Background

FDA is amending 21 CFR 812.119(a) to include references to CBER and CDER. This regulation pertains to the disqualification of a clinical investigator. Currently, only a reference to the Center for Devices and Radiological Health

is listed in this regulation. The appropriate Center that has regulatory responsibility for the medical device subject to this regulation is responsible for corresponding with the investigator of the study concerning any possible violations of the applicable requirements. Therefore, FDA is updating this regulation to include the references to CBER and CDER.

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 references in the Code of Federal Regulations, and is nonsubstantive.

List of Subjects in 21 CFR Part 812

Health records, Medical devices, Medical research, 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 part 812 is amended as follows:

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

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

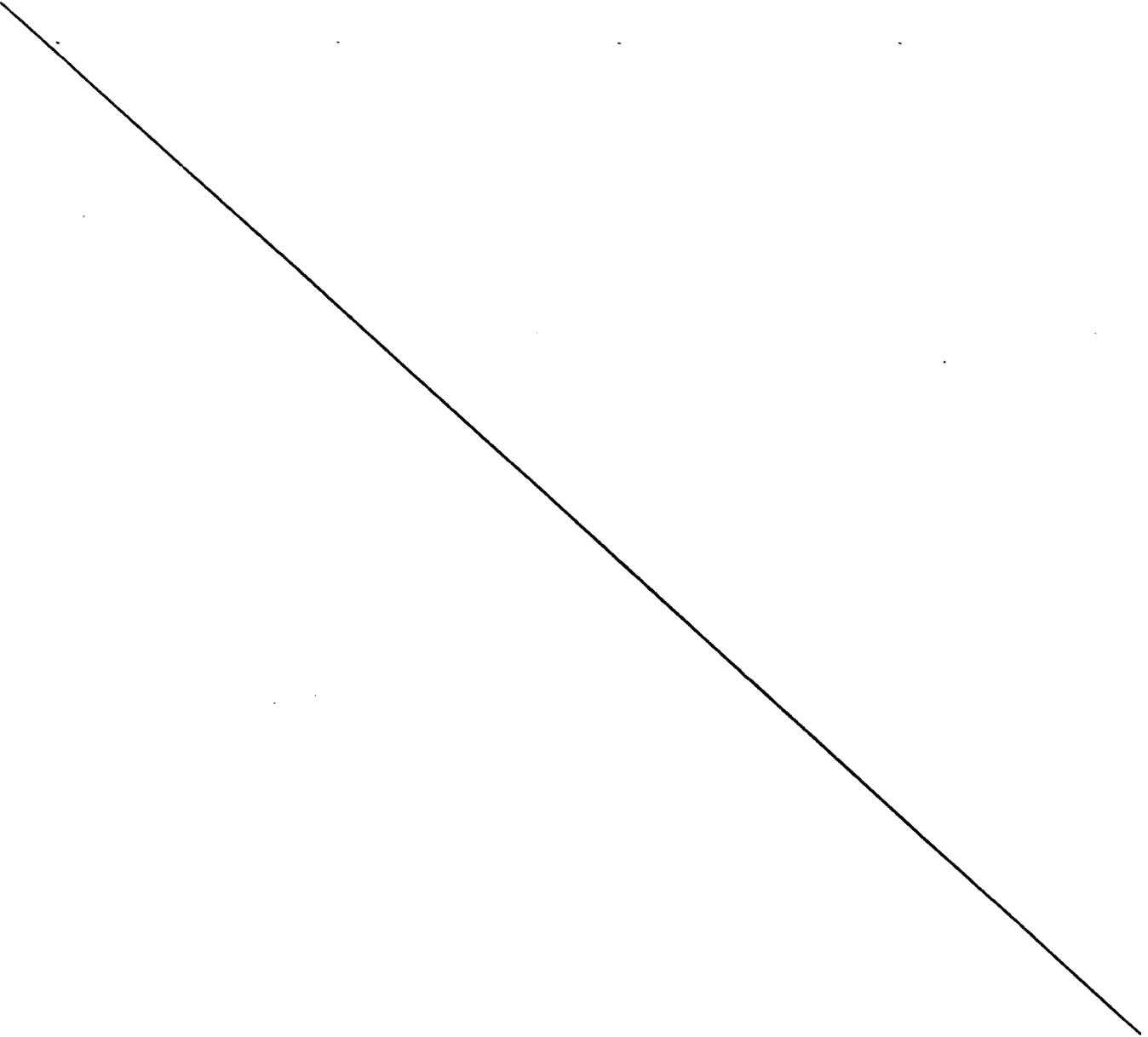
Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 2. Section 812.119 is amended by revising paragraph (a) to read as follows:

§ 812.119 Disqualification of a clinical investigator.

(a) If FDA has information indicating that an investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has repeatedly or deliberately submitted false

information either to the sponsor of the investigation or in any required report, the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, or the Center for Drug Evaluation and Research will furnish the investigator written notice of the matter under complaint and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the applicable Center, the disqualification process will be terminated. If an explanation is offered but not accepted by the Center, the investigator will be given an opportunity for a regulatory hearing under part



16 of this chapter on the question of whether the investigator is entitled to receive investigational devices.

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Dated: 12/12/06
December 12, 2006.



Jeffrey Shoren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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