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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0173]

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Certifier A. Corbin

Draft Guidance for Industry on Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory Responsibilities of Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory Responsibilities of Investigators.” This draft guidance is intended to assist investigators in meeting their responsibilities with respect to protecting human subjects and ensuring the integrity of data in the conduct of clinical investigations. The draft guidance also clarifies FDA’s expectations concerning the investigator’s responsibility for supervising a clinical study in which some study tasks are delegated to employees of the investigator or to outside parties.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Critical Path Programs (HF-18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

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Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Critical Path Programs (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7864.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory Responsibilities of Investigators.” Under the regulations in part 312 (21 CFR part 312) (Investigational New Drug Application) and part 812 (21 CFR part 812) (Investigational Device Exemptions), an investigator is responsible for ensuring that a clinical investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator’s care; and for the control of drugs, biological products, and devices under investigation (§§ 312.60 and 812.100). This draft guidance clarifies the responsibilities of investigators in the conduct of clinical investigations conducted under parts 312 and 812, particularly the responsibilities to supervise the conduct of the clinical investigation, and to protect the rights, safety, and welfare of study participants in drug, biologic, and medical device clinical trials. The draft guidance also provides recommendations on how

investigators should supervise the study-related actions of persons not in the direct employ of the investigator, including certain study staff and parties conducting associated testing and assessments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the supervisory responsibilities of investigators. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 312 have been approved under OMB Control No. 0910–0014; and the collections of information in part 812 have been approved under OMB Control No. 0910–0078.

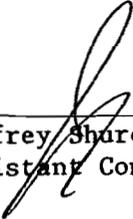
III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 5/2/07
May 2, 2007,



Jeffrey Shuren,
Assistant Commissioner for Policy.

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