

permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

There are no other changes to the meeting.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: May 7, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7-9053 Filed 5-9-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0440]

Guidance for Industry on Computerized Systems Used in Clinical Investigations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Computerized Systems Used in Clinical Investigations," dated May 2007. This document provides to sponsors, contract research organizations, data management centers, clinical investigators, and institutional review boards, recommendations regarding the use of computerized systems in clinical investigations. Because the source data in source documentation are necessary for the reconstruction and evaluation of the trial to determine the safety and effectiveness of new human and animal drugs, and medical devices, this guidance is intended to assist in ensuring confidence in the reliability, quality, and integrity of electronic source data and source documentation, i.e., electronic records. This guidance supersedes the guidance entitled "Computerized Systems Used in Clinical Trials," dated April 1999; finalizes the draft guidance of the same title dated September 2004; and supplements the guidance for industry entitled "Part 11, Electronic Records; Electronic Signatures—Scope and Application," dated August 2003, and FDA's international harmonization efforts when applying guidance to source data generated at clinical study sites.

DATES: Submit written or electronic comments on agency guidance at any time.

ADDRESSES: Submit written requests for single copies of this 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. Submit phone requests to 800-835-4709 or 301-827-1800. Submit written comments on the 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia M. Beers Block, Good Clinical Practice Program (HF-34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Computerized Systems Used in Clinical Investigations." This document provides to sponsors, contract research organizations, data management centers, clinical investigators, and institutional review boards, recommendations regarding the use of computerized systems in clinical investigations. There is an increasing use of computerized systems in clinical trials to generate and maintain source data and source documentation on each clinical trial subject. Such source data and source documentation must meet certain fundamental elements of data quality, e.g., attributable, legible, contemporaneous, original, and accurate, that are expected of paper records. FDA's acceptance of data from clinical trials for decisionmaking purposes depends on FDA's ability to verify the quality and integrity of the data during FDA onsite inspections and audits.

In the **Federal Register** of October 4, 2004 (69 FR 59239), FDA announced the availability of the draft guidance entitled "Computerized Systems Used in Clinical Trials," dated September 2004. FDA considered the comments submitted to the docket in revising this guidance. This guidance supersedes the guidance of the same title dated April 1999; finalizes the draft guidance dated September 2004; and supplements the

guidance for industry entitled "Part 11, Electronic Records; Electronic Signatures—Scope and Application," dated August 2003, and FDA's international harmonization efforts when applying guidance to source data generated at clinical study sites.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on computerized systems used in clinical investigations. 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 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 21 CFR part 11 have been approved under OMB Control No. 0910-0303. The collections of information in 21 CFR 312.62 have been approved under OMB Control No. 0910-0014. The collections of information in 21 CFR 511.1(b)(7)(ii) have been approved under OMB Control No. 0910-0117. The collections of information in 21 CFR 812.140 have been approved under OMB Control No. 0910-0078.

III. Comments

Interested persons may, at any time, 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/oc/gcp> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 4, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-9056 Filed 5-9-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0173]

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 July 9, 2007. 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. 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: May 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-9055 Filed 5-9-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Women’s Physical Activity and Healthy Eating Tools Assessment: NEW

The HRSA Office of Women’s Health (OWH) developed the Bright Futures for Women’s Health and Wellness (BFWHW) Initiative to help expand the scope of women’s preventive health activities, particularly related to nutrition and physical activity. An intermediate assessment of the BFWHW