

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0440]

Draft Guidance for Industry on Computerized Systems Used in Clinical Trials; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Computerized Systems Used in Clinical Trials.” This document provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA. This draft guidance, when finalized, will supercede the guidance of the same name issued in April 1999.

DATES: Submit written or electronic comments on the draft recommendations by *[insert date 90 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857; to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448; to the Office of Health and

Industry Programs, Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850-4307, Manufacturers Assistance: 800-638-2041 or 301-443-6597; or the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

Joseph Salewski, Center for Drug Evaluation and Research (HFD-45), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-0020; or

Patricia Holobaugh, Center for Biologics Evaluation and Research (HFM-664), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6347; or

John Murray, Jr., Center for Devices and Radiological Health (HFZ-340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4646, ext. 107; or

John Welsh, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 1110 Vermont Ave., NW, Washington, DC 20005, 202-418-3057; or

Vernon Toelle, Center for Veterinary Medicine (HFV-234), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20835, 301-827-0312;

or

James McCormack, Office of Enforcement (HFC-230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20857, 301-827-0425;

or

Patricia Beers Block, Good Clinical Practice Programs (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 draft guidance for industry entitled “Computerized Systems Used in Clinical Trials.” This document provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA. These data form the basis for the agency’s decisions regarding the safety and effectiveness of new human and animal drugs, biological products, medical devices, and certain food and color additives. As such, these data have broad public health significance and are expected to be of the highest quality and integrity.

This draft guidance, when finalized, will supercede the guidance of the same name issued in April 1999. This draft guidance is being revised to make it consistent with agency policy as reflected in the guidance for industry on “Part 11, Electronic Records; Electronic Signatures—Scope and Application,” which issued in August 2003. It also reflects policy consistent with regard to the agency’s international harmonization efforts.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This draft guidance, when

finalized, will represent the agency's current thinking on computerized systems used in clinical trials. 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 the approach satisfies the requirements of the applicable statute and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of any comments are to be submitted, 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, <http://www.fda.gov/cvm/guidance/guidance.html>, and <http://www.fda.gov/oc/gcp/draft.html>.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S