writing, on issues pending before the committee. Written submissions may be made to the contact person by July 3, 1997. Oral presentations from the public will be scheduled between approximately 12:45 p.m. and 1:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 3, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed committee deliberations: On July 10, 1997, from 11:45 a.m. to 12:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the research program.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 12, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–15989 Filed 6–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0228]

Draft Guidance for Industry: Computerized Systems Used in Clinical Trials; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials.'' The draft guidance document addresses issues pertaining to computer systems used to generate, collect, maintain, and transmit clinical data intended for submission to FDA in support of marketing or research applications. The data, whether collected or reported electronically or in paper form, must meet certain quality standards, and this draft guidance document is intended to provide information on how these standards might be met by computerized systems.

DATES: Written comments on the draft guidance document may be submitted by August 18, 1997. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, 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 written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Office of Enforcement (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0425.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials.'' In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a regulation providing criteria for electronic records and electronic signatures (part 11 (21 CFR part 11)). The preamble to part 11 stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to comment on draft guidance documents. In light of this rule and the existing rules and guidance concerning clinical trials, this draft guidance document on the use of computerized systems in clinical trials has been prepared by an agency working group representing the Bioresearch Monitoring Program Managers from each Center within FDA and the Office of Regulatory Affairs, and it is available for public comment.

The draft guidance document addresses issues pertaining to computer systems used to generate, collect, maintain, and transmit data intended for submission to FDA in support of marketing or research applications. These data have broad public health significance and, whether collected electronically or on paper, must be of the highest quality and integrity. For example, all data should be attributable, original, accurate, contemporaneous, and legible. The draft guidance document provides information intended to help establish and maintain these and other standards in an electronic environment.

The draft guidance document provides specific information on generating and securing electronic data; establishing standard operating procedures; data entry, including electronic signatures, audit trails, and date/time stamps; system design, security, and dependability; system controls; personnel training; records inspection; and certification of electronic signatures.

This draft guidance document represents 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 such approach satisfies the requirement of the applicable statute, regulations, or both.

II. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document. FDA invites comments on whether any provisions in the guidance might inhibit use of computers in clinical trials. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this draft guidance document is available on the Internet using the World Wide Web (www) at http://www.fda.gov/cder/guidance.htm.

Dated: June 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–15992 Filed 6–17–97; 8:45 am]

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