application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before July 18, 1997 file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 4, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–15990 Filed 6–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Antiviral Drugs Advisory Committee. This meeting was announced in the **Federal Register** of May 19, 1997. The amendment is being made to add another meeting day, July 16, 1997, and include another topic for discussion. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 19, 1997 (62 FR 27261), FDA announced that a meeting of the Antiviral Drugs Advisory Committee would be held on July 14 and 15, 1997.

On page 27261, beginning in the third column, the ''*Date and Time*'' and the ''*Agenda*'' portions for the Antiviral Drugs Advisory Committee meeting are amended as follows:

Date and Time: The meeting will be held on July 14, 15, and 16, 1997, 8:30 a.m. to 5 p.m.

Agenda: On July 14 and 15, 1997, the committee will discuss the utility of plasma human immunodeficiency virus (HIV) RNA measurement as an endpoint in clinical trials for drugs to treat HIV infection. In light of the rapid changes in knowledge about the pathophysiology of HIV infection, the advances in the technologies to quantify HIV in plasma, and the evolution of antiviral therapy, FDA is soliciting opinions and advice from the advisory committee on this topic. On July 16, 1997, the committee will discuss data relevant to new drug application (NDA) 50–740, AmBisome® (liposomal amphotericin B, Fujisawa, USA), as empirical therapy for presumed fungal infection in febrile neutropenic patients.

Dated: June 12, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–15991 Filed 6–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on July 10, 1997, 11 a.m. to 1:45 p.m.

Location: Food and Drug Administration, Bldg. 29, conference room 121, 8800 Rockville Pike, Bethesda, MD. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the intramural scientific programs of the Laboratory of Pediatric and Respiratory Viral Diseases.

Procedure: On July 10, 1997, from 11 a.m. to 11:45 a.m., and from 12:45 p.m. to 1:45 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in

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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