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