duplicates information previously reviewed by this panel.

On March 10, 1997, CDRH approved the 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 June 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: April 22, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–13023 Filed 5–16–97; 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). The meeting will be open to the public.

Name of Committee: Blood 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 June 19, 1997, 9 a.m. to 2:30 p.m., and June 20, 1997, 8:30 a.m. to 1:30 p.m.

Location: Quality Suites Hotel, Potomac Ballrooms I, II, and III, Three Research Ct., Rockville, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, 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: On June 19, 1997, the committee will sit as a Medical Device Panel to review agency recommendations for the following reclassification changes under 21 CFR part 860, subpart C: (1) Inclusion of automated infectious disease test systems used for donor screening, and (2) reclassification of class I medical devices used in collection and processing of blood. On June 20, 1997, the committee will hear discussion and provide recommendations regarding inadvertent contamination of plasma used for fractionation.

Procedure: 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 June 13, 1997. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before June 13, 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 required to make their presentation.

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

Dated: May 13, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–13020 Filed 5–16–97; 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). The meeting will be open to the public.

Name of Committee: Antiviral Drugs 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 14 and 15, 1997, 8:30 a.m. to 5 p.m..

Location: Armory Place, rm. 204, 925 Wayne Ave., Silver Spring, MD.

Contact Person: 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.

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.

Procedure: 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 7, 1997. Oral presentations from the public will be scheduled on July 14, 1997, between approximately 11 a.m. to 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 7, 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.

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

Dated: May 13, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–13022 Filed 5–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0192]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use; Use of Form FDA 356h'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 13, 1997 (62 FR 11899), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). OMB has now approved the information collection and has assigned OMB control number 0910–0338. The approval expires on April 30, 2000. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: May 13, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–13021 Filed 5–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HSQ–242–N]

Approval of the Commission on Office Laboratory Accreditation for Immunohematology.

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the approval of the Commission on Office Laboratory Accreditation (COLA), which is an accrediting organization for clinical laboratories under the Clinical Laboratory Improvement Amendments (CLIA) program, for the addition of the full specialty of immunohematology. This approval adds immunohematology to the specialties and subspecialties approved by HCFA in a notice published in the **Federal Register** on December 23, 1993 (58 FR 68148). We have found that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by it for immunohematology meet the conditions required by Federal law and regulations. Consequently, laboratories that voluntarily become accredited by COLA for the specialty of immunohematology in lieu of receiving direct Federal oversight and continue to meet COLA requirements would meet the CLIA immunohematology condition level requirements for laboratories. These laboratories performing immunohematology testing are not subject to routine inspection by State survey agencies to determine their compliance with applicable Federal requirements. They are, however, subject to validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective for the period May 19, 1997 through November 1, 1997.

FOR FURTHER INFORMATION CONTACT: Valerie Coppola, (410) 786–3354.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On October 31, 1988, the Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. 100–578. CLIA replaced in its entirety section 353 of the Public Health Service Act (PHSA), as enacted by the Clinical Laboratories Improvement Act of 1967, and made every laboratory in the United States and its territories that tests human specimens for health reasons subject to the requirements established by HHS and Federal regulation whether or not it participates in the Medicare or Medicaid program and whether or not it tests specimens in interstate commerce. New section 353 requires HHS to establish certification requirements for any laboratory that performs tests on human specimens and certify through issuance of a certificate that those laboratories meet the certificate requirements established by HHS.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101–239, amended the Social Security Act (the Act) to require that laboratories participating in the Medicare program meet the certificate requirements of section 353 of the PHSA. Subject to specified exceptions, laboratories must have a current unrevoked and unsuspended certificate to be eligible for reimbursement in the Medicare or Medicaid programs, or both. Laboratories that are accredited by an accreditation organization approved under section 353 of the PHSA will automatically be eligible for Medicare and Medicaid participation as long as they meet applicable state requirements.

On February 28, 1992, we published several final rules in the **Federal Register** (57 FR 7002) that implemented the amendments to section 353 of the PHSA. The technical and scientific portions of these rules were drafted by the Centers for Disease Control and Prevention (CDC) of the Public Health Service (PHS).

We established regulations at 42 CFR part 493 that—

- Require laboratories to pay fees for issuance of registration certificates, certificates of waiver, certificates of accreditation, or other applicable certificates and to fund activities to