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