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

determine compliance with our performance requirements;

- Specify the performance requirements that apply to laboratories subject to CLIA and list requirements for laboratories performing certain limited testing to be eligible for a certificate of waiver; and
- Set forth the rules for the enforcement of CLIA requirements on laboratories that are found not to meet Federal requirements.

On July 31, 1992, we issued additional final rules (57 FR 33992), under authority found in section 353(e)(2) of the PHSA, that establish that we may approve a private, nonprofit organization as an accreditation organization for clinical laboratories under the CLIA program if that organization's requirements for its accredited laboratories are equal to or more stringent than the applicable CLIA program requirements of part 493 of our regulations. Therefore, a laboratory accredited by an approved organization that meets and continues to meet all of the accreditation organization's requirements would meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations listed in subpart E of part 493 specify the requirements an accreditation organization must meet in order to be approved. We may approve an accreditation organization under § 493.501(d) of our regulations for a period not to exceed six years.

In general, the accreditation organization must—

- Use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by HCFA;
- Apply standards and criteria that are equal to or more stringent than those condition level requirements established by HHS when taken as a whole;
- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories;
- Provide HCFA, within 30 days of the event, with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked;
- Notify HCFA at least 30 days prior to changing its standards; and
- If HCFA withdraws its approval, notify its accredited laboratories of the withdrawal within ten days of the withdrawal.

A laboratory can be accredited if it meets the standards of an approved accreditation body and authorizes the accreditation body to submit to HCFA records and other information HCFA may require.

Along with requiring the promulgation of criteria for approving an accreditation body and for withdrawing such approval, CLIA requires HCFA to perform an annual evaluation by inspecting a sufficient number of laboratories accredited by an approved accreditation organization as well as by any other means that HCFA determines appropriate. Under section 353(o) of the PHSA, the Secretary may, by agreement, use the services or facilities of any other Federal, State or local public agency, or nonprofit private organization to conduct inspections of laboratories performing clinical testing on human specimens in the United States and its territories for the purpose of determining compliance with CLIA requirements.

II. Notice of Approval of COLA as an Accrediting Organization for the Specialty of Immunohematology

In this notice, we approve COLA as an organization that may accredit laboratories for purposes of establishing their compliance with CLIA requirements for the specialty of immunohematology. HCFA and the CDC have examined the COLA application and all subsequent submissions against the requirements under subpart E of part 493 that an accreditation organization must meet in order to be granted approved status under CLIA for immunohematology. We have determined that COLA has complied with the applicable CLIA requirements as of May 19, 1997 and grant HCFA approval to COLA as an accreditation organization under this subpart through November 1, 1997, for the specialty of immunohematology.

As a result of this determination, any laboratory that is accredited by COLA during this time period for the specialty of immunohematology meets the CLIA requirements for laboratories found in part 493 of our regulations and, therefore, is not subject to routine inspection by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory performing immunohematology testing, however, is subject to validation and complaint investigation surveys performed by HCFA, or by any other Federal, State or local public agency, or nonprofit private organization which acts in conformance to an agreement with the Secretary.

III. Evaluation of COLA

The following describes the process we used to find that COLA, as a private, nonprofit organization, provides reasonable assurance that those laboratories it accredits for the specialty of immunohematology will meet the applicable requirements of Federal law and regulations.

A. Requirements for Approving an Accreditation Organization Under CLIA

To determine whether we should grant approval to COLA as a private, nonprofit organization for accrediting laboratories under CLIA for the immunohematology specialty of human specimen testing it requested, we conducted a detailed and in-depth comparison of COLA's requirements for its laboratories to those of CLIA. We evaluated whether COLA's standards are at least as stringent as the applicable requirements of 42 CFR part 493 when taken as a whole. In summary, we evaluated whether COLA—

- Provides reasonable assurance to us that it requires the laboratories it accredits to meet requirements that are equal to or more stringent than the CLIA condition level requirements for the requested specialty and would, therefore, meet the condition level requirements of CLIA if those laboratories had not been granted deemed status and had been inspected against condition level requirements; and
- Meets the requirements of § 493.506, which specifies the Federal review and approval requirements of private, nonprofit accreditation organizations.

As specified in the regulations at § 493.506, our review of a private, nonprofit accreditation organization seeking approved status under CLIA includes, but is not limited to, an evaluation of—

- Whether the organization's requirements for immunohematology for its accredited laboratories are equal to or more stringent than the applicable condition level requirements of the CLIA regulations;
- The organization's inspection process to determine:

—The composition of the inspection teams, qualifications of the inspectors, and the ability of the organization to provide continuing education and training to all of its inspectors;

—The comparability of the organization's full inspection and complaint inspection requirements to those of HCFA, including, but not limited to, inspection frequency, and the ability to investigate and respond to complaints against its accredited laboratories;

—The organization's procedures for monitoring laboratories that it has

found to be out of compliance with its requirements;
—The ability of the organization to provide HCFA with electronic data and reports that are necessary for effective validation and assessment of the organization's inspection process;
—The ability of the organization to provide HCFA with electronic data, related to the adverse actions resulting from unsuccessful proficiency testing (PT) participation in HHS approved PT programs, as well as data related to the PT failures, within 30 days of the initiation of the action;
—The ability of the organization to provide HCFA with electronic data for all its accredited laboratories;
—The adequacy of numbers of staff and other resources; and
—The organization's ability to provide adequate funding for performing the required inspections.

- The organization's agreement with HCFA that requires it to—

—Notify HCFA of any laboratory that has had its accreditation denied, limited, suspended, withdrawn, or revoked by the accreditation organization, or that has had any other adverse action taken against it by the accreditation organization within 30 days of the action taken;
—Notify HCFA within ten days of a deficiency identified in an accredited laboratory where the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public;
—Notify HCFA of all newly accredited laboratories, or laboratories whose areas of specialty or subspecialty are revised, within 30 days;
—Notify each laboratory accredited by the organization within ten days of HCFA's withdrawal of recognition of the organization's deeming authority;
—Provide HCFA with inspection schedules, as requested, for the purpose of conducting onsite validation inspections;
—Provide HCFA, the State survey agency, or other HCFA agent with any facility-specific data that includes, but is not limited to, PT results that constitute unsuccessful participation in an approved PT program and notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation;
—Provide HCFA with written notification at least 30 days in advance of the effective date of any proposed changes in its requirements; and
—Make available, on a reasonable basis, any laboratory's PT results upon request by any person, with such explanatory information needed to assist in the interpretation of the results.

- Laboratories that are accredited by an accreditation organization must—

—Authorize the organization to release to HCFA all records and information required by HCFA as required by § 493.501;
—Permit inspections as required by the CLIA regulations at part 493, subpart Q;
—Obtain a certificate of accreditation as required by § 493.632; and
—Pay the applicable fees as required by §§ 493.638 and 493.645.

B. Evaluation of the COLA Request for Approval

COLA has formally applied to HCFA for approval as an accreditation organization for the specialty of immunohematology which would be an addition 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 evaluated the COLA application to determine equivalency with our implementing regulations and the deeming/exemption requirements of the CLIA rules. We also verified the organization's assurance that it requires the laboratories it accredits to be, and that the organization is, in compliance with the following subparts of 42 CFR part 493 as explained below:

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

COLA has submitted a request for HCFA approval for the specialty of immunohematology to be added to the specialties and subspecialties for which it received approval in December, 1993. COLA had previously submitted a comparison of individual accreditation and condition level requirements, a description of its inspection process, PT monitoring process, and its data management and analysis system. In addition, it had submitted a listing of the size, composition, education and experience of its inspection teams, its investigative and complaint response procedures, its notification agreements with HCFA, its removal or withdrawal of laboratory accreditation procedures, its current list of accredited laboratories, and its announced or unannounced inspection process. We have determined that COLA has complied with the general requirements under § 493.501, the applicable parts of § 493.506, and the CLIA requirements for approval as an accreditation organization under various subparts of part 493 for the additional specialty.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both

COLA's requirements for PT are equal to those of CLIA. All of COLA's accredited laboratories are required to participate in a HCFA approved PT program for all tests that are not waived. CLIA, however, requires laboratories that perform any of the tests listed in subpart I to participate in a HCFA approved PT program for those tests only, rather than all of the tests they may perform. COLA also encourages its accredited laboratories to participate in PT for tests that are waived under CLIA.

Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both

COLA requirements are equal to the CLIA requirements at §§ 493.1101 through 493.1111 on an overall basis for the specialty of immunohematology.

Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both

The quality control requirements of COLA have been evaluated against the applicable requirements of the CLIA regulations for immunohematology. We have determined that COLA's requirements, when taken as a whole, are equal to or more stringent than the CLIA requirements. The specific areas that are more stringent are—

- Safety requirements for moderate and high complexity testing;
- Calibration/recalibration requirements for moderate complexity testing;
- A requirement that the laboratory director sign, review, and approve the procedure manual annually; and
- The use of a negative control for ABO antisera is required.

COLA recognizes the categorization of tests for quality control purposes.

Subpart M—Personnel for Moderate and High Complexity Testing

COLA states, as general policy under its personnel standards, that the laboratory director and laboratory personnel must meet all Federal and State educational and experience requirements necessary to perform their assigned tasks. It has adopted the Federal personnel requirements for education, training, and experience, and recognizes the various positions and the responsibilities of each of the positions cited in the CLIA regulations.

All COLA accredited laboratories are currently required to meet these CLIA standards. We have, therefore, found the COLA personnel requirements to be equal to the CLIA personnel requirements.

Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both

We have determined that COLA's requirements for immunohematology are equal to the CLIA requirements of this subpart. COLA also makes educational materials available to its accredited laboratories, which provide further information on quality assurance in the office laboratory.

Subpart Q—Inspections

The COLA inspection process, which is announced and performed on-site on a biennial basis, is equal to the applicable CLIA requirements at §§ 493.1777. Therefore, we have determined that COLA's requirements are equal to the requirements of this subpart.

Subpart R—Enforcement Procedures for Laboratories

COLA meets the requirements of subpart R to the extent it applies to accreditation organizations. COLA policy stipulates the action it takes when laboratories it accredits do not comply with its essential standards pertaining to immunohematology. When appropriate, COLA will deny accreditation to a laboratory and report the denial to HCFA within 30 days. COLA also provides an appeals process for laboratories that have had accreditation denied.

We have determined that COLA's laboratory enforcement and appeal policies are essentially equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of COLA accredited laboratories, as specified in § 493.507, may be conducted on a representative sample basis or in response to substantial allegations of noncompliance, ''complaint inspections''. The outcome of those validation inspections, performed by HCFA, the State survey agency, or a HCFA agent, will be HCFA's principal means for verifying that the laboratories accredited by COLA remain in compliance with CLIA requirements. This Federal monitoring is an on-going process.

V. Removal of Approval as an Accrediting Organization

Our regulations at § 493.511 provide that the approval of an accreditation organization, such as that of COLA, may be removed by HCFA for cause, prior to the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings as described at § 493.509(a), HCFA will conduct a review of the accreditation organization's program. A review is also conducted when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate widespread or systematic problems in the organization's processes. These findings provide evidence that the organization's requirements are no longer equivalent to the CLIA requirements.

If it is determined that COLA has failed to adopt requirements that are equal to or more stringent than the CLIA requirements, or widespread systemic problems exist in its inspection process, a probationary period, not to exceed one year, may be given to allow COLA to adopt comparable requirements. Based on an evaluation of any of the items stipulated at § 493.511(d), a determination will be made as to whether or not COLA retains its approved status as an accreditation organization under CLIA. If approved status is denied, an accreditation organization such as COLA may resubmit its application when it: (1) Has revised its program to address the rationale for the denial; (2) demonstrated that it can reasonably assure that its accredited laboratories meet CLIA condition level requirements; and (3) resubmits its application for approval as an accreditation organization in its entirety. If, however, an accrediting organization requests reconsideration of an adverse determination in accordance with subpart D of part 488 of our regulations, it may not submit a new application until a final reconsideration determination is issued.

Should circumstances result in COLA having its approval withdrawn, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: March 16, 1997.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 97–12959 Filed 5–16–97; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting of the Advisory Committee to the Director, NIH

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, June 5, 1997, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland 20892.

The entire meeting will be open to the public from 8:30 a.m. to adjournment. The topics proposed for discussion may include (1) the future of research careers in biology and medicine; (2) clinical research; (3) further implementation of the recommendations of the Report of the NIH AIDS Research Program Evaluation Task Force, particularly in regard to the development of an HIV vaccine; (4) activities related to research misconduct; and (5) infectious diseases in Africa. Attendance by the public will be limited to space available.

Ms. Janice Ramsden, Program Specialist, Office of the Deputy Director, National Institutes of Health, 1 Center Drive MSC 0159, Bethesda, Maryland 20892–0159, telephone (301) 496–0959, fax (301) 496–7451, will furnish the meeting agenda, roster of committee members, and substantive program information upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Ramsden no later than May 30, 1997.

Dated: May 14, 1997.

LaVeen Ponds,

Acting Committee Management Officer, NIH.

[FR Doc. 97–13061 Filed 5–16–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute on Drug Abuse