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Dated: October 24, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–27832 Filed 10–26–00; 10:43 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Renewals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewals of certain FDA advisory committees by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the charters of the committees listed below for an additional 2 years beyond charter expiration date. The new charters will be in effect until the dates of expiration listed below. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pubic Law 92–463 (5 U.S.C. app. 2)).

DATES: Authority for these committees will expire on the dates indicated below unless the Commissioner formally determines that renewal is in the public interest.

Name of committee	Date of expiration
Gastrointestinal Drugs Advisory Committee	March 3, 2002
Advisory Committee for Reproductive Health Drugs	March 23, 2002
Arthritis Advisory Committee	April 5, 2002
Veterinary Medicine Advisory Committee	April 24, 2002
Anesthetic and Life Support Drugs Advisory Committee	May 1, 2002
Blood Products Advisory Committee	May 13, 2002
Pulmonary-Allergy Drugs Advisory Committee	May 30, 2002
Drug Abuse Advisory Committee	May 31, 2002
Science Advisory Board to the National Center for Toxicological Research	June 2, 2002
Peripheral and Central Nervous System Drugs Advisory Committee	June 4, 2002
Psychopharmacologic Drugs Advisory Committee	June 4, 2002
Transmissible Spongiform Encephalopathies Advisory Committee	June 9, 2002
Science Board to the Food and Drug Administration	June 26, 2002
Allergenic Products Advisory Committee	July 9, 2002
Cardiovascular and Renal Drugs Advisory Committee	August 27, 2002
Endocrinologic and Metabolic Drugs Advisory Committee	August 27, 2002
Oncologic Drugs Advisory Committee	September 1, 2002

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–5496.

Dated: October 23, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–27835 Filed 10–30–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2118–N]

Medicare, Medicaid, and CLIA Programs; Continuance of the Approval of COLA as a CLIA Accreditation Organization

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

ACTION: Notice.

SUMMARY: This notice announces the continued approval of COLA (formerly the Commission on Office Laboratory Accreditation) as an accreditation organization for laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program. We have found that the accreditation process of this organization provides reasonable assurance that the laboratories accredited by it meet the conditions required by CLIA law and regulations. Consequently, laboratories that voluntarily become accredited by COLA in lieu of direct Federal oversight and continue to meet COLA requirements would meet the CLIA condition level requirements for laboratories and, therefore, are not subject to routine inspection by State survey agencies to determine their compliance with CLIA requirements. They are, however, subject to Federal validation and complaint investigation surveys.

EFFECTIVE DATE: This notice is effective for the period October 31, 2000, through December 31, 2002.

FOR FURTHER INFORMATION CONTACT: Val Coppola, (410) 786–3531.

SUPPLEMENTARY INFORMATION:

I. Background and Legislative Authority

On July 31, 1992, HCFA issued a final rule (57 FR 33992). Under section 353(e)(2) of the Public Health Service Act (PHSA), HCFA may approve a private, nonprofit organization to accredit clinical laboratories (an ''approved accreditation organization'') under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program if the organization meets certain requirements. An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 Code of Federal Regulations (CFR), part 493 (Laboratory Requirements). Therefore, a laboratory accredited by an approved accreditation organization that meets and continues to meet all of the accreditation organization's requirements would be considered to meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations listed in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) of part 493 specify the requirements an accreditation organization must meet to be an approved accreditation organization. HCFA approves an accreditation organization for a period not to exceed 6 years.

In general, the approved accreditation organization must among other conditions and requirements:

- 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 HCFA when taken as a whole.
- Provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories;
- Provide HCFA with the name of any laboratory that has had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action taken.
- Notify HCFA in writing at least 30 days before the effective date of any proposed changes in its standards.
- If HCFA withdraws its approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal. A laboratory can be accredited if, among other things, it meets the standards of an approved accreditation organization 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 the accreditation body and for withdrawing this 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.

II. Notice of Continued Approval of COLA as an Accreditation Organization

In this notice, we approve COLA as an organization that may continue to accredit laboratories for purposes of establishing their compliance with CLIA requirements. HCFA and Centers for Disease Control and Prevention (CDC) have examined the COLA application and all subsequent submissions to determine equivalency with HCFA requirements under subpart E of part 493 that an accreditation organization must meet to be granted approved status under CLIA. We have determined that COLA has complied with the applicable CLIA requirements as of October 31, 2000, and grant COLA approval as an accreditation organization under subpart E, through August 31, 2002, for the following specialty/subspecialty areas:

- Bacteriology.
- Mycobacteriology.
- Mycology.
- Parasitology.
- Virology.
- Syphilis Serology.
- General Immunology.
- Routine Chemistry.
- Endocrinology.
- Toxicology.
- Urinalysis.
- Hematology.
- Immunohematology.

As a result of this determination, any laboratory that is accredited by COLA during this time period for an approved specialty/subspecialty (listed above) is deemed to meet the applicable CLIA condition level requirements for the laboratories found in part 493 and, therefore, is not subject to routine inspection by a State survey agency to determine its compliance with CLIA requirements. The accredited laboratory, however, is subject to validation and complaint investigation surveys performed by HCFA, or by any other Federal or State or local public agency or nonprofit private organization under an agreement with the Secretary.

III. Evaluation of COLA

The following describes the process used to determine that COLA, as a private, nonprofit organization, provides reasonable assurance that laboratories it accredits will meet the applicable requirements of the CLIA and applicable regulations.