

before accepting materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or the impairment of, or assessment of the health of human beings. The type of CLIA certificate a laboratory obtains depends upon the complexity of the tests it performs. CLIA regulations describe three levels of test complexity: Waived tests, moderate complexity tests, and high complexity tests.

On January 31, 2000, the responsibility for categorization of commercially marketed in vitro diagnostic (IVD) tests was transferred from the Centers for Disease Control and Prevention to FDA (64 FR 73561, December 30, 1999). This allows IVD test manufacturers to submit premarket (510(k)) notifications or applications and requests for complexity categorization under CLIA to one agency. This notice announces the availability of a guidance document that describes the general administrative procedures FDA uses to assign a device's complexity category under CLIA.

The draft of this guidance was issued August 14, 2000, and the comment period closed on November 13, 2000. FDA did not receive any comments concerning the "Draft Guidance on Administrative Procedures for CLIA Categorization." In preparing the final guidance, however, FDA needed to obtain an approval for a new collection of information from the Office of Management and Budget (OMB). We obtained this approval (see section IV. Paperwork Reduction Act of 1995) and are now issuing the final guidance. Updates added to the guidance include a revised background section and procedures for CLIA categorization for 510(k) submissions submitted electronically. The guidance also notes that manufacturers who wish to request CLIA waiver for a device (other than those devices already waived under 42 CFR 493.15), should refer to the guidance entitled "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices," issued in January 2008.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on administrative procedures for CLIA categorization. It does not create or confer any rights for or on any person and does not operate

to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Administrative Procedures for CLIA Categorization," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1143 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.regulations.gov>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in this guidance were approved under OMB control number 0910-0607.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management

System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: April 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-10178 Filed 5-6-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Office of Biotechnology Activities; Recombinant DNA Research; Notice of a Meeting of an NIH Blue Ribbon Panel

There will be a meeting of the NIH Blue Ribbon Panel to advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories (NEIDL) at Boston University Medical Center. The meeting will be held on Friday, May 16, 2008, at The Commonwealth of Massachusetts Bureau of State Office Buildings, State House, Gardner Auditorium, 24 Beacon Street, Boston, Massachusetts 02133, from approximately 9 a.m. to 12 p.m.

Discussions will include the charge to the Panel and the process and framework for deliberations. There will also be time allotted on the agenda for public comment. Sign up for public comment will begin at approximately 8 a.m. on May 16, 2008. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments using the address below.

To file written comments or for further information concerning this meeting contact Ms. Laurie Lewallen, Advisory Committee Coordinator, Office of Biotechnology Activities, Office of the Director, National Institutes of Health, Mail Stop Code 7985, Bethesda, MD 20892-7985, 301-496-9838, lewalla@od.nih.gov

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed above in advance of the meeting. Any interested person may file written comments with the panel by forwarding the statement to the Contact Person listed on this notice. The statement should include the name,

address, telephone number and when applicable, the business or professional affiliation of the interested person.

An agenda and any additional information for the meeting will be posted on the agency's Web site: <http://www.nih.gov/about/director/acd/index.htm>.

Background information may be obtained by contacting NIH OBA by e-mail oba@od.nih.gov

Dated: April 29, 2008.

Amy P. Patterson,

Director, Office of Biotechnology Activities.

[FR Doc. E8-10011 Filed 5-6-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group; Subcommittee F—Manpower & Training; NCI-F Manpower and Training Grants.

Date: May 19, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Old Town Alexandria, 1767 King Street, Alexandria, VA 22314.

Contact Person: Lynn M. Amende, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8105, Bethesda, MD 20892, 301-451-4759, amendel@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology

Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 30, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-10013 Filed 5-6-08; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

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 meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Open: June 17, 2008, 8:30 a.m. to 3:20 p.m.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Closed: June 17, 2008, 3:20 p.m. to 5 p.m.

Agenda: Review of grant applications.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Open: June 18, 2008, 8:30 a.m. to 12 p.m.

Agenda: Program reports and presentations; Business of the Board.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327, (301) 496-5147.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page <http://deainfo.nci.nih.gov/advisory/ncab.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 30, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-10014 Filed 5-6-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Office of Liaison, Policy and Review; Meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM)

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: *COM057* Meeting announcement and request for comment.

SUMMARY: Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of SACATM on June 18-19, 2008, at the