Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the documents.

Submit written comments concerning these documents to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ginette Y. Michaud, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as GHTF to facilitate harmonization. Subsequent meetings have been held in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using its own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice relates to documents that have been developed by one of the Study Groups (Study Group 1).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidelines that could help lead to harmonization. As a result of its efforts, this group has developed SG1(PD)/N055R6:2008 and SG1/N045:2008.

The proposed document SG1(PD)/N055R6:2008 entitled ''Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer'' provides a harmonized definition of the terms ''manufacturer,'' ''authorised representative,'' ''distributor,'' and ''importer''.

The final document SG1/N045:2008 entitled ''Principles of In Vitro Diagnostic (IVD) Medical Devices Classification'' assists a manufacturer in allocating an IVD medical device to the appropriate risk class by using a set of harmonized classification principles. It bases such classification principles on an IVD medical device's intended use and allows regulatory authorities to rule upon matters of interpretation for a particular IVD medical device, when appropriate.

II. Significance of Guidance

These documents represent recommendations from the GHTF study group and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particularly where they are not consistent with current practices for the manufacture of products in the United States.

III. Electronic Access

Persons interested in obtaining a copy of these documents may do so by using the Internet. The Center for Devices and Radiological Health (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. Information on the GHTF may be accessed at *http://www.ghtf.org*. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding these documents. 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: October 22, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–27466 Filed 11–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel, Biomaterials and Tissue Engineering.

Date: December 8–9, 2008.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alexander Gubin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 5144, MSC 7812, Bethesda, MD 20892, 301–435–2902, *gubina@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Exploratory Research Centers of Excellence for Minority, Health and Health Disparities (P20).

Date: December 9–11, 2008.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ann A. Jerkins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6154, MSC 7892, Bethesda, MD 20892, 301–435–4514, *jerkinsa@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Exploratory Research Centers of Excellence for Minority Health and Health Disparities (P20).

Date: December 9–11, 2008.

Time: 7 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Stuart B. Moss, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–1044, *mossstua@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Roadmap RAID.

Date: January 14–15, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: James J. Li, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301–435–2417, *lijames@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Transplantation, Tolerance, and Tumor Immunology Study Section.

Date: January 23–24, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Monterey, 1 Old Golf Course Road, Monterey, CA 93940.

Contact Person: Cathleen L. Cooper, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892, 301–435–3566, *cooperc@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics, Integrated Review Group Enabling Bioanalytical and Biophysical Technologies Study Section.

Date: January 29–30, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Vonda K. Smith, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7806, Bethesda, MD 20892, 301–435–1789, *smithvo@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group, Molecular and Integrative Signal Transduction Study Section.

Date: January 29–30, 2009.

Time: 8 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Deflina Santa Monica Hotel, 530 Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Raya Mandler, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5134, MSC 7840, Bethesda, MD 20892, (301) 402–8228, *rayam@csr.nih.gov.*

Name of Committee: Oncological Sciences Integrated Review Group, Developmental Therapeutics Study Section.

Date: January 29–30, 2009.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Sharon K. Gubanich, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–1767, *gubanics@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics, Integrated Review Group Macromolecular Structure and Function A Study Section.

Date: January 30, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 Pico Boulevard, Santa Monica, CA 90405.

Contact Person: David R. Jollie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4150, MSC 7806, Bethesda, MD 20892, (301) 435–1722, *jollieda@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 10, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–27257 Filed 11–18–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 meetings.

The meetings 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 Institute of Environmental Health Sciences Special Emphasis Panel, Worker Education and Hazardous Material Training.

Date: December 3, 2008.

Time: 1 pm to 5 pm.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Sally Eckert-Tilotta, PhD, Scientific Review Administrator, National Inst. of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541–1446, *eckertt1@niehs.nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Beryllium: Exposure, Immune and Genetic Mechanisms.

Date: December 9, 2008.

Time: 1 pm to 4 pm.

Agenda: To review and evaluate grant applications.