SUMMARY: The Food and Drug Administration (FDA) is announcing the Web site location where it will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development. In addition, FDA has established a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

DATES: Submit either written or electronic comments at any time.

ADDRESSES: Submit written comments 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.


SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of guidance documents that CDRH is considering for development and providing stakeholders an opportunity to provide comments and/or draft language for those topics, or suggestions for new or different guidances. This notice announces the Web site location of the list of guidances on which CDRH is intending to work over the next Fiscal Year (FY). We note that the agency is not required to issue guidance on the list, nor is it excluded from issuing guidance documents that are not on the list. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued level 1 drafts that may be finalized following review of public comments. We will consider stakeholder comments as we prioritize our guidance efforts. FDA and CDRH priorities are subject to change. Topics on this and past guidance priority lists may be removed or modified based on current priorities. We also note that CDRH’s experience over the years has shown that there are many reasons CDRH staff does not complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the Center is required each year to issue a number of guidances that it cannot anticipate at the time the annual list is generated. These may involve newly identified public health issues as well as special control guidance documents for de novo classifications of devices. It will be helpful, therefore, to receive comments that indicate the relative priority of different guidance topics to interested stakeholders.

Through feedback from stakeholders, including draft language for guidance documents, CDRH expects to be able to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. This year’s fourth annual list CDRH has posted, FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the list. FDA has established a docket where comments about the FY 2011 list, draft language for guidance documents on those topics, and suggestions for new or different guidances may be submitted (see ADDRESSES). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual agency-wide notice issued by FDA under its good guidance practices (21 CFR 10.115(f)(5)). This CDRH list, however, will be focused exclusively on device-related guidances and will be made available on FDA’s Web site prior to the beginning of each FY from 2008 to 2012.

To access the list of the guidance documents CDRH is considering for development in FY 2011, visit the FDA Web site http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm1091916.htm.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.


Nancy K. Stade,
Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–24960 Filed 9–30–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention

Board of Scientific Counselors (BSC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC and NCEH/ATSDR announces the following committee meeting:

TIMES AND DATES:
8:30 a.m.–4:15 p.m., October 21, 2010.
8:30 a.m.–12 p.m., October 22, 2010.

PLACE: CDC, 4770 Buford Highway, Atlanta, Georgia 30341.

STATUS: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

PURPOSE: The Secretary, Department of Health and Human Services (HHS) and by delegation, the Director, CDC and Administrator, NCEH/ATSDR, are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to: (1) Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist States and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and well being; and (3) train State and local personnel in health work. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agency’s...
mission to protect and promote people’s health. The board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America’s health.

**MATTERS TO BE DISCUSSED:** The agenda items for the BSC Meeting on October 21–22, 2010 will include presentations from the Division of Environmental Hazards and Health Effects to the BSC on Air Pollution and Respiratory Health, Environmental Health Tracking, and Climate Control; a discussion of ATSDR Funded State Reports; an update on Amyotrophic Lateral Sclerosis (ALS) Registry; Director Updates on ATSDR; Director Updates on NCEH and Program Response to BSC Program Peer Review of the Division of Laboratory Sciences.

**SUPPLEMENTARY INFORMATION:** The public comment period is scheduled from 3:45 p.m. until 4 p.m. October 21, 2010.

**CONTACT PERSON FOR MORE INFORMATION:** Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, CDC, 4770 Buford Highway, Mail Stop F–61, Chamblee, Georgia 30345; telephone 770/488–0575, fax 770/488–3377; E-mail: smalcom@cdc.gov. The deadline for notification of attendance is October 15, 2010.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and NCEH/ATSDR.

**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. App.), 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:** Healthcare Delivery and Methodologies Integrated Review Group, Biostatistical Methods and Research Design Study Section.

**Date:** October 21, 2010.

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

**Agenda:** To review and evaluate grant applications.

**Place:** InterContinental Mark Hopkins Hotel, 999 California Street, San Francisco, CA 94108.

**Contact Person:** Tom Drgon, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892, 301–435–1017, tdrgon@csr.nih.gov.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Member Conflict: Enabling Bioanalytical and Imaging Technologies.

**Date:** October 29, 2010.

**Time:** 10 a.m. to 1 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)

**Contact Person:** Allen Richon, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301–435–2902, allen.richon@nih.hhs.gov.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Member Conflict: Topics in Microbial Diseases.

**Date:** November 1–2, 2010.

**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:** Liangbiao Zheng, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301–402–5671, zhengli@csr.nih.gov.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Diabetes, Obesity and Endocrine Disorders.

**Date:** November 2–3, 2010.

**Time:** 11 a.m. to 2 p.m.

**Agenda:** To review and evaluate grant applications.

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

**Contact Person:** Krish Krishnan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435–1041, krishnak@csr.nih.gov.

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Fellowships: Physiology and Pathobiology of Cardiovascular and Respiratory Systems.

**Date:** November 18–19, 2010.

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

**Agenda:** To review and evaluate grant applications.

**Place:** The Fairmont San Francisco, 950 Mason Street, San Francisco, CA 94108.

**Contact Person:** Abdelouahab Aitouche, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7812, Bethesda, MD 20892, 301–435–2365, aitouchea@csr.nih.gov.


**Dated:** September 27, 2010.

**Jennifer S. Spaeth,**

**Director, Office of Federal Advisory Committee Policy.**

**[FR Doc. 2010–24680 Filed 9–30–10; 8:45 am]**

**BILLING CODE 4140–01–P**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Privacy Act of 1974; Report of an Altered System of Records**

**AGENCY:** Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA).

**ACTION:** Notice of an Altered System of Records (SOR).

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974, the Health Resources and Services Administration (HRSA) is publishing a notice to alter the system of records for the National Practitioner Data Bank for Adverse Information on Physicians and other Health Care Practitioners, HHS/HRSA/BHPR. The SORN 09–15–0054 was last published March 17, 1997. In accordance with the Health Care Quality Improvement Act of 1986, as amended, title IV of Public Law 99–660 (42 U.S.C. 11101 et seq.) authorizes the Secretary to establish a National Practitioner Data Bank (NPDB) to collect and release certain information relating to the professional competence and conduct of physicians, dentists, and other health care practitioners. This information is releasable only to specific entities described in the SORN. It requires the