

includes 29 specific questions and answers for IRBs as well as guidance to HDE holders on whether and how they may become eligible to receive profit from the sale of their device. In the **Federal Register** of August 5, 2008 (73 FR 45460), FDA published a 60-day notice requesting public comment. The comment period closed on November 3, 2008. FDA published a 30-day notice on September 30, 2009 (74 FR 50214), but republished a 30-day notice on February 18, 2010 (75 FR 7270), to provide a more descriptive response to the comments received in response to the August 5, 2008, notice. This document supersedes: Humanitarian Device Exemption (HDE) Regulation: Questions and Answers, issued July 18, 2006.

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 the "HDE Regulation: Questions and Answers." 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 "HDE Regulation: Questions and Answers," 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 301-847-8149 to receive a hard copy. Please use the document number 1668 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (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 0910-0661, May 31, 2013, expiration date.

V. 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.

Dated: July 1, 2010.

Nancy Stade,

Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.

[FR Doc. 2010-16548 Filed 7-7-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

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 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 Institute of Child Health and Human Development Special Emphasis Panel: Therapeutic Application of Dyrk1A Inhibitors for Down Syndrome.

Date: July 26, 2010.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Neelakanta Ravindranath, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01G, Bethesda, MD 20892-7510, (301) 435-6889, ravindrn@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 30, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-16472 Filed 7-7-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Health Resources and Services Administration

CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the CDC and HRSA announce the following committee meeting.

Time and Date: 2 p.m.-3:30 p.m., July 29, 2010.

Place: Teleconference. To participate, please dial (877) 952-1988 and enter passcode 2162797 for access.

Status: Open to the public, limited only by availability of telephone ports.

Purpose: This Committee is charged with advising the Director, CDC and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS and other STDs, the support of health care services to persons living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS and other STDs.

Matters To Be Discussed: The purpose of the teleconference is for CHACHSPT to deliberate and discuss the outcomes of a CDC/HRSA Advisory Committee workgroup that will convene on July 8, 2010. The workgroup will conduct a program review to provide information to CHACHSPT on the strategic realignment of funding to support priorities in sexual health and STD disparities among racial and ethnic minorities. The objectives of the workgroup are: (1) To identify to CHACHSPT future opportunities to accelerate the impact in health disparities through programs, policy, and research and public health ethics; (2) To provide information to CHACHSPT regarding potential use of realigned funding; and, (3) To provide key principles (e.g., program, policy, research) to be considered by CHACHSPT in the development of a new funding opportunity announcement for the use of realigned resources.

For More Information Contact: Margie Scott-Cseh, CDC, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB

Prevention, 1600 Clifton Road, NE., Mailstop E-07, Atlanta, Georgia 30333, Telephone (404) 639-8317.

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 the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 30, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-16613 Filed 7-7-10; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, Announces the Following Meeting

Name: ICD-9-CM Coordination and Maintenance Committee meeting.

Time and Date: 9 a.m.-4:30 p.m., September 15-16, 2010.

Place: Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland.

Status: Open to the public.

Purpose: The ICD-9-CM Coordination and Maintenance (C&M) Committee will hold its second meeting of the 2010 calendar year cycle on Wednesday and Thursday September 15-16, 2010. The C&M meeting is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Ninth-Revision, Clinical Modification.

Matters To Be Discussed

Section 10109(c) of the Patient Protection and Affordable Care Act and the Reconciliation Act of 2010 (PPACA) requires the Secretary of Health and Human Services (HHS) to task the C&M Committee to convene a meeting before January 1, 2011, to receive stakeholder input regarding the crosswalk between the Ninth and Tenth Revisions of the International Classification of Diseases (ICD-9, and ICD-10, respectively), posted to the CMS Web site at <http://www.cms.gov/ICD10>, for the purpose of making appropriate revisions to said crosswalk. Section 10109(c) further states that any revised crosswalk be treated as a code set for which a standard has been adopted by the Secretary, and that revisions to this

crosswalk be posted to the CMS Web site.

The C&M Committee will use the first half of the first day of the September C&M Committee meeting, 9 a.m. to 12:30 p.m. Wednesday, September 15, 2010, to fulfill the above-referenced PPACA requirements for this meeting to be held prior to January 1, 2011, and receive public input regarding the above-referenced crosswalk revision. No other meeting will be convened by the C&M Committee for this purpose. Interested parties and stakeholders should be prepared to submit their written comments and other relevant documentation at the meeting, or no later than November 12, 2010 to the following addresses:

Pat Brooks, RHIA, Senior Technical Advisor, Centers for Medicare & Medical Services, Hospital and Ambulatory Policy Group, Mail Stop C4-08-06, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Patricia.brooks2@cms.hhs.gov.

Donna Pickett, RHIA, MPH, Medical Systems Administrator, National Center for Health Statistics, Centers for Disease Control and Prevention, Classifications and Public Health Data Standards, 3311 Toledo Road, Room 2337, Hyattsville, MD 20782.

DPickett@cdc.gov.

Additional Information: Additional information regarding the tentative diagnosis and procedures topics will be published in a separate notice one month prior to the meeting.

Notice: Because of increased security requirements CMS has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show an official form of picture I.D., (such as a drivers license), and sign-in at the security desk upon entering the building.

Those who wish to attend a specific ICD-9-CM C&M meeting in the CMS auditorium must submit their name and organization for addition to the meeting visitor list. Those wishing to attend the September 15-16, 2010 meeting must submit their name and organization by September 10, 2010 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting. Those who attended previous ICD-9-CM C&M meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you attend. Register to attend the meeting on-line at: <http://www.cms.hhs.gov/apps/events/>.

Notice: This is a public meeting, however, due to fire code requirements seating may be limited.

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 the Agency for Toxic Substances and Disease Registry.

Dated: June 30, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010-16610 Filed 7-7-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Request for Nominations of Candidates To Serve on the Board of Scientific Counselors (BSC), National Center for Environmental Health/ Agency for Toxic Substances and Disease Registry (NCEH/ATSDR), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS)

The NCEH/ATSDR is soliciting nominations for possible membership on the BSC. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agencies' mission to protect and promote people's health. The Board provides advice and guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America's health.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the Board's objectives. Nominees will be selected from experts having experience in preventing human diseases and disabilities caused by environmental conditions. Experts in the disciplines of toxicology, epidemiology, environmental or occupational medicine, behavioral science, risk assessment, exposure assessment, and experts in public health and other related disciplines will be considered. Consideration is given to representation from diverse geographic areas, gender, ethnic and minority groups, and the disabled. Members may be invited to