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Dated: October 29, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–26479 Filed 11–2–09; 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. 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: Center for Scientific Review Special Emphasis Panel; Brain Disorders in the Developing World 1.

Date: November 18, 2009.

Time: 3 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Dan D. Gerendasy, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5132, MSC 7843, Bethesda, MD 20892, 301–594–6830, *gerendad@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; Brain Disorders in the Developing World 2.

Date: November 19, 2009.

Time: 6 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Dan D. Gerendasy, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5132, MSC 7843, Bethesda, MD 20892, 301–594–6830, *gerendad@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.

(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: October 27, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–26424 Filed 11–2–09; 8:45 am]

BILLING CODE 4140–01–P

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: Center for Scientific Review Special Emphasis Panel; Health of the Population Fellowships.

Date: November 18–19, 2009.

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: Karin F. Helmers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 3166 MSC 7770, Bethesda, MD 20892, 301–435–1017, *helmersk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; NCRR Electron Microscopy Resource Review.

Date: November 30–December 2, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza-Albany City Center, 30 Lodge Street, Albany, NY 12207.

Contact Person: Raymond Jacobson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5858, MSC 7849, Bethesda, MD 20892, 301–996–7702, *jacobsonrh@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: October 27, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–26422 Filed 11–2–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel; NIMH Brain Bank Resource.

Date: December 2, 2009.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

Contact Person: Rebecca C Steiner, PhD., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6149, MSC 9608, Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: October 27, 2009

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–26421 Filed 11–2–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): CDC Grants for Public Health Research Dissertation (Panel D), Funding Opportunity Announcement (FOA) PAR07–231, Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned SEP:

Time and Date: 12:30 p.m.–4:30 p.m., December 1, 2009 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''CDC Grants for Public Health Research Dissertation, FOA PAR07–231, Panel D.''

Contact Person for More Information: Maurine Goodman, MA, MPH, Scientific Review Administrator, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone (404)639–4747.

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: October 23, 2009.

Elaine L. Baker,

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

[FR Doc. E9–26389 Filed 11–2–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0519]

Public Workshop: International Conference on Harmonisation S2 Genetic Toxicology Issues; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''ICH S2 Genetic Toxicology Issues.'' The 1-day public workshop is intended to seek constructive input from experts in the field of genetic toxicology on proposed changes to the International Conference on Harmonisation (ICH) guidance ''S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use'' that was published in March 2008.

DATES: The public workshop will be held on January 25, 2010, from 8:30 a.m. to 5 p.m. Register by January 15, 2010, to make a presentation at the workshop. See section II in the **SUPPLEMENTARY INFORMATION** section for information on how to attend the workshop. We are opening a docket to receive your written or electronic comments. Written or electronic comments must be submitted to the docket by February 24, 2010, to receive consideration.

ADDRESSES: The public workshop will be held at the Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. Submit written or electronic requests to make a presentation to Adele Seifried (see **FOR FURTHER INFORMATION CONTACT**). 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*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Adele Seifried, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6482, Silver Spring, MD 20993–0002, 301–796–0535, FAX: 301–796–9855, e-mail: *Adele.Seifried@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Objectives

The objectives of this workshop are to provide a scientific forum where experts in the field of genetic toxicology can provide their views on proposed changes to ICH S2(R1). These proposed changes are described in the following paragraphs.

A. The Genetox Battery and Followup Testing: Options 1 and 2

The ICH steering committee agreed that revision of ICH S2 was appropriate because the 2 guidances that comprise it, ICH S2A and ICH S2B, were finalized nearly 15 years ago and much has been learned in the interim. ICH S2(R1) is a draft version that discusses the components of a basic genetic toxicology battery as well as in vivo followup testing that should be conducted when in vitro tests are positive. ICH S2(R1) offers two test options: Option 1 is similar to the current ICH and CDER test battery with some modifications. Option 2 removes the in vitro mammalian cell test from the test battery and instead includes two in vivo endpoints that can be assessed in a single assay. The workshop will examine these options in addressing what constitutes an adequate genetic toxicology battery, including which tests are reasonable followups to a positive in vitro cytogenetic assay or mouse lymphoma assay. The workshop will also examine the following: (1) Whether an in vivo comet assay is a reasonable followup test to a positive in vitro cytogenetic or mouse lymphoma assay, and if not, what alternatives exist, and (2) whether the two-option system being proposed would provide comparable or superior patient protection to the current single-option test battery.

B. Top Concentration for Mammalian In Vitro Genotoxicity Assays

The current ICH safety guidances specify that drug substances should be tested up to a concentration of 10 millimolars (mM) in vitro if no toxicity is seen at lower concentrations. The draft ICH S2(R1) proposes to lower this top concentration for required testing to 1 mM. This workshop will examine the scientific basis for this proposal and its potential effect on patient safety.

II. Attendance and Registration to Speak

There is no fee to attend the workshop, and attendees who do not wish to make a formal presentation to the scientific panel do not need to register. Seating will be on a first-come,