

electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Mary Parks, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3362, Silver Spring, MD 20993-0002, 301-796-2290.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes." Diabetes mellitus is associated with an increased risk of cardiovascular disease. Reducing long-term cardiovascular complications in patients with diabetes should be an important goal of disease management. There are compelling data in patients with type 2 diabetes supporting a reduced risk of microvascular complications with improved long-term glycemic control. This guidance makes recommendations about how to demonstrate that a new antidiabetic therapy to treat type 2 diabetes is not associated with an unacceptable increase in cardiovascular risk.

On March 3, 2008, FDA issued the draft guidance for industry entitled "Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention" (73 FR 11420). On July 1 and 2, 2008, the Endocrinologic and Metabolic Drugs Advisory Committee met to discuss the role of cardiovascular assessment in the premarketing and postmarketing settings for drugs and therapeutic biologics developed for the treatment of type 2 diabetes mellitus. After considering the discussion at this meeting as well as other available data and information, we have determined that concerns about cardiovascular risk should be more thoroughly addressed during drug development. We are issuing this guidance to ensure that our recommendations reach all sponsors who may submit applications for approval of drugs to treat type 2 diabetes mellitus.

We are issuing this level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA is not seeking comment before implementing this guidance because of the need to immediately notify sponsors with ongoing development programs of the need to address cardiovascular risk in ongoing drug development programs.

If FDA receives comments on this guidance, it will consider the comments and incorporate final recommendations into the final version of the March 2008 draft guidance.

This guidance represents the agency's current thinking on evaluating cardiovascular risk in new antidiabetic therapies to treat type 2 diabetes. 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 21 CFR part 312 have been approved under 0910-0014, and the collections of information in 21 CFR part 314 have been approved under 0910-0001.

III. 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>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.regulations.gov>.

Dated: December 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-30086 Filed 12-17-08; 11:15 am]

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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, Prevention, Interventions: Alcohol, Diabetes and Smoking.

Date: January 6, 2009.

Time: 1 p.m. to 2:30 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: Anna L. Riley, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301-435-2889, rileyann@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, Member Conflicts in Microbiology.

Date: January 8-9, 2009.

Time: 8:30 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Guangyong Ji, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301-435-1146.

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, EPIC Member Conflicts SEP.

Date: January 15, 2009.

Time: 10:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Elisabeth Koss, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3152, MSC 7770, Bethesda, MD 20892, (301) 435-1721, kosse@csr.nih.gov.

Name of Committee: Center for Scientific Review, Special Emphasis Panel, Infectious Diseases and Microbiology Member SEP.

Date: January 21–22, 2009.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Soheyla Saadi, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301-435-0903, saadisoh@csr.nih.gov.

Name of Committee: Digestive Sciences Integrated Review Group, Hepatobiliary Pathophysiology Study Section.

Date: February 2–3, 2009.

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

Agenda: To review and evaluate grant applications.

Place: DoubleTree Hotel & Executive Meeting Center, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Rass M. Shayiq, PhD., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435-2359, shayiqr@csr.nih.gov.

Name of Committee: Cardiovascular Sciences Integrated Review Group, Lung Injury, Repair, and Remodeling Study Section.

Date: February 2–3, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ghenima Dirami, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4112, MSC 7814, Bethesda, MD 20892, 301-594-1321, diramig@csr.nih.gov.

Name of Committee: Oncological Sciences Integrated Review Group, Clinical Oncology Study Section.

Date: February 2–3, 2009.

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

Agenda: To review and evaluate grant applications

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Malaya Chatterjee, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 192, MSC 7804, Bethesda, MD 20892, 301-451-0131, chatterm@csr.nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Anterior Eye Disease Study Section.

Date: February 2–3, 2009.

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: Jerry L. Taylor, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301-435-1175, taylorje@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience, Integrated Review Group, Molecular Neuropharmacology and Signaling Study Section.

Date: February 2–3, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Suffer, San Francisco, CA 94102.

Contact Person: Deborah L. Lewis, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7850, Bethesda, MD 20892, 301-435-1224, lewisdeb@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience, Integrated Review Group, Cognitive Neuroscience Study Section.

Date: February 2, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 W. Mission Bay Drive, San Diego, CA 92109.

Contact Person: Judith A. Finkelstein, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5178, MSC 7844, Bethesda, MD 20892, 301-435-1249, jinkelsj@csr.nih.gov.

Name of Committee: Digestive Sciences Integrated Review Group, Gastrointestinal Cell and Molecular Biology Study Section.

Date: February 2, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Najma Begum, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, MSC 7818, Bethesda, MD 20892, 301-435-1243, begumn@csr.nih.gov.

Name of Committee: Cardiovascular Sciences Integrated Review Group,

Atherosclerosis and Inflammation of the Cardiovascular System Study Section.

Date: February 2–3, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Larry Pinkus, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435-1214, pinkusl@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience, Integrated Review Group, Biological Rhythms and Sleep Study Section.

Date: February 2, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 W. Mission Bay Drive, San Diego, CA 92109.

Contact Person: Michael Selmanoff, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1208, MSC 7844, Bethesda, MD 20892, 301-435-1119, mselmanoff@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience, Integrated Review Group, Neurotoxicology and Alcohol Study Section.

Date: February 2–3, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 W. Mission Bay Drive, San Diego, CA 92109.

Contact Person: Brian Hoshaw, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7844, Bethesda, MD 20892, 301-435-1033, hoshawb@csr.nih.gov.

Name of Committee: Risk, Prevention and Health Behavior, Integrated Review Group Behavioral Medicine, Interventions and Outcomes Study Section.

Date: February 2–3, 2009.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: Lee S. Mann, JD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301-435-0677, mannl@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience, Integrated Review Group Somatosensory and Chemoreceptor Systems Study Section.

Date: February 3–4, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 W. Mission Bay Drive, San Diego, CA 92109.

Contact Person: Daniel R. Kenshalo, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, 301-435-1255, kenshalod@csr.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience, Integrated Review Group Neuroendocrinology, Neuroimmunology, and Behavior Study Section.

Date: February 3-4, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 W. Mission Bay Drive, San Diego, CA 92109.

Contact Person: Michael Selmanoff, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892, 301-435-1119, mselmanoff@csr.nih.gov.

Name of Committee: Genes, Genomes, and Genetics, Integrated Review Group, Molecular Genetics C Study Section.

Date: February 3-4, 2009.

Time: 8 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications

Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037

Contact Person: Barbara Whitmarsh, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, 301-435-4511, whitmarshb@csr.nih.gov.

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

Date: February 3-4, 2009.

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

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Mike Radtke, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892, 301-435-1728, rادتke@csr.nih.gov.

Name of Committee: Cardiovascular Sciences Integrated Review Group, Respiratory Integrative Biology and Translational Research Study Section.

Date: February 3-4, 2009.

Time: 8:30 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Everett E. Sinnett, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, (301) 435-1016, sinnett@nih.gov.

Name of Committee: Infectious Diseases and Microbiology, Integrated Review Group, Host Interactions with Bacterial Pathogens Study Section.

Date: February 4-5, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar, 2121 P Street, NW., Washington, DC 20037.

Contact Person: Marian Wachtel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3208, MSC 7858, Bethesda, MD 20892, 301-435-1148, wachtelm@csr.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics B Study Section.

Date: February 4-5, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.

Contact Person: Richard A. Currie, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, (301) 435-1219, currieri@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: December 11, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-30118 Filed 12-18-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 publication(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 on Alcohol Abuse and Alcoholism Special Emphasis Panel, Review of New Investigators' Grant Applications.

Date: March 17, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel, at the Chevy Chase Pavilion, 4300 Military Road, Washington, DC 20015.

Contact Person: Katrina L Foster, PhD, Scientific Review Officer, National Inst on Alcohol Abuse & Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rm. 2019, Rockville, MD 20852, 301-443-4032, katrina@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: December 12, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-30119 Filed 12-18-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, Review of Conflicted Applications.

Date: March 17, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel, At the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rm 2081, Rockville, MD 20852, 301-443-0800, bbuzas@mail.nih.gov.