

3. Provides development and assessment of methodologies and best practices for active and passive surveillance systems and for incorporating such data, when appropriate, into the review of the postmarketing safety of drugs.

4. Reviews and analyzes drug utilization information.

5. Performs epidemiologic research on drug safety issues.

6. Provides epidemiologic and drug utilization expertise to support medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations and related documents.

7. Provides input on epidemiologic and drug utilization aspects of information for the public related to significant postmarketing safety information regarding drugs, biologics, devices, and foods.

8. Develops and implements internal MAPPs and guidance on epidemiologic and drug utilization initiatives.

Division of Epidemiology II

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and analyzes epidemiologic study protocols and results of epidemiologic studies submitted by industry from the literature or other sources that are related to the postmarketing safety of drugs.

3. Provides for the development and assessment of methodologies and best practices for scientifically-sound observational studies related to postmarketing safety of drugs.

4. Reviews and analyzes drug utilization information.

5. Performs epidemiologic research on drug safety issues.

6. Provides epidemiologic and drug utilization expertise to support medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations and related documents.

7. Provides input on epidemiologic and drug utilization aspects of information for the public related to significant postmarketing safety information regarding drugs, biologics, devices, and foods.

8. Develops and implements internal MAPPs and guidance on epidemiologic and drug utilization initiatives.

Division of Pharmacovigilance I

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and provides analysis of adverse event reports from industry submissions and from reports submitted directly to FDA related to marketed drugs in order to detect safety signals and evaluate risk; and performs followup when such signals are detected.

3. Provides development and assessments of methodologies and best practices for scientifically-sound safety signal detection and drug risk evaluation related to the postmarketing safety of drugs.

4. Provides safety signal detection and drug risk evaluation support to medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations.

5. Provides recommendations on safety signal detection and drug risk evaluation aspects of proposed and implemented RiskMAPs or RMPs.

6. Provides input on signal detection and drug risk evaluation included in information for the public related to significant safety information regarding drugs, biologics, devices, and foods.

7. Develops and implements internal MAPPs and guidance on safety signal detection and drug risk evaluation initiatives.

Division of Pharmacovigilance II

1. Provides leadership, direction, planning, budgeting, management, and supervision of Division programs and staff.

2. Reviews and provides analyses of adverse event reports from industry submissions and from reports submitted directly to FDA related to marketed drugs in order to detect safety signals and evaluate risk; performs followup when such signals are detected.

3. Provides development and assessment of methodologies and best practices for scientifically-sound safety signal detection and drug risk evaluation related to the postmarketing safety of drugs.

4. Provides safety signal detection and drug risk evaluation support to medical review divisions in areas of responsibility, as well as, for Advisory Committee presentations.

5. Provides recommendations on safety signal detection and drug risk evaluation aspects of proposed and implemented RiskMAPs or RMPs.

6. Provides input on signal detection and drug risk evaluation included in information for the public related to significant safety information regarding drugs, biologics, devices, and foods.

7. Develops and implements internal MAPPs and guidance on safety signal detection and drug risk evaluation initiatives.

III. Delegation of Authority

Pending further delegation, directives or orders by the Commissioner of the Food and Drugs or the Center Director, CDER, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

Dated: April 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-8313 Filed 4-6-11; 8:45 am]

BILLING CODE 4160-01-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. 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: National Institute of Environmental Health Sciences Special Emphasis Panel, Baseline Study For Arsenic Exposure.

Date: April 27, 2011.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Sally Eckert-Tilotta, Ph.D., Scientific Review Administrator, Nat. Institute of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233 MD EC-30, Research Triangle Park, NC 27709, (919) 541-1446, eckertt1@niehs.nih.gov.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Loan Repayment Program.

Date: May 2, 2011.

Time: 1 p.m. to 5 p.m.

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, (Virtual Meeting).

Contact Person: RoseAnne M. McGee, Associate Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-0752, mcgee1@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: March 31, 2011.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-8316 Filed 4-6-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Center for Scientific Review Advisory Council.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Center for Scientific Review Advisory Council.

Date: May 2, 2011.

Time: 8:15 a.m. to 4 p.m.

Agenda: Provide advice to the Director, Center for Scientific Review (CSR), on matters related to planning, execution, conduct, support, review, evaluation, and receipt and referral of grant applications at CSR.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room E1/E2, Bethesda, MD 20892.

Contact Person: Cheryl A. Kitt, Ph.D., Executive Secretary, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3030, MSC 7776, Bethesda, MD 20892, 301-435-1112, kittc@csr.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(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: March 31, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-8315 Filed 4-6-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of 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 National Advisory Council for Complementary and Alternative Medicine (NACCAM) meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract Proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine.

Date: June 3, 2011.

Closed: June 3, 2011, 8:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Open: June 3, 2011, 11 a.m. to 4 p.m.

Agenda: Opening remarks by the Director of the National Center for Complementary and Alternative Medicine, presentation of a new research initiative, and other business of the Council.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Martin H. Goldrosen, Ph.D., Executive Secretary, Director, Division of Extramural Activities, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594-2014.

The public comments session is scheduled from 3:30 to 4 p.m. on June 3, 2011, but could change depending on the actual time spent on each agenda item. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives of organizations are requested to notify Dr. Martin H. Goldrosen, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland, 20892, 301-594-2014, Fax: 301-480-9970. Letters of intent to present comments, along with a brief description of the organization represented, should be received no later than 5 p.m. on May 26, 2011. Only one representative of an organization may present oral comments. Any person attending the meeting who does not request an opportunity to speak in advance of the meeting may be considered for oral presentation, if time permits, and at the discretion of the Chairperson. In addition, written comments may be submitted to Dr. Martin H. Goldrosen at the address listed above up to ten calendar days (June 13, 2011) following the meeting.

Copies of the meeting agenda and the roster of members will be furnished upon request by contacting Dr. Martin H. Goldrosen, Executive Secretary, NACCAM, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland 20892, 301-594-2014, Fax 301-480-9970, or via e-mail at naccames@mail.nih.gov.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: nccam.nih.gov/about/naccam, where an