DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Eye Institute; 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 Eye Institute Special Emphasis Panel, NEI Institutional Training Grant Applications II
Date: September 1, 2010.
Time: 12:30 p.m. to 1:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, NEI, 5635 Fliers Lane, Rockville, MD 20892.
(Telephone Conference Call)
Contact Person: Anne E. Schaffner, PhD, Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fliers Lane, Suite 1300, MSC 9300, 301–451–2020, aes@nei.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. 93.867, Vision Research, National Institutes of Health, HHS

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

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2010–N–0001]
Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.
General Function of the Committee: To provide advice and recommendations to the agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on September 20, 2010, from 8 a.m. to 5 p.m.


Contact Person: Anuja Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., White Oak Bldg. 32, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8540, email: anuja.patel@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency’s Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 22–512, dabigatran etexilate mesylate capsules, sponsored by Boehringer Ingelheim Pharmaceuticals, Inc., for the proposed indication of prevention of stroke in patients with atrial fibrillation (abnormally rapid contractions of the atria, the upper chambers of the heart).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 8, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 30, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to select the speakers for the scheduled open public hearing session. The contact person will...
notify interested persons regarding their request to speak by August 31, 2010.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Anuja Patel at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.


Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 a meeting of the National Advisory Child Health and Human Development 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.

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 material, 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 Child Health and Human Development Council.

Date: September 20, 2010.

Open: 8 a.m. to 12:20 p.m.

Agenda: (1) A report by the Director, NICHD; (2) Developmental Biology, Genetics and Teratology Presentation; (3) a discussion on the planning of the NICHD Science Vision; and other business of the Council.

Place: National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

Closed: 12:20 p.m. to 5 p.m.

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

Place: National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Conference Room 6, Bethesda, MD 20892.

Contact Person: Yvonne T. Maddox, PhD, Deputy Director, National Institute of Child Health and Human Development, NIH, 9000 Rockville Pike, MSC 7510, Building 31, Room 2A03, Bethesda, MD 20892, (301) 496–1848.

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 taxi, 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: http://www.nichd.nih.gov/about/nachhd.htm, where an agenda and any additional information for the meeting will be posted when available.

In order to facilitate public attendance at the open session of Council, reserve seating will be made available to the first five individuals reserving seats in the main meeting room, Conference Room 6. Please contact Ms. Lisa Kaeser, Program and Public Liaison Office, NICHD, at 301–496–0536 to make your reservation. Additional seating will be available in the meeting overflow rooms, Conference Rooms 7 and 8. Individuals will also be able to view the meeting via NIH Videocast. Please go to the following link for Videocast access instructions: http://www.nichd.nih.gov/about/overview/advisory/nachhd/virtual-meeting-201010.cfm. The meeting is partially closed to the public.

(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)


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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 a meeting of the Board of Scientific Counselors, NIDDK.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Diabetes and Digestive and Kidney Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDDK.

Date: October 14–15, 2010.

Time: October 14, 2010, 8:15 a.m. to 3 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive, Conference Room 9S235, Bethesda, MD 20892.

Time: October 15, 2010, 8:15 a.m. to 4 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 10 Center Drive, Conference Room 9S235, Bethesda, MD 20892.

Contact Person: IRA W. LEVIN, PhD, Director, Division of Intramural Research, National Institute of Diabetes and Digestive and Kidney Diseases, NIH, Bethesda, MD 20892, 301–496–6844, iwlev@helix.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 taxi, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one