

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: June 26, 2009.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-15689 Filed 7-1-09; 8:45 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. 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; Informatics Training for Global Health.

Date: July 13, 2009.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

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; Biology of Development and Aging SBIR/STTR Review.

Date: July 13, 2009.

Time: 1 p.m. to 5 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: Dan D. Gerendasy, PhD, Scientific Review Administrator, 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; Member Conflicts: Integrative Neuroscience.

Date: July 14-15, 2009.

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

Agenda: To review and evaluate grant applications.

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

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.

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 Conflict: Ethanol and Neurotoxicology.

Date: July 15-16, 2009.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Christine L. Melchior, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435-1713, melchioc@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; Neurodevices and Neuroimaging.

Date: July 17, 2009.

Time: 2 p.m. to 5 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: Vilen A. Movsesyan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040M, MSC 7806, Bethesda, MD 20892, 301-402-7278, movsesyanv@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; Diversity Fellowships: Division of Translational and Clinical Sciences.

Date: July 23, 2009.

Time: 8 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: Lee Rosen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435-1171, rosenl@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Disease Revision Grant Applications.

Date: July 23-24, 2009.

Time: 8 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: Alexander D. Politis, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, (301) 435-1150, politisa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; OBT Competitive Revision Applications.

Date: July 23-24, 2009.

Time: 1 p.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: Cathleen L. Cooper, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892, 301-435-3566, cooperc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Chronic Fatigue Syndrome, Fibromyalgia Syndrome, Temporomandibular Disorders.

Date: July 28-29, 2009.

Time: 8 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: Lynn E. Luethke, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 435-1018, luethkel@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Diabetes, Obesity, Nutrition and Reproductive Sciences.

Date: July 30-31, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Krish Krishnan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435-1041, krishnak@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Developmental Pharmacology.

Date: August 4–5, 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: Janet M. Larkin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7840, Bethesda, MD 20892, 310-435-1026, larkinja@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: June 26, 2009.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Circulatory System Devices Panel of the Medical Devices 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices 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 July 22 and 23, 2009, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: James Swink, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4050, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512625. 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: On July 22, 2009, the committee will discuss, make recommendations, and vote on a Humanitarian Device Exemption (HDE) application, sponsored by Medtronic, Inc., for the MEDTRONIC MELODY Transcatheter Pulmonary Valve (Model PB10) and MEDTRONIC ENSEMBLE Transcatheter Valve Delivery System (NU10). The MEDTRONIC MELODY Transcatheter Pulmonary Valve (Model PB10) and MEDTRONIC ENSEMBLE Transcatheter Valve Delivery System (NU10) is indicated for use in patients with the following clinical conditions:

Regurgitant (insufficient or leaky)

Right Ventricular Outflow Tract (RVOT)—The right ventricular outflow tract is that portion of the right ventricle leading up to the pulmonary valve and pulmonary artery. When the ventricles contract, blood moves along the outflow tract and through the pulmonary valve; blood then flows to the lungs where gas exchange takes place.

Conduits—In the context of this device, a surgically implanted tube that allows blood to pass from the heart to the pulmonary arteries.

- *Stenotic* (stiff valve leaflets that cannot open or close properly) RVOT conduits where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting.

- *Existence of a full* (circumferential) RVOT conduit that was equal to or greater than 16 millimeters (mm) in diameter when originally implanted.

On July 23, 2009, from 8 a.m. to 10 a.m., and from 1 p.m. to 6 p.m., the committee will discuss general questions about adhesion barriers for cardiovascular use. Some of these questions will focus on understanding the target population (pediatric and/or adult) that would benefit from these devices and the development of appropriate endpoints for a clinical trial.

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>, click on the year 2009, scroll down to the appropriate advisory committee link.

Procedure: On July 22, 2009, from 8 a.m. to 6 p.m., and on July 23, 2009, from 8 a.m. to 10 a.m. and from 1 p.m. to 6 p.m., the meeting is open to the public. 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 July 15, 2009. Oral presentations from the public will be scheduled approximately 30 minutes at the beginning of committee deliberations and approximately 30 minutes near the end of the deliberations. 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 July 7, 2009. 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 determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 8, 2009.

Closed Presentation of Data: On July 23, 2009, from 10 a.m. to 12 noon, the meeting will be closed to permit discussion and review of trade secret and confidential commercial information (5 U.S.C. 552b(c)(4)) related to the design of a potential clinical trial.

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 AnnMarie Williams, Conference Management Staff, at 240-276-8932, at least 7 days in advance of the meeting. FDA is committed to the orderly conduct of its advisory committee meetings. Please