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: Anti-Infective 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 November 28, 2012, from 8 a.m. to 5 p.m.

Location: DoubleTree by Hilton Hotel Washington DC—Silver Spring, The Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel’s phone number is 301–589–5200.

Contact Person: Diane Goyette, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: AIDAC6@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8136 (301–433–0572 in the Washington, DC area). 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 at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of new drug application (NDA) 204384, bedaquiline tablets, submitted by Janssen Therapeutics, Division of Janssen Products, LP. The proposed indication (use) for this product is for the treatment of patients with multi-drug resistant pulmonary tuberculosis.

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 meeting 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 November 13, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making 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 November 2, 2012. 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 November 5, 2012.

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 Diane Goyette 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.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 18, 2012.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.
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; Program Projects: Fungal Secondary Metabolites.

Date: October 23–24, 2012.
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, (Telephone Conference Call).

Name of Committee: Center for Scientific Review Special Emphasis Panel; Research Enhancement Review.

Date: October 24, 2012.
Time: 8 a.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Drug Discovery for the Nervous System.

Date: October 24, 2012.
Time: 1:30 p.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group; Electrical Signaling, Ion Transport, and Arrhythmias Study Section.

Date: October 25, 2012.
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.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Acute Neural Injury and Epilepsy Study Section.

Date: October 25–26, 2012.
Time: 8 a.m. to 12 p.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Molecular Oncogenesis Study Section.

Date: October 25–26, 2012.
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.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Rehabilitation Sciences Study Section.

Date: October 25–26, 2012.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Name of Committee: Cognitive Neuroscience and Arrhythmias Study Section.

Date: October 26, 2012.
Time: 8 a.m. to 12 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Name of Committee: Rehabilitation Integrated Review Group; Acute Neural Injury and Epilepsy Study Section.

Date: October 26, 2012.
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.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Acute Neural Injury and Epilepsy Study Section.

Date: October 25–26, 2012.
Time: 8 a.m. to 12 p.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Avenue NW., Washington, DC 20037.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Molecular Oncogenesis Study Section.

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Date: October 25–26, 2012.
Time: 8 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.