DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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.


Date: July 27, 2010.

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.

(Telephone Conference Call.)

Contact Person: Holly K Krull, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892–7924. 301–435–0280. krullh@nhlbi.nih.gov

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel.

Date: July 16, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: William J Johnson, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892–7924. 301–435–0725. johnsonw@nhlbi.nih.gov

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Coordinating Center for Systems Biology Approach to the Mechanisms of Tuberculosis (TB) Latency and Reactivation.

Date: July 16, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sahira Rafiullah, MD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7178, Bethesda, MD 20892–7924. 301–435–0250. rafiullah@nhlbi.nih.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps (NHSC).

Date and Time: August 4, 2010, 9 a.m.–4 p.m.


Status: The meeting will be open to the public.

Agenda: The Council will be convening in Washington, DC to hear updates on the NHSC program and to review and discuss the NHSC's vision, mission and values statements.

FOR FURTHER INFORMATION CONTACT:

Njeri Jones, Bureau of Clinician Recruitment and Service, Health Resources and Services Administration, Parklawn Building, Room 8A–46, 5600 Fishers Lane, Rockville, MD 20857; e-mail: njones@hrsa.gov; telephone: 301–443–2541.


Sahira Rafiullah,
Director, Division of Policy Information and Coordination.

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BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management 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 Committees: Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee.
General Function of the Committees: To provide advice and recommendations to the agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on August 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., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: anuja.patel@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512532 and 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: On August 20, 2010, the committees will discuss new drug application (NDA) 22–531, sodium oxybate, 375 milligrams per milliliter (mg/ml) oral solution, sponsored by Jazz Pharmaceuticals, with a proposed indication for the treatment of fibromyalgia for patients 18 years of age and older. The safety and efficacy findings for sodium oxybate in the fibromyalgia population and the proposed Risk Evaluation and Mitigation Strategy (REMS) for this product will be discussed.

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 August 6, 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 July 29, 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 determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 30, 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/ucm11462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under 5 U.S.C. app. 2). Dated: June 18, 2010.

Thinh Nguyen,
Acting Associate Commissioner for Special Medical Programs.

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: Peripheral and Central Nervous System 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 August 11, 2010, from 8 a.m. to 5 p.m.


Contact Person: Dien-Kieu Ngo, 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: diem.ngo@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512543. 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 August 11, 2010, the committee will discuss new drug application (NDA) 22–345, with the proposed trade name POTIGA (ezogabine) Tablets, by Valeant Pharmaceuticals North America. The proposed indication for this new drug product is adjunctive therapy in patients with partial-onset seizures.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2010–N–0001]

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.