

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.

Location: Bethesda Marriott, The Ballrooms, 5151 Pooks Hill Rd., Bethesda, MD. The hotel phone number is 301-897-9400.

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 3014512535. 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/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: June 18, 2010.

Thin Nguyen,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-15507 Filed 6-24-10; 8:45 am]

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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.

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.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301-589-5200.

Contact Person: Diem-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.

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 July 28, 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 20, 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 21, 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 Diem-Kieu Ngo 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: June 18, 2010.

Think Nguyen,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-15504 Filed 6-24-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 Institute of Child Health and Human Development Initial Review Group Obstetrics and Maternal-Fetal Biology Subcommittee.

Date: July 12, 2010.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Legacy Hotel and Meeting Center, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Peter Zelazowski, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child, Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6902, PETER.ZELAZOWSKI@NIH.GOV.

(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)

Dated: June 21, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-15491 Filed 6-24-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 USC, as amended. The grant applications 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, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Medications Development for Substance Related Disorders (R01).

Date: July 7-8, 2010.

Time: 9 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Jose F. Ruiz, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Blvd., Bethesda, MD 20892. 301-451-3086. ruizjf@nida.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Medications Development for Cannabis-Related Disorders (R01).

Date: July 8, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Jose F. Ruiz, PhD, Scientific Review Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Blvd., Bethesda, MD 20892. 301-451-3086. ruizjf@nida.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, NIDA-K Conflicts SEP.

Date: July 13, 2010.

Time: 5:30 p.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Eliane Lazar-Wesley, PhD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401. 301-451-4530. elazarwe@nida.nih.gov.