

with a “vCJD-implicated” plasma-derived coagulation factor VIII (pdFVIII) and whether this information or any other recent scientific information about the vCJD epidemic substantially alters FDA’s risk assessment for U.S.-licensed preparations of pdFVIII products. In the afternoon the committee will hear informational presentations on animal models of vCJD, diagnostic test development for transmissible spongiform encephalopathies (TSEs) and bovine spongiform encephalopathy (BSE) surveillance and risk management.

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 will be available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2009 and 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 June 4, 2009. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:15 a.m. and between 5:00 p.m. and 5:30 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 May 26, 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 May 28, 2009.

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 William Freas or Rosanna Harvey 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/oc/advisory/default.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: April 28, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–10454 Filed 5–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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: National Center for Research Resources Special Emphasis Panel. RCMI 1.

Date: June 10–11, 2009.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Steven Birken, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., Dem. 1, Room 1078, MSC 4874, Bethesda, MD 20892–4874. 301–435–0815. birkens@mail.nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel. Comparative Medicine.

Date: July 9, 2009.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Guo Zhang, MD, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Rm. 1064, Bethesda, MD 20892–4874. 301–435–0812. zhanggu@mail.nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel. Pre-application for a Biomedical Technology Research Resource.

Date: July 20, 2009.

Time: 8 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Martha F. Matocha, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Rm. 1070, Bethesda, MD 20892. 301–435–0810. matocham@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: April 29, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–10444 Filed 5–5–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health;

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 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel. SBIR Contract Review.

Date: May 20, 2009.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Aileen Schulte, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892-9608. 301-443-1225. aschulte@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: April 29, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-10430 Filed 5-5-09; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0197]

Psychopharmacologic 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:

Psychopharmacologic 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 June 9, 2009 from 8 a.m. to 6 p.m. and June 10, 2009, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to <http://www.regulations.gov>. Enter "FDA-2009-N-0197 Use of Antipsychotics for Schizophrenia and Bipolar Disorder in Pediatric and Adolescent Patients" and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm.

1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. Comments received on or before May 26, 2009, will be provided to the committee before the meeting.

Location: Marriott Conference Centers, UMUC Inn and Conference Center, 3501 University Blvd. East, Adelphi, MD. The hotel telephone number is 301-985-7385.

Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: diem.ngo@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512544. 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 both days, the committee will discuss safety and efficacy issues for the following new drug applications (NDAs): (1) NDA 20-639/S-045 and S-046: SEROQUEL (quetiapine fumarate) Tablets, AstraZeneca Pharmaceuticals LP, for the acute treatment of schizophrenia in adolescents from 13 to 17 years of age, and the acute treatment of bipolar mania in children from 10 to 12 years of age and adolescents from 13 to 17 years of age; (2) NDA 20-825/S-032: GEODON (ziprasidone hydrochloride) Capsules, Pfizer Inc., for the acute treatment of manic or mixed episodes associated with bipolar disorder, with or without psychotic features in children and adolescents ages from 10 to 17 years of age; and (3) NDA 20-592/S-040 and S-041: ZYPREXA (olanzapine) Tablets, Eli Lilly and Co., for the acute treatment of manic or mixed episodes associated with bipolar I disorder and the acute treatment of schizophrenia in adolescents. The committee will be asked to vote on whether or not these products have been shown to be effective and acceptably safe for these pediatric indications.

FDA intends to make background material available to the public no later than 2 business days before the meeting.

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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 May 26, 2009. Oral presentations from the public will be scheduled between approximately 4 p.m. and 6 p.m. on June 9, 2009. 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 May 22, 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 May 26, 2009.

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