

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 April 7 and 8, 2009, from 8 a.m. to 5 p.m.

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

Contact Person: Yvette Waples, 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:

yvette.waples@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 hotline/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 7, 2009, the committee will discuss safety and efficacy issues of new drug application (NDA) 20-644, sertindole (Serdolect) tablets, Lundbeck USA, proposed for the treatment of schizophrenia. On April 8, 2009, the committee will discuss safety and efficacy issues of supplemental new drug applications (sNDAs) 22-047/S-010/S-011/S-012, quetiapine b6 maleate (Seroquel XR), Astra Zeneca Pharmaceuticals LP, proposed for the treatment of major depressive disorder and 22-047/S-014/S-015, Seroquel XR (quetiapine maleate), Astra Zeneca Pharmaceuticals LP, proposed for the treatment of generalized anxiety disorder. Particular safety issues for discussion on April 8, 2009, regarding the Seroquel XR applications are concerns regarding exposing a greatly expanded population to a drug with known metabolic side effects and a possible risk of tardive dyskinesia.

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/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 March 27, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. 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 March 18, 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 March 23, 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 John Luttman 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: February 26, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9-4523 Filed 3-3-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Reimbursement of Travel and Subsistence Expenses Toward Living Organ Donation Eligibility Guidelines

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Request for comments on proposed change to the Reimbursement of Travel and Subsistence Expenses Program Eligibility criteria.

SUMMARY: HRSA published the final eligibility guidelines for the Reimbursement of Travel and Subsistence Expenses Program in the **Federal Register** on October 5, 2007 (72 FR 57049). A subsequent amendment to the Program guidelines was published in the **Federal Register** on June 20, 2008 (73 FR 35143). HRSA is requesting public comments concerning recommended changes to a specific section of the reimbursement program eligibility guidelines. On page 35145, under the *Qualifying Expenses* Section, the first paragraph states:

For the purposes of the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program, *qualifying expenses* presently include only travel, lodging, and meals and incidental expenses incurred by the donor and/or his/her accompanying person(s) as part of:

- (1) Donor evaluation, clinic visit or hospitalization,
- (2) Hospitalization for the living donor surgical procedure, and/or
- (3) Medical or surgical follow-up clinic visit or hospitalization within 90 days following the living donation procedure.

HRSA wishes to amend the first item of this paragraph to read: "(1) Donor evaluation (including, if applicable, clinic visits or hospitalization) and/or". This is a technical change to clarify that the expenses referred to are all related to the donor evaluation. In addition, HRSA wishes to amend the third item of this paragraph to read: "(3) Medical or surgical follow-up, clinic visits, or hospitalization within 2 calendar years following the living donation procedure (or beyond the 2-year period if exceptional circumstances exist)." This change in the follow-up period would bring the National Living Donor Assistance Center follow-up period in line with the Organ Procurement and Transplantation Network policy requiring follow-up of living organ donors for a period of 2 years. Adding the exceptional circumstances language at the end of this item would allow reimbursement for post-surgical follow-

up beyond the anticipated 2-year period in unusual circumstances.

HRSA is requesting your comments on this specific section.

DATES: Written comments must be submitted to the office in the address section below by mail or e-mail on or before April 3, 2009.

ADDRESSES: Please send all written comments to Richard Durbin, Acting Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Room 12C-06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301) 594-6095; or e-mail: rdurbin@hrsa.gov.

FOR FURTHER INFORMATION CONTACT:

Richard Durbin, Acting Director, Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 12C-06, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301) 594-6095; or e-mail: rdurbin@hrsa.gov.

Dated: February 12, 2009.

Elizabeth M. Duke,
Administrator.

[FR Doc. E9-4519 Filed 3-3-09; 8:45 am]

BILLING CODE 4165-15-P

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. Appendix 2), 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; Special: Biomaterials and Biointerfaces.

Date: March 9, 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, (Telephone Conference Call).

Contact Person: Ross D. Shonat, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7849, Bethesda, MD 20892, 301-435-2786, shonatr@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; Growth Factors, Cell Migration and Mechanosensors.

Date: March 10, 2009.

Time: 11 a.m. to 1 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: Joseph D. Mosca, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7808, Bethesda, MD 20892, (301) 435-2344, moscajos@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; DIG Member Conflicts.

Date: March 11, 2009.

Time: 3 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: Ryan G. Morris, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4205, MSC 7814, Bethesda, MD 20892, 301-435-1501, morrisr@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; ZRG1 CB P 40 P: Program Project: WNT Signaling.

Date: March 16-17, 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: Elena Smirnova, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301-435-1236, smirnov@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; Review of Fellowships for Training in HIV Research.

Date: March 18-19, 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: Mary Clare Walker, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435-1165, walkermc@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; Nature's Solutions.

Date: March 18, 2009.

Time: 2 p.m. to 3:30 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: Anshumali Chaudhari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435-1210, chaudhaa@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; RFA/PA # RMO8-019 Membrane Protein Production Centers.

Date: March 23-24, 2009.

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.

Contact Person: Nuria E. Assa-Munt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451-1323, assamunu@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biobehavior and Addiction.

Date: March 24, 2009.

Time: 9 a.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Biao Tian, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3089B, MSC 7848, Bethesda, MD 20892, (301) 402-4411, tianbi@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Epidemiology and Genetics Member Conflict Reviews.

Date: March 31, 2009.