

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: AIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 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.

[FR Doc. 2012-23573 Filed 9-25-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****Epilepsy Program**

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Noncompetitive Program Expansion Supplemental Award to the Epilepsy Foundation of America.

SUMMARY: The Health Resources and Services Administration will be issuing noncompetitive supplemental funding under the Maternal and Child Health Bureau's Epilepsy Program to the Epilepsy Foundation of America (U23MC19824) to support additional evaluation activities.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Epilepsy Foundation of America.

Amount of the Noncompetitive Supplemental Funding: \$250,700.

Authority: Section 501(a)(2) of the Social Security Act, as amended.

CFDA Number: 93.110.

Project Period: September 1, 2012, through August 31, 2013, for a total of 12 months.

Justification for the Exception to Competition: The Epilepsy Foundation of America currently contracts with Mathematica to evaluate the HRSA Epilepsy Program. There is a need to increase their allotted award through program expansion supplemental funds to support additional evaluation activities for Year 3. Mathematica will conduct a more comprehensive evaluation of the entire Epilepsy Program in order to determine the extent to which the program has addressed the legislative requirements, increased access to care in medically underserved areas, and developed/implemented evidence-based strategies to achieve the legislative purpose of the program. As a result of the evaluation, a quality improvement strategy for the Epilepsy Program will be developed and implemented by the Quality Improvement (QI) contractor. Results should provide a more comprehensive understanding of the impact across the entire program. Indicators and measures developed will also be used for the next competitive cycle to track performance, quality and outcomes within the context of the legislation and the newly published Institute of Medicine recommendations for the Epilepsies, focusing on evaluating prevention efforts.

Mathematica, John Snow Inc. (QI Contractor), and the Epilepsy

Foundation of America will work collectively to develop an evaluation plan that will contain state, local, community/stakeholder and family perspectives on the overall impact of services for the Epilepsy Program.

FOR FURTHER INFORMATION CONTACT: Diana Denboba, Chief, Integrated Services Branch, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 13-61, Rockville, Maryland 20857, via email at ddenboba@hrsa.gov or call 301-443-2370.

Dated: September 20, 2012.

Mary K. Wakefield,
Administrator.

[FR Doc. 2012-23656 Filed 9-25-12; 8:45 am]

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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 10, 2012.

Time: 2 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: Richard Panniers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2212, MSC 7890, Bethesda, MD 20892, (301) 435-1741, pannierr@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; Small Business: Innovative Neuroscience K-12 Education.

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, (Virtual Meeting).

Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301-435-2406, ariasj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Surgical Sciences and Bioengineering.

Date: October 23, 2012.

Time: 12 p.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: Malgorzata Klosek, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7849, Bethesda, MD 20892, (301) 435-2211, klosekm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Healthcare Delivery and Methodologies Academic 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,

Contact Person: Melinda Jenkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892, 301-437-7872, jenkinsml2@mail.nih.gov.

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).

Contact Person: Geoffrey G. Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040-A, MSC 7850, Bethesda, MD 20892, 301-435-1235, geoffreys@csr.nih.gov.

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.

Contact Person: Yuanna Cheng, MD, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301)435-1195, Chengy5@csr.nih.gov.

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,

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237-9838, bhagavas@csr.nih.gov.

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.

Contact Person: Nywana Sizemore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892, 301-435-1718, sizemoren@csr.nih.gov.

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.

Contact Person: Jo Pelham, BA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4102, MSC 7814, Bethesda, MD 20892, (301) 435-1786, pelhamj@csr.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 19, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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