

Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

*Location:* Hilton Washington DC North/Gaithersburg, Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

*Contact Person:* Margaret McCabe-Janicki, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002, 301-796-7029, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 30 and 31, 2011, the committee will discuss and make recommendations on postmarketing issues related to silicone gel-filled breast implants. This meeting is regarding the discussion of different innovative methodological approaches to the conduct of postmarket studies regarding silicone gel breast implants. Additionally, the panel will discuss key long-term safety issues associated with silicone gel breast implants in the real-world setting.

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 24, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 3 p.m. on August 30, 2011, and between approximately 8 a.m. and 10 a.m. on August 31, 2011. 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 August 15, 2011. 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 August 17, 2011.

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 AnnMarie Williams, Conference Management Staff, 301-796-5966, 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 23, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-16952 Filed 7-6-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Design of Clinical Trials for Systemic Antibacterial Drugs for the Treatment of Acute Otitis Media; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop regarding the design of Clinical Trials for Systemic Antibacterial Agents for the Treatment of Acute Otitis Media. This public workshop is intended to provide information for and gain perspective from health care providers, patients and patient advocacy organizations, academia, and industry on various aspects of the design of clinical trials. The input from this public workshop will help in developing topics for further discussion.

*Dates and Times:* The public workshop will be held on September 7, 2011 from 8:30 a.m. to 5 p.m.

*Location:* The public workshop will be held at the Crowne Plaza, 8777 Georgia Ave., Silver Spring, MD 20910, 301-589-0800. Seating is limited and available only on a first-come, first-served basis.

*Contact Persons:* Christine Moser or Ramou Mauer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6193, Silver Spring, MD 20993-0002, 301-796-1300.

*Registration:* Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to [Otitisworkshop@fda.hhs.gov](mailto:Otitisworkshop@fda.hhs.gov). Persons without access to the Internet may call 301-796-1300 to register. Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner (see *Contact Persons*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** FDA is announcing a public workshop regarding scientific considerations in the design of clinical trials of antibacterial agents for the treatment of acute otitis media (middle ear infection). Discussions will focus on

appropriate endpoints for informative clinical trials, the role and effect of tympanocentesis (drainage of fluid from the middle chamber of the ear) in clinical trials, and the feasibility and acceptability of different kinds of clinical trial designs including superiority trial designs, the data available that might scientifically support feasible non-inferiority trial designs, and what additional data may be useful to scientifically support non-inferiority trial designs.

The Agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop. *Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet <http://www.fda.gov/Drugs/NewsEvents/ucm205809.htm> approximately 45 days after the workshop.

Dated: June 30, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-16962 Filed 7-6-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Cancer Institute Board of Scientific Advisors; caBIG® Oversight Ad hoc Subcommittee.

*Date:* July 25, 2011.

*Time:* 12 p.m. to 4 p.m.

*Agenda:* Evaluation of Scientific Merit of caBIG® program, ongoing and planned initiatives.

*Place:* Hilton Chicago O'Hare, Hilton Chicago O'Hare International Airport, Terminal 3, Access Road 5, Room 2051, Chicago, IL 60666.

*Contact Person:* John Czajkowski, MPA, Deputy Director for Management, Office of the Director, National Cancer Institute, National Institutes of Health, 31 Center Drive, Rm. 11A48, Bethesda, MD 20892, 301-435-2455, [john.czajkowski@nih.gov](mailto:john.czajkowski@nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/bsa.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 30, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-17075 Filed 7-6-11; 8:45 am]

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## 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 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 Mental Health Special Emphasis Panel; Fellowships and Dissertation Grants.

*Date:* July 20, 2011.

*Time:* 1:30 p.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* David W Miller, 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, 301-443-9734, [millerda@mail.nih.gov](mailto:millerda@mail.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.

(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: June 30, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-17073 Filed 7-6-11; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Aviation Security Advisory Committee

**AGENCY:** Transportation Security Administration, DHS.

**ACTION:** Committee Management; Notice of Federal Advisory Committee Re-Establishment.

**SUMMARY:** The Transportation Security Administration (TSA) announces the re-establishment of the Aviation Security Advisory Committee (ASAC). The Secretary of Homeland Security has determined that the re-establishment of ASAC is necessary and is in the public interest in connection with the performance of duties of TSA. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

**FOR FURTHER INFORMATION CONTACT:** Dean Walter, ASAC Designated Federal Official, Transportation Security Administration (TSA-28), 601 12th St. South, Arlington, VA 20598-4028, [Dean.Walter@dhs.gov](mailto:Dean.Walter@dhs.gov), 571-227-2645.

**SUPPLEMENTARY INFORMATION:**