DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 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 Phase II Topic 50.

Date: August 18, 2010.

Time: 1 p.m. to 3 p.m.

D. Step Four—Enter Your DFUF Order PIN and PCN

Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, 301–402–8152, mbroitma@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; SBIR Phase II Topic 50.

Date: August 20, 2010.

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: Marina Broitman, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, 301–402–8152, mbroitma@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)


Jennifer Spaeth.

Director, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Design of Clinical Trials of Aerosolized Antimicrobials for the Treatment of Cystic Fibrosis: 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 scientific issues in clinical development of aerosolized antimicrobials for the management and/or treatment of patients with cystic fibrosis. Aerosolized antimicrobials are used to treat chronic bacterial infection in the lungs and thus improve the respiratory symptoms in patients with cystic fibrosis. 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 of aerosolized antimicrobials in patients with cystic fibrosis. 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 23, 2010, from 8:30 a.m. to 5:30 p.m. and on September 24, 2010, from 8 a.m. to 4 p.m.

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

Contact Persons: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Antimicrobial Products, 10903 New Hampshire Ave., Bldg. 22, rm. 6209, Silver Spring, MD 20993–0002, 301–796–1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. 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 CFWORKSHOP@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 aerosolized antimicrobials to treat chronic bacterial infection in the lungs and thus improve the respiratory symptoms in patients with cystic fibrosis. The development of clinical trial endpoints to establish efficacy is a major challenge in the design of informative clinical trials of aerosolized antimicrobials for the management and/or treatment of patients with cystic fibrosis. The workshop will include discussion of clinical trial endpoints to establish efficacy, such as timing and definitions of pulmonary exacerbations, changes in the results of pulmonary function testing, and changes on patient reported outcome measures. An important consideration will be the evaluation of new aerosolized antimicrobials in the context of approved aerosolized antimicrobials on the basis of these or other efficacy endpoints. Other issues in the design of clinical trials of aerosolized antimicrobials include: The development of drug resistance and
other safety concerns, microbiologic testing such as sputum bacterial density, the utility of in-vitro susceptibility testing, and the need for pediatric use information.

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 (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, 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: July 29, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19008 Filed 8–2–10; 8:45 am]
BILLING CODE 4160–01–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. App.), notice is hereby given of the following meetings.

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Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Endocrinology and Obesity.

Date: August 17–18, 2010.

Time: 9 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: Ann A. Jerkins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6154, MSC 7892, Bethesda, MD 20892, 301–435–4514, jerkinsa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Oral Microbiology.

Date: August 25, 2010.

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: Baljit S. Moonga, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7806, Bethesda, MD 20892, 301–435–1777, moongabs@mail.nih.gov.


Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Library of Medicine; 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.

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Name of Committee: National Library of Medicine Special Emphasis Panel, Conflicted Applications.

Date: September 22, 2010.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20817. (Telephone Conference Call).

Contact Person: Zoe H. Huang, Scientific Review Officer, Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20817.