

you have any problems with this process, e-mail: reglist@cdhrh.fda.gov or call 301-796-7400 for assistance. (Note: this e-mail address and this telephone number are for assistance with establishment registration only, and not for any other aspects of medical device user fees.) Problems with BER should be directed to bloodregis@fda.hhs.gov or call 301-827-3546.

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

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to companies who only manufacture licensed biologics devices. Fees are only required for those establishments defined in section I of this document.

Dated: July 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-19038 Filed 8-2-10; 8:45 am]

BILLING CODE 4160-01-S

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 60.

Date: August 18, 2010.

Time: 1 p.m. to 3 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.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; SBIR Phase II Topic 59.

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)

Dated: July 28, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-19012 Filed 8-2-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 can 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. 2010-19044 Filed 8-2-10; 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, 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.

(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: July 28, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-19014 Filed 8-2-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Review of a Deferred Application.

Date: August 13, 2010.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Room 3AN12, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Mona R. Trempe, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301-594-3998, trempepmo@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. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: July 28, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-19008 Filed 8-2-10; 8:45 am]

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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.

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 materials, 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 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