

you have any problems with this process, e-mail: reglist@cdhr.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]

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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