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 a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended, for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Mental Health, including consideration of personnel qualifications and performances, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Mental Health.

Date: June 27–29, 2010.

Time: June 27, 2010, 7 p.m. to 10 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Time: June 28, 2010, 8:30 a.m. to 12:40 p.m.

Agenda: To review and evaluate the Intramural Laboratories with site visits of the Section on Cognitive Neuroscience, the Section on the Neurobiology of Learning and Memory, and the Unit on Learning and Plasticity and meetings with the PIs, Training Fellows, and Staff Scientists.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Time: June 28, 2010, 1 p.m. to 5 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Time: June 28, 2010, 7 p.m. to 10 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Time: June 29, 2010, 8:30 a.m. to 12:40 p.m.

Agenda: To review and evaluate the Intramural Laboratories with site visits of the Unit on Cognitive Neurophysiology and Imaging, the Section on Neural Coding and Computation, the Section on Critical Brain Dynamics, and meetings with the PIs, Training Fellows, and Staff Scientists.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Time: June 29, 2010, 1 p.m. to 4 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Dawn M. Johnson, PhD, Executive Secretary, Division of Intramural Research Programs, National Institute of Mental Health, 10 Center Drive, Building 10, Room 4N222, Bethesda, MD 20892, 301–402–5234, *dawnjohnson@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: June 1, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–13741 Filed 6–7–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Issues in the Development of Medical Products for the Prophylaxis and/or Treatment of Acute Antibody Mediated Rejection in Kidney Transplant Recipients; 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 medical products (i.e., human drugs, therapeutic biological products, and medical devices) for prophylaxis and/or treatment of acute antibody mediated rejection (AMR) in kidney transplant recipients. This public workshop is intended to provide information for and gain perspective from health care providers, academia, and industry on various aspects of development of medical products for prophylaxis and/or treatment of acute AMR in kidney transplant recipients, including clinical trial design and endpoints. The input from this public workshop will help in developing topics for further discussion.

Date and Time: The public workshop will be held on June 28, 2010, from 8 a.m. to 6:30 p.m. and on June 29, 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.

Contacts: Christine Moser or Ramou Mauer, 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 or 301–796–1600.

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 *AMRworkshop@fda.hhs.gov*. Persons without access to the Internet can call Christine Moser at 301–796–1300 or Ramou Mauer at 301–796–1600 to register. Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Ramou Mauer (see *Contacts*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding medical product development for the prophylaxis and/or treatment of acute AMR in kidney transplant recipients. This public workshop will focus on scientific considerations in the clinical development of medical products for prophylaxis and/or treatment of acute AMR in kidney transplant recipients, including the following topics:

- Definition and diagnosis of acute AMR
- Importance of validation and standardization of devices and diagnostic testing to establish the diagnosis of AMR and to identify patients at high risk of AMR
- Results of clinical trials evaluating treatment of acute AMR
- Endpoints to be evaluated to assess outcome
- Outcomes achieved with currently used regimens

Additional discussion will include animal models in AMR, previous experiences in desensitization and prophylaxis of AMR, and chronic AMR.

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