

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.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: March 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-4841 Filed 3-5-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; "Modeling Immunity for Biodefense".

Date: April 6-7, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate contract proposals.

Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Paul A. Amstad, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive,

MSC 7616, Bethesda, MD 20892-7616, 301-402-7098, pamstad@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Regulatory T cells in Autoimmune and Inflammatory Diseases.

Date: April 30, 2010.

Time: 11 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, 3118, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Sujata Vijh, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301-594-0985, vijhs@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 2, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-4836 Filed 3-5-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; 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: National Human Genome Research Institute Special Emphasis Panel; NHGRI MAP Review Teleconference Spring 2010.

Date: March 23, 2010.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: NHGRI Twinbrook Library, 5635 Fishers Lane, Suite 4076, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Keith McKenney, PhD, Scientific Review Officer, NHGRI, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814, 301-594-4280, mckenneyk@mail.nih.gov.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; LRP 2010 Teleconference.

Date: April 7, 2010.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: NHGRI Twinbrook Library, 5635 Fishers Lane, Suite 4076, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Keith McKenney, PhD, Scientific Review Officer, NHGRI, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814, 301-594-4280, mckenneyk@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: March 1, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-4839 Filed 3-5-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 13, 2010, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Anuja Patel, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: Anuja.Patel@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 301-451-2539. 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 April 13, 2010, the committee will receive presentations from the Office of Generic Drugs and discuss two bioequivalence topics relevant to generic drug approval: (1) Revising the BE approaches for critical dose drugs and (2) the use of partial area under the curve (AUC) for the evaluation of abbreviated new drug applications for products with complex pharmacokinetic profiles. Bioequivalence refers to the evaluation of equivalence in the rate and extent of drug absorption between two preparations of the same drug. Critical dose drugs are medicines that require a narrow (or "critical") dose range to achieve and maintain their intended effects and to reduce serious adverse drug reactions. The "area under the curve" is the area under a plot of drug concentration in the bloodstream versus time; it is a measure of the extent of exposure to a drug after a dose is administered.

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 March 30, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 March 22, 2010. 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 March 23, 2010.

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 Anuja Patel 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: March 2, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-4812 Filed 3-5-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; 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 Eye Institute Special Emphasis Panel; NEI Clinical Grant Applications and Cooperative Agreements.

Date: April 12, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Anne E Schaffner, PhD, Scientific Review Officer, Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, Msc 9300, Bethesda, MD 20892-9300, (301) 451-2020, aes@nei.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: February 25, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-4584 Filed 3-5-10; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, March 22, 2010, 8 a.m. to March 23, 2010, 5 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on February 24, 2010, 75 FR 8371-8372.

The meeting will be held March 29, 2010 to March 30, 2010. The meeting time and location remain the same. The meeting is closed to the public.

Dated: February 26, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-4589 Filed 3-5-10; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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