patient. The numerical values generated by susceptibility testing to determine whether a particular microorganism is susceptible to a particular antimicrobial drug—the antimicrobial susceptibility test interpretive criteria—are commonly referred to as breakpoints. These breakpoints are specified in the antimicrobial drug product's label. The antimicrobial susceptibility test interpretive criteria can be used to interpret results from either manual or automated AST devices.

On September 27, 2007, FDAAA (Public Law 110–85) was signed into law. Section 1111 of FDAAA requires FDA to identify and periodically update susceptibility test interpretive criteria for antibacterial drug products and to make those findings publicly available. By enacting section 1111 of FDAAA, Congress recognized the importance of maintaining updated susceptibility test interpretive criteria.

In the **Federal Register** of June 12, 2008 (73 FR 33438), FDA issued a draft guidance entitled ''Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' The draft guidance described procedures for FDA, drug application holders, and AST device manufacturers to ensure that updated susceptibility test information is available to health care providers. The draft guidance explained that where appropriate, FDA intends to identify susceptibility test interpretive criteria, quality control parameters, and susceptibility test methods by recognizing annually, in a **Federal Register** notice, standards developed by one or more nationally or internationally recognized standard development organizations. The draft guidance described, for holders of applications for approved antibacterial drug products, the option of relying on such standards to update their product labeling. The draft guidance explained that the agency intends to make the updated information available by publicly posting changes to the drug product labeling within 30 days following approval of a supplement that includes a change to the *Microbiology* subsection of the product labeling. The draft guidance also described, for manufacturers of in vitro diagnostic AST devices, the process for updating the susceptibility test information in their labeling to conform with updated labeling for a relevant antibacterial drug product.

FDA has carefully reviewed comments received on the draft guidance (11 comments were submitted to the public docket). This final version of the guidance reflects our consideration of these comments, as well as our experience updating the labeling of susceptibility test information in systemic antibacterial drug products and AST devices. Most of the changes to the guidance were made to clarify statements in the draft guidance. The following changes in the final version of the guidance are noteworthy:

- The guidance clarifies that FDA is not imposing new requirements by recommending that drug application holders submit revised labeling or an explanation of why revisions are not needed within a specific time period after FDA recognizes a standard that is different from the information in the *Microbiology* subsection of the labeling for the application holder's drug product. (See 21 CFR 201.56(a)(2).)
- The agency revised the recommended time period for submitting revised labeling by extending the period from 60 days to 90 days.

Certain requests that the guidance provide greater detail regarding the procedures for updating in vitro AST devices have not been addressed in this guidance but will be addressed when FDA updates ''Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA.'' This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a 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. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910-0638.

IV. Electronic Access

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

Dated: June 26, 2009.

David Horowitz,

Assitant Commissioner for Policy

[FR Doc. E9–15682 Filed 7–1–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health 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 Environmental Health Sciences Special Emphasis Panel; Research Conference Grants with an Environmental Health Focus.

Date: July 30, 2009.

Time: 2 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Linda K. Bass, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709. (919) 541–1307. *bass@niehs.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund

Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: June 26, 2009.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–15689 Filed 7–1–09; 8:45 am]

BILLING CODE 4140–01–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.

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; Informatics Training for Global Health.

Date: July 13, 2009.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Dan D. Gerendasy, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5132, MSC 7843, Bethesda, MD 20892, 301–594–6830, *gerendad@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biology of Development and Aging SBIR/STTR Review.

Date: July 13, 2009.

Time: 1 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: Dan D. Gerendasy, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5132, MSC 7843, Bethesda, MD 20892, 301–594–6830, *gerendad@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Integrative Neuroscience.

Date: July 14–15, 2009.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Brian Hoshaw, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7844, Bethesda, MD 20892, 301–435–1033, *hoshawb@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Ethanol and Neurotoxicology.

Date: July 15–16, 2009.

Time: 8 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: Christine L. Melchior, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, (301) 435–1713, *melchioc@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neurodevices and Neuroimaging.

Date: July 17, 2009.

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: Vilen A. Movsesyan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040M, MSC 7806, Bethesda, MD 20892, 301–402–7278, *movsesyanv@csr.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Diversity Fellowships: Division of Translational and Clinical Sciences.

Date: July 23, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lee Rosen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435–1171, *rosenl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Disease Revision Grant Applications.

Date: July 23–24, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Alexander D. Politis, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, (301) 435–1150, *politisa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; OBT Competitive Revision Applications.

Date: July 23–24, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cathleen L. Cooper, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892, 301–435–3566, *cooperc@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Chronic Fatigue Syndrome, Fibromyalgia Syndrome, Temporomandibular Disorders.

Date: July 28–29, 2009.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lynn E. Luethke, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5166, MSC 7844, Bethesda, MD 20892, (301) 435–1018, *luethkel@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Diabetes, Obesity, Nutrition and Reproductive Sciences.

Date: July 30–31, 2009.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Krish Krishnan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435–1041, *krishnak@csr.nih.gov.*