

diagnostic devices (IVDs) intended for the detection of antibodies to *Borrelia burgdorferi*. These devices are used to aid in the diagnosis of Lyme disease. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 5, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Prasadi Rao, Center for Devices and Radiological Health Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5508, Silver Spring, MD 20993-0002, 301-796-6203.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This draft guidance recommends studies for establishing the performance characteristics of in vitro diagnostic devices for the detection of antibodies to *B. burgdorferi* in human serum, plasma, and blood. These devices are used to aid in the diagnosis of Lyme disease. This document does not apply to *B. burgdorferi* nucleic acid amplification assays. A manufacturer who intends to market an in vitro device for the detection of antibodies to *B. burgdorferi* must conform to the general controls of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and, unless exempt,

obtain premarket clearance or approval prior to marketing the device.

**II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the Agency's current thinking on establishing the performance characteristics of in vitro diagnostic devices for the detection of antibodies to *B. burgdorferi*. 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 statute and regulations.

**III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1721 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 42 CFR 493.15 have been approved under OMB control number 0910-0598; the collections of information 21 CFR 50.23 have been approved under OMB control number 0910-0586 and the collections of

information in 21 CFR 56.115 have been approved under OMB control number 0910-0130.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Dated: December 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-33293 Filed 1-4-11; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Nursing Research; Notice of 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 National Advisory Council for Nursing Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Council for Nursing Research.

*Date:* January 18-19, 2011.

*Open:* January 18, 2011, 1 p.m. to 4:45 p.m.

*Agenda:* Discussion of Program Policies and Issues.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6C, Room 6, Bethesda, MD 20892.

*Closed:* January 19, 2011, 9 a.m. to 1 p.m.  
*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6C, Room 6, Bethesda, MD 20892.

*Contact Person:* Mary E. Kerr, FAAN, RN, PhD, Deputy Director, National Institute of Nursing, National Institutes of Health, 31 Center Drive, Room 5B-05, Bethesda, MD 20892-2178, 301/496-8230, [kerrme@mail.nih.gov](mailto:kerrme@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.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: [http://www.nih.gov/ninr/a\\_advisory.html](http://www.nih.gov/ninr/a_advisory.html), where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: December 29, 2010.

**Anna P. Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-33331 Filed 1-4-11; 8:45 am]

**BILLING CODE 4140-01-P**

## 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 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 Mental Health Special Emphasis Panel K99.

*Date:* February 3, 2011.

*Time:* 1:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive

Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Megan Libbey, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9609, Rockville, MD 20852-9609, 301-402-6807, [libbeym@mail.nih.gov](mailto:libbeym@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel ITVC Conflicts.

*Date:* February 9, 2011.

*Time:* 10:30 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Enid Light, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6132, MSC 9608, Bethesda, MD 20852-9608, 301-443-3599, [elight@mail.nih.gov](mailto:elight@mail.nih.gov).

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel, Conte Centers for Basic and Translational Mental Health Research.

*Date:* February 25, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

*Contact Person:* Rebecca C Steiner, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, [steinerr@mail.nih.gov](mailto:steinerr@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: December 29, 2010.

**Anna P. Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-33330 Filed 1-4-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering Special Emphasis Panel.

*Date:* March 14-16, 2011.

*Time:* 6 p.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* JW Marriott, 900 W. Olympic Blvd., Los Angeles, CA 90015.

*Contact Person:* Manana Sukhareva, PhD, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Suite 959, Bethesda, MD 20892, 301-451-3397, [sukharem@mail.nih.gov](mailto:sukharem@mail.nih.gov).

Dated: December 29, 2010.

**Anna P. Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-33325 Filed 1-4-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of 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 open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel.

*Date:* January 19, 2011.

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

*Agenda:* To provide concept review of proposed concept review.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Sathasiva B. Kandasamy, PhD, Scientific Review Administrator, Division of Scientific Review, National