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Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Haja Sittana El Mubarak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5519, Silver Spring, MD 20993–0002, 301–796–6193.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document provides recommendations on the types of information and data that FDA believes needs to be included in a premarket notification 510(k) submission for HSV types 1 and 2 serological assays. HSV serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the assays consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome. We have revised the existing guidance by rewriting the method comparison section and the sample selection inclusion and exclusion criteria section. The revisions defined and differentiated the required studies and the study populations for the assessment of the safety and effectiveness of the different types of HSV 1 and HSV 2 serological assays. Additionally, we made several corrections and clarifications throughout the document to ensure accuracy, consistency, and ease of reading. Elsewhere in this issue of the **Federal Register**, FDA is proposing to designate this guidance as the class II special control for HSV types 1 and 2 serological assays. If this classification rule is finalized, FDA intends that this guidance document will serve as the special control for this device.

Following the effective date of any final classification rule based on this proposal, any firm submitting a premarket notification (510(k)) for HSV types 1 and 2 serological assays will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

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 HSV types 1 and 2 serological assays. 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. To receive "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays," you may either send an email request to *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 1713 to identify the guidance you are requesting. 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*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information 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 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 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

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: September 16, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–23640 Filed 9–27–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR); Notice of National Conversation on Public Health and Chemical Exposures Leadership Council Meeting

Time and Date: 9 a.m.—5 p.m. EDT, Tuesday, October 5, 2010.

Location: Omni Shoreham Hotel, 2500 Calvert Street NW., Washington, DC 20008.

Status: Open to the public, on a first come, first served basis, limited by the space available. An opportunity for the public to listen to the meeting by phone will be available. For information on observing the meeting in person or by phone, *see* "contact for additional information" below.

Purpose: This is the sixth meeting of the National Conversation on Public

Health and Chemical Exposures Leadership Council, which is convened by RESOLVE, a non-profit independent facilitator. The National Conversation on Public Health and Chemical Exposures is a collaborative initiative supported by NCEH/ATSDR and through which many organizations and individuals are helping develop an action agenda for strengthening the nation's approach to protecting the public's health from harmful chemical exposures. The Leadership Council provides overall guidance to the National Conversation project and is responsible for issuing the final action agenda. For additional information on the National Conversation on Public Health and Chemical Exposures, visit this Web site: *http://www.atsdr.cdc.gov/nationalconversation/*.

Meeting Agenda: The purpose of the meeting is to discuss key themes and recommendations to feature in the draft action agenda, drawing on draft work group reports and the results of various stakeholder and public engagement activities.

Contact for additional information: If you would like to receive additional information on attending this meeting in person or listening by telephone, please contact: *nationalconversation@cdc.gov* or Ben Gerhardstein at 770–488–3646.

Dated: September 21, 2010.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2010–24260 Filed 9–27–10; 8:45 am]

BILLING CODE 4163–18–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; Member Conflict: Neurodevices, Neuroimaging, and Bioengineering.

Date: October 20, 2010.

Time: 2 p.m. to 6 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.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Electromagnetic Devices.

Date: October 26, 2010.

Time: 12 p.m. to 3:30 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: Antonio Sastre, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5215, MSC 7412, Bethesda, MD 20892, 301–435–2592, *sastrea@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: AIDS Predoctoral and Postdoctoral.

Date: October 27–28, 2010.

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: Shiv A. Prasad, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Dermatology, Rheumatology and Inflammation.

Date: November 1, 2010.

Time: 11:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Aftab A. Ansari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301–594–6376, *ansaria@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Stem Cells in Cancer.

Date: November 1, 2010.

Time: 1 p.m. to 4 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: Nywana Sizemore, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892, 301–435–1718, *sizemoren@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Tooth Development and Mineralization.

Date: November 3, 2010.

Time: 3 p.m. to 5:30 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: Priscilla B. Chen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892, (301) 435–1787, *chenp@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–08–147: Quick Trials on Imaging and image-Guided Intervention.

Date: November 4, 2010.

Time: 2 p.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: John Firrell, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, MSC 7854, Bethesda, MD 20892, 301–435–2598, *firrellj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel. Fellowships: Neurodevelopment, Synaptic Plasticity and Neurodegeneration.

Date: November 11–12, 2010.

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

Agenda: To review and evaluate grant applications.

Place: The Westin San Diego, 400 West Broadway, San Diego, CA 92101.

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.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Digestive Sciences.

Date: November 15–16, 2010.

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: Bonnie L. Burgess-Beusse, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301–435–1783, *beusseb@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Diet and Physical Activity Methodologies.

Date: November 16–17, 2010.