

days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the FD&C Act, FDA has determined, under 21 CFR 10.115(g)(2), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying focused ultrasound stimulator systems for aesthetic use into class II (special controls) under section 513(f)(2) of the FD&C Act.

## II. Significance of Guidance

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of focused ultrasound stimulator system for aesthetic use classified under 878.4590 (21 CFR Part 878). In order to be classified as a class II device under 878.4590, an ultrasound stimulator for aesthetic use must comply with the requirements of special controls; a manufacturer must address the issues requiring special controls as identified in the guidance, either by following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

## III. Electronic Access

Persons interested in obtaining a copy of the 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 "Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use," 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 1701 to identify the guidance you are requesting

## IV. Paperwork Reduction Act of 1995

This 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 (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; the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR 50.23 have been approved under OMB control number 0910-0586; the collections of information in 21 CFR Part 58 have been approved under OMB control number 0910-0119; and the collections of information in 21 CFR Part 801 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: July 15, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011-18280 Filed 7-19-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Neurological Disorders and Stroke; 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 materials, 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 Neurological Disorders and Stroke Special Emphasis Panel, Stem Cells.

*Date:* July 27, 2011.

*Time:* 9 a.m. to 3 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:* Raul A. Saavedra, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, [saavedrr@ninds.nih.gov](mailto:saavedrr@ninds.nih.gov).

This notice is being published less than 15 days prior to the meeting due to timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Rare Diseases.

*Date:* August 2, 2011.

*Time:* 9 a.m. to 3 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:* Raul A. Saavedra, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, [saavedrr@ninds.nih.gov](mailto:saavedrr@ninds.nih.gov).

This notice is being published less than 15 days prior to the meeting due to timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Epilepsy Genetic Centers Without Walls.

*Date:* August 5, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Amalfi Hotel, 20 West Kinzie Street, Chicago, IL 60654.

*Contact Person:* William C. Benzing, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-0660, [Benzingw@mail.nih.gov](mailto:Benzingw@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: July 13, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 2011-18286 Filed 7-19-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Child Health and Human Development Special Emphasis Panel, The Development of Infant Behavioral Affect Specificity to Discrete Emotions.

*Date:* July 25, 2011.

*Time:* 11:30 a.m. to 12:20 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Carla T. Walls, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 435-6898, [wallsct@mail.nih.gov](mailto:wallsct@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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 14, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 2011-18299 Filed 7-19-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 Child Health and Human Development Special Emphasis Panel, Children in Rural Poverty.

*Date:* August 9, 2011.

*Time:* 9 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Renaissance Mayflower Hotel, 1127 Connecticut Avenue, NW., Washington, DC 20036.

*Contact Person:* Marita R. Hopmann, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6911, [hopmannm@mail.nih.gov](mailto:hopmannm@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 14, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 2011-18297 Filed 7-19-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development, Special Emphasis Panel, FES Controller for Upper Limb Movement.

*Date:* August 9, 2011.

*Time:* 1 to 3 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Sathasiva B. Kandasamy, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301-435-6680, [skandasa@mail.nih.gov](mailto:skandasa@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 14, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory  
Committee Policy.*

[FR Doc. 2011-18288 Filed 7-19-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **National Institute of General Medical 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