will be required as part of a REMS. Under section 505–1(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355–1(e)), FDA may require that a REMS for a drug include one or more of the elements described in section 505–1(e), including the requirement for an applicant to develop a Medication Guide for distribution to each patient when the drug is dispensed (when the criteria in part 208 (21 CFR part 208) are met). Since the enactment of the Food and Drug Administration Amendments Act of 2007, FDA has, as a matter of policy, considered any new Medication Guide (or safety-related changes to an existing Medication Guide) to be part of a REMS. However, the Agency has the authority to determine, based on the risks of a drug and public health concern, how a Medication Guide should be required when the standard in part 208 is met. Based on the risks and public health concern, the Agency may require: (1) A Medication Guide in accordance with part 208 that is not an element of a REMS or (2) A Medication Guide in accordance with part 208 and section 505–1 of the FD&C Act that is an element of a REMS, which may include other elements of a REMS (such as elements to assure safe use).

In the **Federal Register** of February 28, 2011 (76 FR 10908), FDA announced the availability of a draft guidance for industry entitled ''Medication Guides—Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS).'' The notice gave interested parties the opportunity to comment by May 31, 2011. The Agency considered all of the comments received and made minor editorial and clarifying changes to the guidance.

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 when FDA intends to exercise enforcement discretion regarding Medication Guide distribution and inclusion of Medication Guides in REMS. 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**) 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.

## III. 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 314.70 and 601.12 have been approved under OMB control numbers 0910–0001 and 0910–0338, respectively; the collections of information in part 208 have been approved under OMB control number 0910–0393.

## IV. Electronic Access

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

Dated: November 14, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–29877 Filed 11–17–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To obtain a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: National Survey of Organ Donation Attitudes and Practices (OMB No. 0915–xxxx)—[New]**

The Division of Transplantation (DoT), Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), is planning to conduct a telephone survey of public knowledge, perceptions, opinion, and behaviors related to organ donation. Two key missions of the DoT are (1) to provide oversight for the Organ Procurement and Transplantation Network and policy development related to organ donation and transplantation and (2) to implement efforts to increase public knowledge about the need for increased organ donation.

With a constantly growing deficit between the number of Americans needing donor organs (currently approximately 112,000) and the annual number of donors (14,505 in 2010), raising the American public's willingness to donate becomes increasingly critical. Effective education and outreach campaigns need to be based on knowledge of the public's attitudes and perceptions about, and perceived impediments to, organ donation. Two national surveys using nearly identical survey instruments to identify public views and behaviors related to organ donation were conducted in 1993 and 2005.

The proposed study will identify current organ donation views and practices of the American public and various population subgroups using a survey instrument similar to the two earlier studies in order to track changes over time. It will measure issues such as public knowledge about and attitudes toward organ donation, public commitment to or willingness to donate, impediments to public willingness to donate, and attitudes toward living donation, donation practices, policy issues, allocation policy, presumed consent, and financial incentives for donation. Demographic information also will be collected. The randomly drawn sample will consist of 3,250 adults (age 18 and over), including an oversample of Asians, Hispanics, African Americans, and Native Americans, and will be geographically representative of the United States. The survey instrument will be administered in both English and Spanish through computer-assisted telephone interviews.

In addition to being useful to the DoT (especially in its donation outreach initiatives), results of this survey also will be of assistance to the donation and transplant community, DoT grantees and other research efforts, and to the

Secretary's Advisory Committee on Organ Transplantation (ACOT) as it fulfills its charge to advise the Secretary of Health and Human Services on the numerous and often controversial issues related to donation and transplantation. In its first meeting, the ACOT suggested such a survey to gather information to inform both public education efforts and policy decisions on the issue of organ donation.

The annual estimate of burden is as follows:

| Instrument | Number of respondents | Responses per respondent | Total responses | Hours per response | Total burden hours |
|---|---|---|---|---|---|
| Telephone survey | 3,250 | 1 | 3,250 | 0.3 | 975 |
| Total | 3,250 | 1 | 3,250 | 0.3 | 975 |

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

A similar request for public comments was published in the **Federal Register** on September 20, 2011 (76 FR 58282).

Dated: November 14, 2011.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

[FR Doc. 2011–29830 Filed 11–17–11; 8:45 am]

**BILLING CODE 4165–15–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, RFA Panel: Interventions for SIDS and Other Sleep Related Infant Deaths.

*Date:* December 7–8, 2011.

*Time:* 10 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:* Kevin Walton, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, (301) 435–1785, *kevin.walton@nih.hhs.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Program Project: Cell Biology.

*Date:* December 13–14, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Homewood Suites Hotel, 2 Farm Glen Boulevard, Farmington, CT 06032.

*Contact Person:* David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, (301) 435–1022, *balasundaramd@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 9, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–29891 Filed 11–17–11; 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, Member Conflict: Integrative Neurosensory Studies.

*Date:* December 7–8, 2011.

*Time:* 9 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:* Wei-Qin Zhao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181 MSC 7846, Bethesda, MD 20892–7846, (301) 435–1236, *zhaow@csr.nih.gov.*

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Integrative Neuroscience.

*Date:* December 15, 2011.

*Time:* 5 p.m. to 8 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:* Kirk Thompson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, (301) 435–1242, *kgt@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 14, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–29887 Filed 11–17–11; 8:45 am]

**BILLING CODE 4140–01–P**