

supporting, or life sustaining, if FDA finds that such a device should be subject to part 803 in order to protect the public health (section 519(a)(1)(B)(i)(III) of the FD&C Act). If such class I or class II devices are not the subject of an FDA notice or letter, the malfunction reports for these devices are to be submitted in accordance with the criteria established by the Secretary (and, by delegation, FDA), which criteria shall require the reports to be in summary form and made on a quarterly basis (section 519(a)(1)(B)(ii) of the FD&C Act).

Under section 519(a) of the FD&C Act, as amended by FDAAA, there is no change to the obligation for an importer to submit malfunction reports to the manufacturer in accordance with part 803 for devices that it imports into the United States (section 519(a)(1)(B)(iii) of the FD&C Act).

FDA intends to provide notice in the **Federal Register** that lists the types of devices that should be subject to part 803 in order to protect the public health, as required by section 519(a)(1)(B)(i)(III) of the FD&C Act. In addition, FDA intends to, by rulemaking, establish malfunction reporting criteria for devices subject to section 519(a)(1)(B)(ii) of the FD&C Act. In the interim, in the interest of public health, FDA is publishing this notice under section 519(a)(1)(B)(i)(III), to clarify that, to the extent there is any confusion as to current malfunction reporting requirements, all device manufacturers and importers of class I and those class II devices that are not permanently implantable, life supporting, or life sustaining, must continue to report in full compliance with part 803, pending further FDA notice under section 519(a)(1)(B)(i)(III), as to specific devices or device types subject to part 803, and the establishment of criteria in accordance with section 519(a)(1)(B)(ii). FDA considers it necessary to subject all such devices to part 803 in the interim, in order to protect the public health by ensuring that there is no gap in malfunction reporting for any device.

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.

Dated: March 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-5146 Filed 3-7-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute On Deafness and Other Communication Disorders; 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 on Deafness and Other Communication Disorders Special Emphasis Panel; Clinical Trials—Communications.

Date: March 31, 2011.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call.)

Contact Person: Christine A. Livingston, PhD, Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892, (301) 496-8683, livingsc@mail.nih.gov.

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; P50 Grant Review.

Date: April 8, 2011.

Time: 11 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6120 Executive Blvd., Rockville, MD 20852. (Telephone Conference Call.)

Contact Person: Christine A. Livingston, PhD, Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIDCD, 6120 Executive Blvd.—MSC 7180, Bethesda, MD 20892, (301) 496-8683, livingsc@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: March 2, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-5228 Filed 3-7-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; 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 Center for Complementary and Alternative Medicine Special Emphasis Panel, NCCAM Education Panel.

Date: March 24–25, 2011.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Peter Kozel, PhD., Scientific Review Officer, NCCAM, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892-5475, 301-496-8004, kozelp@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: March 2, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-5226 Filed 3-7-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as