

device, including, but not limited to, implanted electrical urinary continence devices; implanted mechanical/hydraulic urinary continence devices; urological clamp for males; nonimplanted, peripheral and other electrical continence devices; protective garment for incontinence; surgical mesh; electrosurgical cutting and coagulation device and accessories; perineometer; gynecologic laparoscope and accessories; and vaginal pessary.

In the **Federal Register** of September 19, 2008 (73 FR 54406), FDA announced the availability of the draft guidance. Comments on the draft guidance were due by December 18, 2008. Two comments were received with each comment making multiple recommendations on changes to the content of the guidance document.

The comments included recommended changes to or removals of primary, secondary, and composite endpoints and changes to the recommended clinical study design. In response to these comments, FDA has clarified the appropriate context for recommended endpoints and a sponsor's options with respect to use of a given endpoint. FDA also revised the recommended requirements for use of voiding diaries and clarified the recommendation regarding the randomization of subjects.

Comments also involved recommendations on the categorization of adverse events. In response to these comments, FDA clarified the recommendation for categorization of adverse events as either device- or procedure-related.

## II. Significance of 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 clinical investigations of devices intended to treat urinary incontinence. 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 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 "Clinical Investigations of

Devices Indicated for the Treatment of Urinary Incontinence," 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 1636 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 812 have been approved under OMB control number 0910-0078; 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 814 have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR parts 50.23 and 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: March 2, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-5148 Filed 3-7-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0097]

### Medical Device Reporting; Malfunction Reporting Frequency

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is clarifying that device manufacturers and importers of

all devices, including class I and those class II devices that are not permanently implantable, life supporting, or life sustaining, must continue to submit malfunction reports in full compliance with FDA's Medical Device Reporting regulation, pending future FDA notice under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

**DATES:** Submit either electronic or written comments by May 9, 2011.

**ADDRESSES:** Submit electronic comments on this document 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:

Victoria Schmid, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3236, Silver Spring, MD 20993-0002, 301-796-6108.

## I. Background

Title II, section 227 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85), amended section 519(a) of the FD&C Act (21 U.S.C. 360i(a)), relating to the reporting of malfunctions to FDA under part 803 (21 CFR part 803). The malfunction reporting requirements for class III devices and those class II devices that are permanently implantable, life supporting, or life sustaining were not altered by FDAAA. Under the amended section 519(a), device manufacturers and importers are to continue to submit malfunction reports in accordance with part 803 for all class III devices and for those class II devices that are permanently implantable, life supporting, or life sustaining, unless the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) grants an exemption, variance from, or an alternative to, a requirement under such regulations under § 803.19 (section 519(a)(1)(B)(i) of the FD&C Act).

However, FDAAA changed malfunction reporting requirements for class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining. Under section 519(a) of the FD&C Act, as amended by FDAAA, the Secretary (and, by delegation, FDA) is required to publish a notice in the **Federal Register** or send a letter to the person who is the manufacturer or importer of a class I device or a class II device that is not permanently implantable, life

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]

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## 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](mailto: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](mailto: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]

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## 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](mailto: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