

document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### IV. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cvm/cloning.htm>. In an effort to better ensure broad awareness of this **Federal Register** notice, FDA will announce it and make copies available through the FDA Dockets Listserv (<http://www.fda.gov/ohrms/dockets/FDAMAIL/DMBemaillist.htm>). To be added to any of FDA's free e-mail subscription services go to <http://www.fda.gov>. Click on "Subscribe to FDA's E-mail Lists," then follow the instructions provided.

Dated: August 18, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 06-9927 Filed 12-28-06; 11:00 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006D-0504]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; Radio-Frequency Wireless Technology in Medical Devices; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Draft Guidance for Industry and FDA Staff; Radio-Frequency Wireless Technology in Medical Devices." This draft guidance document addresses issues relevant to the safe and effective use of radio frequency (RF) wireless technology in medical devices, including wireless coexistence, performance, data integrity, security, and electromagnetic compatibility (EMC). These issues involve all stages of the product life cycle and should be considered in preparing premarket submissions; identifying, documenting, and implementing product design requirements, as well as design verification and validation; and risk management processes and procedures.

**DATES:** Submit written or electronic comments on the draft guidance by April 2, 2007.

**ADDRESSES:** Submit written requests for single copies of the draft guidance

entitled "Draft Guidance for Industry and FDA Staff; Radio-Frequency Wireless Technology in Medical Devices" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

#### **FOR FURTHER INFORMATION CONTACT:**

Donald Witters, Center for Devices and Radiological Health (HFZ-130), Food and Drug Administration, 12725 Twinbrook Pkwy., Rockville, MD 20852, 301-827-4955.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA has developed this draft guidance document to assist industry, systems and service providers, consultants, FDA staff, and others in the design, development, and evaluation of RF wireless technology in medical devices. The RF wireless emissions from one product or device can affect the function of another, the electromagnetic environments where medical devices are used may contain many sources of RF energy, and the use of RF wireless technology in and around medical devices is increasing. As a result, the draft guidance recommends that manufacturers address concerns about the potential effects of the use of RF wireless technology in and around medical devices on the ability of medical devices to function properly and the resultant safety of patients and operators.

This draft guidance references national and international standards and discusses some of FDA's regulatory requirements, including premarket requirements (21 CFR parts 807 and 814). The draft guidance document also discusses quality system requirements as they specifically apply to RF wireless technology in medical devices, including design and development activities (21 CFR part 820).

##### **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 RF wireless technology in and around medical devices. 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 "Draft Guidance for Industry and FDA Staff; Radio-Frequency Wireless Technology in Medical Devices" you may either send an e-mail request to [ds mica@fda.hhs.gov](mailto:ds mica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1618 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

#### **IV. Paperwork Reduction Act of 1995**

This draft 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 801 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807 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 part 820 have been approved under OMB control number 0910-0073.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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: December 19, 2006.

**Linda S. Kahan,**

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

[FR Doc. E6-22449 Filed 12-29-06; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Cancer Institute Initial Review Group, Subcommittee J—Population and Patient-Oriented Training.

*Date:* February 19–20, 2007.

*Time:* 8 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Westin Arlington Gateway, 801 North Glebe Road, Arlington, VA 22203.

*Contact Person:* Ilda M McKenna, PhD, Scientific Review Administrator, Research Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard Room 8111, Bethesda, MD 20892, 301-496-7481, [mckennai@mail.nih.gov](mailto:mckennai@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS.)

Dated: December 21, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-9952 Filed 12-29-06; 8:45 am]

**BILLING CODE 4140-01-M**

## 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. Appendix 2), 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 of Neurological Disorders and Stroke Special Emphasis Panel, Stroke Panel.

*Date:* January 7–8, 2007.

*Time:* 7:30 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Katherine Woodbury, PhD, Scientific Review Administrator, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892-9529, (301) 496-5980, [kw47o@nih.gov](mailto:kw47o@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.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Training and Career Development.

*Date:* January 9, 2007.

*Time:* 2 p.m. to 3:30 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 Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, NSC; 6001 Executive Blvd., STE. 3208, 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 the timing limitations imposed by the review and funding cycle.

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

*Date:* January 10, 2007.

*Time:* 5 p.m. to 8 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:* William C. Benzing, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 496-0660, [benzingw@mail.nih.gov](mailto:benzingw@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.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Planning Grants Review.

*Date:* January 11, 2007.

*Time:* 2 p.m. to 5 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:* Shantadurga Rajaram, PHD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, Msc 9529, Bethesda, MD 20852, (301) 435-6033, [rajarams@mail.nih.gov](mailto:rajarams@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.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel, K99 R00 Review.

*Date:* January 12, 2007.

*Time:* 2 p.m. to 4 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:* Joann McConnell, PhD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, Msc 9529, Bethesda, MD 20892-9529, (301) 496-5324, [mcconnef@ninds.nih.gov](mailto:mcconnef@ninds.nih.gov).