DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0438]

Guidance for Industry and Food and Drug Administration Staff; Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007.'' The purpose of this guidance is to explain recent changes in the device registration and listing program to owner/operators and official correspondents of device establishments and to help them fulfill these new requirements. The guidance also describes the information that owner/operators of device establishments must submit to register their establishments and list their devices electronically, using FDA Form No. 3673. Those owner/operators seeking a waiver from the electronic submission requirement must submit their requests in writing to FDA with a complete explanation of why their registration and listing information cannot reasonably be submitted electronically. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidelines are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: David Racine, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2672, Silver Spring, MD 20993–0002, 301–796–5777.

SUPPLEMENTARY INFORMATION:

I. Background

In October 2002, section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) was amended by section 207 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) to add a requirement for electronic submission of registration information. On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law–110–85) further amended the device registration and listing provisions in section 510 of the act and also added provisions to sections 737 and 738 of the act (21 U.S.C. 379i and 379j) to require certain types of device establishments to pay user fees in connection with their initial or annual registration beginning on October 1, 2007. As amended, section 510(p) of the act now requires all device establishments to submit their device registration and listing information by electronic means unless FDA grants their request for a waiver.

The guidance described in this document explains the new, electronic process for registration and listing using the Internet and the process for requesting a waiver from FDA. In addition, the guidance specifies the user fee amounts for each fiscal year (FY) through FY 2012.

FDAAA imposes new requirements on device establishments to submit their registration and listing information to FDA through electronic means and to pay user fees in connection with their registration beginning on October 1, 2007. FDAAA was signed into law September 27, 2007. Because the law was immediately in effect, FDA determined that it was not feasible to obtain public participation prior to implementing the new FDAAA requirements described in this guidance. Therefore, in accordance with FDA's GGP procedures at 21 CFR 10.115(g)(2), FDA is issuing this as a level 1 guidance that is immediately in effect and will accept comments on the guidance at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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. To receive ''Implementation of Medical Device Establishment Registration and Device Listing Requirements Established by the Food and Drug Administration Amendments Act of 2007,'' you may either send an e-mail request to *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 (1657) to identify the guidance you are requesting.

CDRH maintains a web site 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 at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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

this guidance were approved under OMB control number 0910–0625.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this guidance document. Submit a single copy of electronic comments or 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: September 30, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–24349 Filed 10–7–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Cancellation of Meeting

Notice is hereby given of the cancellation of the Center for Scientific Review Special Emphasis Panel, October 23, 2009, 8 a.m. to October 23, 2009, 12 p.m., InterContinental Mark Hopkins San Francisco, One Nob Hill, 999 California Street, San Francisco, CA, 94108 which was published in the **Federal Register** on September 25, 2009, 74 FR 48979.

The meeting was cancelled due to administration problems.

Dated: October 1, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–24278 Filed 10–7–09; 8:45 am]

BILLING CODE 4140–01–M

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; Neuroprotection and Neurodegeneration.

Date: October 27–28, 2009.

Time: 8 a.m. to 11:59 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435–1239, *guthriep@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biobehavioral Regulation, Learning and Ethology.

Date: October 27, 2009.

Time: 10 a.m. to 8 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Cheri Wiggs, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3180, MSC 7848, Bethesda, MD 20892, (301) 435–1261, *wiggs@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Diagnostics and Therapeutics SBIR/STTR.

Date: October 29–30, 2009.

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: Lambratu Rahman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301–451–3493, *rahmanl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Signaling and DNA Repair.

Date: October 29, 2009.

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: Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Tooth Development.

Date: October 29, 2009.

Time: 3 p.m. to 5 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: Priscilla B. Chen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4104, MSC 7814, Bethesda, MD 20892, (301) 435–1787, *chenp@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Vascular Biology.

Date: October 30, 2009.

Time: 7 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, (301) 435–1233, *shahb@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Research Resource Review.

Date: November 1–3, 2009.

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

Agenda: To review and evaluate grant applications.

Place: Best Western Boston—The Inn at Longwood Medical, 342 Longwood Avenue, Boston, MA 02115.

Contact Person: Lee Rosen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435–1171, *rosenl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Drug Discovery for Neurodegenerative Diseases and Drug Abuse.

Date: November 3–4, 2009.

Time: 11 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Geoffrey G. Schofield, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040–A, MSC 7850, Bethesda, MD 20892, 301–435–1235, *geoffreys@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Synchrotron Structural Biology Resource.

Date: November 3–5, 2009.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Stanford Park Hotel, 100 El Camino Real, Menlo Park, CA 94025.

Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for