

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices" to the Division of Small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Submit electronic comments on the draft guidance to 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: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5543, Silver Spring, MD 20993-0002, 301-796-6217.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has identified certain Class I and Class II in vitro diagnostic and radiology devices that have established safety and effectiveness profiles and for which it believes 510(k) review is not necessary to assure safety and effectiveness. While FDA intends to exempt these devices from the 510(k) requirement through rulemaking that would reclassify the Class II devices and amend the classification regulations of the Class I devices, FDA no longer believes it is necessary to review premarket notification (510(k)) submissions for these devices before they enter the market. FDA is issuing a draft guidance concerning a policy of exercising enforcement discretion with regard to the 510(k) requirement for such devices. The draft guidance lists the devices for which, when the guidance is finalized, FDA intends to exercise enforcement discretion with regard to premarket notification requirements, subject to the limitations to the exemption criteria found in 21 CFR 862.9, 21 CFR 864.9, 21 CFR 866.9, and 21 CFR 892.9. FDA intends to continue to enforce all other applicable requirements under the FD&C Act, including, but not limited to: Registration and listing (21 CFR part

807); labeling (21 CFR part 801 and 21 CFR 809.10); good manufacturing practice requirements as set forth in the Quality System regulation (21 CFR part 820); and Medical Device Reporting requirements (21 CFR part 803).

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 "Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology 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. 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 "Premarket Notification Enforcement Discretion for Certain In Vitro Diagnostic and Radiology Devices," 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 1752 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. 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 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 807, subparts B and C have been approved under OMB control number 0910-0387; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485; and the collections of

information in 21 CFR part 803 have been approved under OMB control number 0910-0437.

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: July 6, 2011.

Nancy K. Stade,

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

[FR Doc. 2011-17352 Filed 7-11-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Training (2012/01).

Date: October 27, 2011.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar Arlington, 1121 North 19th Street, Arlington, VA 22209.

Contact Person: Ruth Grossman, DDS, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Room 960, Bethesda, MD 20892, 301-496-8775, grossmanr@mail.nih.gov.

Dated: July 6, 2011.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-17448 Filed 7-11-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel, Spectroscopy and Imaging: Enabling Bioanalytical Techniques.

Date: July 26–27, 2011.

Time: 8 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: Vonda K Smith, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7892, Bethesda, MD 20892, 301-435-1789, smithvo@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: July 6, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-17450 Filed 7-11-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering; NACBIB, September, 2011.

Date: September 12, 2011.

Open: 9 a.m. to 1 p.m.

Agenda: Report from the Institute Director, other Institute Staff and presentation of the Strategic Plan Implementation Workgroup.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Independence Room (2nd Level), Bethesda, MD 20817.

Closed: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Independence Room (2nd Level), Bethesda, MD 20817.

Contact Person: Anthony Demsey, PhD, Director, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 241, Bethesda, MD 20892.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://www.nibib1.nih.gov/about/NACBIB/NACBIB.htm>, where an agenda and any

additional information for the meeting will be posted when available.

Dated: July 6, 2011.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-17445 Filed 7-11-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Reducing Emergency Department Use for Recurrent Exacerbations of Asthma.

Date: July 28, 2011.

Time: 1 p.m. to 4 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: Stephanie L Constant, PhD, Scientific Review Officer, Office of Scientific Review, Division of Extramural Research Activities, NHLBI/NIH, 6701 Rockledge Drive, Rm. 7189, Bethesda, MD 20892, 301-443-8784, constantsl@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 5, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-17363 Filed 7-11-11; 8:45 am]

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