

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood; Institute Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

The meeting will be open to the public, 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.

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: April 22, 2015.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: Discussion of Programs.

Place: National Institutes of Health, 6701 Rockledge Drive, 9th Floor, Room 9100/9104, Bethesda, MD 20892.

Contact Person: W. Keith Hoots, MD, Director, Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Suite 9030, Bethesda, MD 20892, 301-435-0080 hootswk@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: March 11, 2015.

Michelle Trout, Program Analyst,

Office of Federal Advisory Committee Policy.

[FR Doc. 2015-05970 Filed 3-16-15; 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.

Date: May 18, 2015.

Open: 9:00 a.m. to 12:30 p.m.

Agenda: Report from the Institute Director, other Institute Staff, scientific presentations, and presentations of task force reports.

Place: The William F. Bolger Center, Franklin Building, Classroom 1, 9600 Newbridge Drive, Potomac, MD 20854.

Closed: 1:30 p.m. to 4:00 p.m.

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

Place: The William F. Bolger Center, Franklin Building, Classroom 1, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Jill Heemskerk, Ph.D., Executive Secretary, Office of Research Administration, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 239, 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: March 11, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-05974 Filed 3-16-15; 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; Technologies to Assess Sleep Health Status in Populations.

Date: April 10, 2015.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Suite 7182, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, sunnarborgsw@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: March 11, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-05971 Filed 3-16-15; 8:45 am]

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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; AIDS and AIDS Related Research.

Date: March 18, 2015.

Time: 11:00 a.m. to 5:00 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: Jose H Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1137, guerrierj@csr.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: Center for Scientific Review Special Emphasis Panel; Small Business: Respiratory Sciences Special Panel.

Date: March 19–20, 2015.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Lawrence E Boerboom, Ph.D., Chief, CVRS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435-8367, boerboom@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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Respiratory Sciences Special Panel.

Date: March 24–25, 2015.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Lawrence E Boerboom, Ph.D., Chief, CVRS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435-8367, boerboom@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.

(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: March 11, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-06036 Filed 3-16-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0293]

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.” This guidance provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices. This guidance document also provides recommendations for the content and review procedures for premarket notification (510(k)) submissions, premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, de novo requests, and investigational device exemption (IDE) applications, concerning the labeling instructions for reprocessing reusable medical devices. This guidance reflects the scientific advances in knowledge and technology involved in reprocessing reusable medical devices, especially more complex, reusable medical device designs that are more difficult to reprocess.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration,

10903 New Hampshire Ave. Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the 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:

Angela C. Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993-0002, 301-796-6380; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, there has been a significant advance in knowledge and technology involved in reprocessing reusable medical devices. Additionally, there has been an evolution towards more complex medical device designs that are more difficult to clean, disinfect, and sterilize. This guidance reflects the scientific advances in these areas. Under section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)), a device must have adequate directions for use, which include instructions on preparing a device for use. Instructions on how to reprocess (*i.e.*, clean, disinfect, and sterilize) a reusable device are critical to ensure that the device is appropriately prepared for its next use.

In the **Federal Register** of May 2, 2011 (76 FR 24494), FDA announced the availability of the draft guidance. Interested persons were invited to comment by August 1, 2011. FDA reviewed and considered all the public comments we received and revised several sections of the guidance, where applicable. On June 8 and 9, 2011, FDA held a public workshop entitled “Reprocessing of Reusable Medical Devices Workshop.” The purpose of the workshop was to discuss factors affecting the reprocessing of reusable medical devices and FDA’s plans to address the identified issues. The discussion during this workshop and the comments received were considered before revising the guidance. This final guidance supersedes “Labeling Reusable