

the following items: (1) Encourage convergence in regulatory practices with respect to ensuring the safety, effectiveness, performance, and quality of medical devices; (2) promote technological innovation; and (3) facilitate international trade. The GHTF's Web site can be accessed at <http://www.ghtf.org>. It provides further information concerning the organization's structure, goals, and procedures.

The pilot premarket review program (STED pilot program), as implemented in the United States by FDA, will rely on the FDA final guidance that is the subject of this notice, and four related documents that are appended to the guidance. These documents are: (1) A letter to the global medical device industry announcing the pilot program (Appendix 1); (2) the draft STED document created by SG1 of GHTF (Appendix 2); (3) the GHTF SG1 final document entitled "Essential Principles of Safety and Performance of Medical Devices," known as "Essential Principles" (Appendix 3); and (4) the document entitled "The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles; Final Guidance for FDA and Industry," issued in October 2002 (Appendix 4).

The FDA guidance document is intended to assist the medical device industry in making submissions to FDA that use the draft STED document format and are consistent with U.S. requirements. The announcement letter provides useful background and summary information regarding the proposed pilot premarket review program. The draft STED document describes a proposed internationally harmonized format and content for premarket submissions, e.g., PMA applications and 510(k) submissions in the United States, based on conformity to the Essential Principles. The Essential Principles are general and specific safety and performance recommendations for medical devices. They were developed by GHTF and are listed in the third document appended to the guidance. A discussion of the least burdensome provisions is provided in the fourth document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGP's regulation (21 CFR 10.115). The guidance represents the agency's current thinking on a way to apply GHTF recommendations as related to premarket submission to FDA. 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

You may obtain a copy of "A Pilot Program to Evaluate a Proposed Globally Harmonized Alternative for Premarket Procedures; Guidance for Industry and FDA Staff," via fax machine by calling the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1347) followed by the pound sign. Follow the remaining voice prompts to complete your request.

You may also obtain a copy of the guidance through the Internet. 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. The CDRH home page is updated on a regular basis and includes: Civil money penalty guidance documents, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), assistance for small manufacturers, information on video conferencing, electronic submissions, mammography devices, and other device-related information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

IV. 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 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: July 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-16825 Filed 7-22-04; 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 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 a meeting of the National Heart, Lung, and Blood Advisory Council.

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 section 552b(c)(6), title 5 U.S.C. as amended. The grant applications and the discussions could disclose confidential trades 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 Advisory Council.

Date: September 2, 2004.

Open: 8:30 a.m. to 2 p.m.

Agenda: For discussion of program policies and issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

Closed: 2 p.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Deborah P Beebe, PhD, Director, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Two Rockledge Center, Room 7100, 6701 Rockledge Drive, Bethesda, MD 20892, 301/435-0260.

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.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page:

www.nhlbi.nih.gov/meetings/index.htm, where an agenda and any additional information for the meeting will be posted when available.

(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 16, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-16780 Filed 7-22-04; 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. 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: Center for Scientific Review Special Emphasis Panel, MDCN Member SEP: Synaptogenesis and Synaptic Transmission.

Date: July 23, 2004.

Time: 1 p.m. to 3 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: Carole L. Jelsema, PhD, Chief and Scientific Review Administrator, MDCN Science Review Group, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (301) 435-1248, jelsemac@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, Mechanism of Vascular Calcification.

Date: July 23, 2004.

Time: 1:30 p.m. to 2:30 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: Larry Pinkus, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892. (301) 435-1214, pinkusl@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, Sensory Motor Integration.

Date: July 27, 2004.

Time: 12 p.m. to 1 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: Daniel R. Kenshalo, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892. (301) 435-1255, kenshalod@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, ZRG1 Neurotechnology Developmental Special Emphasis Panel.

Date: July 28, 2004.

Time: 1 p.m. to 2 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: Carole L. Jelsema, PhD, Chief and Scientific Review Administrator, MDCN Scientific Review Group, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7850, Bethesda, MD 20892. (301) 435-1248, jelsemac@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, Radioimmunotherapy.

Date: July 28, 2004.

Time: 2 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: Syed M. Quadri, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892. (301) 435-1211, quadris@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, Cardiomyocytes and Human Embryonic Stem Cells.

Date: July 29, 2004.

Time: 11:30 a.m. to 12:30 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: Larry Pinkus, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892. (301) 435-1214, pinkusl@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, MDCN Member SEP: Synaptic Functions and Prions.

Date: July 29, 2004.

Time: 1 p.m. to 3 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: Carole L. Jelsema, PhD, Chief and Scientific Review Administrator, MDCN Scientific Review Group, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7850, Bethesda, MD 20892. (301) 435-1248, jelsemac@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, DNA Replication and Repair.

Date: July 29, 2004.

Time: 2 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: Syed M. Quadri, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892. (301) 435-1211, quadris@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, Cardiovascular Bioengineering.

Date: August 2, 2004.

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

Agenda: To review and evaluate grant applications.

Place: Swissotel Washington, The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

Contact Person: Delia Tang, MD, Scientific Review Administrator, Center for Scientific