approval (PMA) requirements (section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e)).

On December 4, 2000, at a public meeting of FDA's Circulatory System Devices Panel (the Panel), the Panel recommended that PTCA catheters, other than cutting/scoring PTCA catheters and standard PTCA catheters for the treatment of in-stent restenosis and/or post-deployment stent expansion, be reclassified from class III to class II, when indicated for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion, or for treatment of acute myocardial infarction. The Panel recommended a guidance document, labeling, and postmarket surveillance as special controls.

FDA considered the Panel's recommendations and, on May 30, 2008, published a proposed rule to reclassify certain PTCA catheters, including standard PTCA catheters for the treatment of in-stent restenosis and/or post-deployment stent expansion, but not cutting/scoring PTCA catheters, into class II. In addition, FDA issued a draft class II special controls guidance document entitled "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" to support the proposed reclassification.

Following publication of the draft guidance, two sets of comments on the guidance were submitted to the FDA. The comments received sought minor clarifications on several pre-clinical testing recommendations, including biocompatibility, shelf-life and performance testing. We considered the suggestions and made appropriate revisions. In addition, the guidance was updated to include more specific recommendations regarding evaluation of coating integrity. FDA is now identifying the guidance document entitled "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" as the guidance document that will serve as the special control for this device type.

The guidance document provides a means by which PTCA catheters, other than cutting/scoring PTCA catheters, may comply with the requirement of special controls for this class II device. Following the effective date of the final reclassification rule, any firm submitting a premarket notification (510(k)) for a PTCA catheter will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on standard PTCA catheters. 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 "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" 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 (1608) 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.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This 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 807, Subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information under CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 820 have been approved under 0910–0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), 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: August 31, 2010.

Nancy K. Stade,

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

[FR Doc. 2010–22303 Filed 9–7–10; 8:45 am]

BILLING CODE 4160–01–S

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, Selected Topics in Transfusion Medicine.

Date: September 27–28, 2010.

Time: 8 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: Bukhtiar H. Shah, DVM, PhD, 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, Member Conflict: Pain and Chemosensory Systems.

Date: September 29–30, 2010.

Time: 8 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: John Bishop, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892. (301) 408–9664. *bishopj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Dermatology.

Date: October 1, 2010.

Time: 2 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: Richard Ingraham, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892. 301–496–8551. *ingrahamrh@mail.nih.gov.*

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group, Neurotechnology Study Section.

Date: October 4, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Savoy Suites, 2505 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Robert C. Elliott, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892. 301–435–3009. *elliotro@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Neurotechnology 3.

Date: October 4, 2010.

Time: 4 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Savoy Suites, 2505 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Robert C. Elliott, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892. 301–435–3009. *elliotro@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Molecular Neuropharmacology and Signaling Study Section.

Date: October 7–8, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Deborah L. Lewis, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892. 301–408–9129. *lewisdeb@csr.nih.gov.*

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group, Molecular Neurogenetics Study Section.

Date: October 7–8, 2010.

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

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Paek-Gyu Lee, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5203, MSC 7812, Bethesda, MD 20892. (301) 435–0902. *leepg@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Neurotechnology Overflow.

Date: October 12–13, 2010.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Savoy Suites, 2505 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Robert C. Elliott, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5190, MSC 7846, Bethesda, MD 20892. 301–435–3009. *elliotro@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Shared Instrumentation: Neurotechnology.

Date: October 13, 2010.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Savoy Suites, 2505 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Robert C. Elliott, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892. 301–435–3009. *elliotro@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Social Science and Population Studies: R03s, R15s, and R21s.

Date: October 14, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Guest Suites Santa Monica, 1707 Fourth Street, Santa Monica, CA 90401.

Contact Person: Suzanne Ryan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892. (301) 435–1712. *ryansj@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Macromolecular Structure and Function E Study Section.

Date: October 14, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Nitsa Rosenzweig, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7760, Bethesda, MD 20892. (301) 435–1747. *rosenzweign@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group, Cardiovascular Differentiation and Development Study Section.

Date: October 14–15, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: Maqsood A Wani, PhD, DVM, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4136, MSC 7814, Bethesda, MD 20892. 301–435–2270. *wanimaqs@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Innate Immunity and Inflammation Study Section.

Date: October 14–15, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Old Town Alexandria, 1767 King Street, Alexandria, VA 22314.

Contact Person: Tina McIntyre, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892. 301–594–6375. *mcintyrt@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Acute Neural Injury and Epilepsy Study Section.

Date: October 14–15, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005.

Contact Person: Seetha Bhagavan, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892. (301) 237–9838. *bhagavas@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Development Methods of In Vivo Imaging and Bioengineering Research.

Date: October 14–15, 2010.

Time: 8 a.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: Behrouz Shabestari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7854, Bethesda, MD 20892. (301) 435–2409. *shabestb@csr.nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group, Molecular Oncogenesis Study Section.

Date: October 14–15, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Old Town Alexandria, 901 North Fairfax Street, Alexandria, VA 22314.

Contact Person: Nywana Sizemore, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6204, MSC 7804, Bethesda, MD 20892. 301–435–1718. *sizemoren@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group, Nuclear and Cytoplasmic Structure/Function and Dynamics Study Section.

Date: October 14–15, 2010.

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

Agenda: To review and evaluate grant applications.

Place: The St. Regis Washington, DC, 923 16th and K Streets, NW., Washington, DC 20006.

Contact Person: David Balasundaram, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892. 301–435–1022. *balasundaramd@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Pathogenic Eukaryotes Study Section.

Date: October 14–15, 2010.

Time: 8:30 a.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: Tera Bounds, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892. 301–435–2306. *boundst@csr.nih.gov.*

Name of Committee: Biology of Development and Aging Integrated Review Group, International and Cooperative Projects—1 Study Section.

Date: October 14, 2010.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

Contact Person: Dan D. Gerendasy, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5132, MSC 7843, Bethesda, MD 20892. 301–594–6830. *gerendad@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Immunity and Host Defense Study Section.

Date: October 14–15, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Old Town Alexandria, 1767 King Street, Alexandria, VA 22314.

Contact Person: Patrick K. Lai, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2215, MSC 7812, Bethesda, MD 20892. 301–435–1052. *laip@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Therapeutic Approaches to Genetic Diseases.

Date: October 14, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Michael K. Schmidt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2214, MSC 7890, Bethesda, MD 20892. (301) 435–1147. *mschmidt@mail.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Cellular and Molecular Immunology—B Study Section.

Date: October 14–15, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Courtyard Magnificent Mile Downtown Chicago, 165 E. Ontario Street, Chicago, IL 60611.

Contact Person: Betty Hayden, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4206, MSC 7812, Bethesda, MD 20892. 301–435–1223. *haydenb@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Genetic Variation and Evolution Study Section.

Date: October 14–15, 2010.

Time: 8:30 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street, NW., Washington, DC 20037.

Contact Person: David J. Remondini, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2210, MSC 7890, Bethesda, MD 20892. 301–435–1038. *remondid@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: SAT and BTSS Study Sections.

Date: October 14, 2010.

Time: 2 p.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: Roberto J. Matus, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892. (301) 435–2204. *matusr@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: September 1, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–22311 Filed 9–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of a Meeting of a Working Group of the NIH Blue Ribbon Panel

The purpose of this notice is to inform the public about a meeting of the NIH Blue Ribbon Panel to Advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories at the Boston University Medical Campus. The meeting will be held Tuesday, October 5, 2010 at the Mainstage at Roxbury Community College, 1234 Columbus Avenue, Roxbury, MA from approximately 6:30 p.m. to 10 p.m.

This public meeting is being held to provide an update to the community on the status and proposed approach of the risk assessment for the BUMC NEIDL. The meeting program will include an update and review of the ongoing supplementary risk assessment study as well as opportunity for oral public comment. In addition, at any time, members of the public may file written comments to the following address: NIH Blue Ribbon Panel, Office of the Director, National Institutes of Health, Mail Stop Code 7985, Bethesda, MD 20892–7985 or by sending an e-mail to: *nih_brp@od.nih.gov.*

An agenda and slides for the meeting will be posted to the NIH Blue Ribbon Panel Web site in advance of the meeting at: *http://nihblueribbonpanel-bumc-neidl.od.nih.gov/.* For additional information concerning this meeting, contact Ms. Kelly Fennington, Senior Health Policy Analyst, Office of Biotechnology Activities, Office of Science Policy, Office of the Director, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892–7985; telephone 301–496–9838; e-mail *fennington@nih.gov.*