epidemiology and risk factors relating to chronic fatigue syndrome, and identifying potential opportunities in these areas; (2) current and proposed diagnosis and treatment methods for chronic fatigue syndrome; and (3) development and implementation of programs to inform the public, health care professionals, and the biomedical, academic, and research communities about advances in chronic fatigue syndrome.

The agenda for this meeting is being developed. The agenda will be posted on the CFSAC Web site, *http://www.hhs.gov/advcomcfs,* when it is finalized. The meeting will be broadcast over the Internet as a real-time streaming video. It also will be recorded and archived on the CFSAC Web site for on demand viewing.

CFSAC Subcommittees will convene scientific review sessions on Tuesday, October 12. The purpose of these sessions is to update the latest developments in etiology, natural history, clinical trials, and related areas for chronic fatigue syndrome. The public is welcome to attend these sessions, which are not a formal part of the Advisory Committee meeting. These sessions will be broadcast over the Internet as a real-time streaming video. It also will be recorded and archived on the CFSAC Web site for on demand viewing. An agenda will be posted on the CFSAC Web site when it becomes available.

Public attendance at the meeting is limited to space available. Individuals must provide a government-issued photo ID for entry into the building where the meeting is scheduled to be held. Those attending the meeting will need to sign-in prior to entering the meeting room. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person at *cfsac@hhs.gov* in advance.

Members of the public will have the opportunity to provide comment at the October 13–14 meeting if pre-registered. Individuals who wish to address the Committee during the public comment session must pre-register by Friday, September 17, 2010, via e-mail at *cfsac@hhs.gov.* Time slots for public comment will be available on a first-come, first-served basis. Public comment will be limited to five minutes per speaker; no exceptions will be made. Individuals registering for public comment should submit a copy of their testimony in advance to *cfsac@hhs.gov,* prior to the close of business on Friday, September 17, 2010.

Members of the public who wish to have printed material distributed to CFSAC members for review should submit one copy of the material to the Executive Secretary, at *cfsac@hhs.gov,* prior to close of business on September 17, 2010. Submissions are limited to five typewritten pages. Any written testimony submitted after this date will be available for inspection on-site and will be posted to the Web site after the meeting.

If you do not submit your written testimony prior to the close of business Friday, September 17, 2010, you may bring a copy of your written testimony to the meeting and present it to the CFSAC Executive Secretary. Your testimony will be included in a notebook that will be available for viewing by the public on a table at the back of the meeting room.

Please ensure that written testimony does not include any personal information including your personal mailing address and that it includes only your name, if you wish to be identified. If you wish to remain anonymous, please notify the CFSAC Executive Secretary upon submission of the materials to *cfsac@hhs.gov.*

Dated: August 31, 2010.

**Wanda K. Jones,**

*Executive Secretary, Chronic Fatigue Syndrome Advisory Committee.*

[FR Doc. 2010–22393 Filed 9–7–10; 8:45 am]

**BILLING CODE 4150–42–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–D–0285]**

### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters." The guidance was developed as a special control to support the reclassification of PTCA catheters, other than cutting/scoring PTCA catheters, from class III (premarket approval) into class II (special controls). This guidance describes a means by which PTCA catheters, other than cutting/scoring PTCA catheters, may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule that codifies the reclassification of this device type from class III (premarket approval) into class II (special controls).

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

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), 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 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:** Kathryn O'Callaghan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6349.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

This guidance document was developed as a special control guidance to support the reclassification of PTCA catheters, other than cutting/scoring PTCA catheters, into class II (special controls). The device is intended 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, treatment of acute myocardial infarction, treatment of in-stent restenosis and/or post-deployment stent expansion. Cutting/scoring PTCA catheters (Product Code: NWX) remain in class III and are subject to premarket

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**

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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, Selected Topics in Transfusion Medicine.

*Date:* September 27–28, 2010.

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