infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–27101 Filed 11–6–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 5 and 6, 2012, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Grand Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD. The hotel phone number is 301–948–8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993 301–796–3063, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On December 5, 2012, during session I, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 [Docket No. FDA–2009–M–0101], for the external counter-pulsating (ECP) devices, one of the remaining pre-Amendment Class III devices. These systems typically consist of a treatment table, pressure cuffs and a controller. They are intended to provide noninvasive circulatory support by applying external pressure to the lower extremities during diastole to increase coronary perfusion pressure, and releasing external pressure during systole to reduce left ventricular workload.

On March 9, 1979 (44 FR 13426), FDA published a proposed rule for classification of ECP devices as class III requiring premarket approval. The Cardiovascular Device Classification Panel (the Panel) recommended class III because the device is life supporting and potentially hazardous to life or health even when used properly. In addition, the Panel believed that sufficient information did not exist to determine the adequacy of general controls or to establish standards to provide a reasonable assurance of the safety and effectiveness of the device. Subsequent to the proposed rule, in 1980, FDA classified external counter-pulsating devices into class III after receiving no comments on the proposed rule (45 FR 7966, February 5, 1980). In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for ECP devices (52 FR 17737, May 11, 1987).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to premarket approval application [PMA]) or reclassify to class I or class II (subject to premarket notification [510(k)]), as directed by section 515(i) of the Federal Food, Drug and Cosmetic Act.

On December 5, 2012, during session II, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 [Docket No. FDA–2009–M–0101], for Intra-aortic balloon and control systems, one of the remaining pre-Amendment Class III devices. Intra-aortic balloon pump (IABP) systems consist of an inflatable balloon and a console which inflates in synchronization with the cardiac cycle. During diastole, the balloon will inflate, creating a rise in pressure in the aorta, thus increasing blood flow to the coronary arteries and increasing myocardial oxygen supply. During systole, deflation of the balloon causes a fall in pressure in the aorta, which assists the left ventricle by reducing the pressure that needs to be generated to achieve ejection through the aortic valve.

On March 9, 1979 (44 FR 13369), FDA published a proposed rule for classification of IABP devices as class III requiring premarket approval. The Panel recommended class III because the device is life supporting and because the Panel believed that insufficient medical and scientific information existed to establish a standard to assure the safety and effectiveness of the device. The Panel also stated that controversy exists as to whether the device is beneficial in many situations in which it is used, and that it is difficult to use the device safely and effectively. Subsequent to the proposed rule, in 1980, FDA classified IABP devices into class III after receiving no comments on the proposed rule (45 FR 7939, February 5, 1980). In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for IABP devices (52 FR 17736, May 11, 1987).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to premarket approval application [PMA]) or reclassify to class I or class II (subject to premarket notification [510(k)]), as directed by section 515(i) of the Federal Food, Drug and Cosmetic Act.

On December 6, 2012, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 [Docket No. FDA–2009–M–0101], for Nonroller-type cardiopulmonary bypass blood pumps, one of the remaining pre-Amendment Class III devices. A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump blood. There are two types of

nonroller-type pumps which have been reviewed by the Agency: (1) Centrifugal type pumps utilize a rotor to impart energy to the blood in an extracorporeal circuit through centrifugal forces. These pumps are part of an extracorporeal circuit usually containing an oxygenator and are intended to provide cardiopulmonary support, during procedures such as cardiopulmonary bypass surgery, for periods lasting 6 hours or less. (2) Micro-axial type pumps are comprised of a pump motor, a cannula and a catheter that connects to a console. These pumps are not designed to be used with an oxygenator but are temporarily placed within the heart or vasculature to provide cardiac support only.

On March 9, 1979 (44 FR 13409), FDA published a proposed rule for classification of nonroller-type cardiopulmonary bypass blood pumps as class III requiring premarket approval. The Panel recommended class III because the device is life sustaining and life supporting and is potentially hazardous to life or health even when properly used. The Panel indicated that general controls alone would not provide sufficient control over the performance characteristics of the device, and that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there was not sufficient information to establish a performance standard. Consequently, the Panel believed that premarket approval was necessary to assure the safety and effectiveness of the device. Subsequent to the proposed rule, in 1980, FDA classified nonroller-type cardiopulmonary bypass blood pumps into class III after receiving no comments on the proposed rule (45 FR 7959, February 5, 1980). In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for nonroller-type cardiopulmonary bypass blood pumps (52 FR 17737, May 11, 1987).

In 1993, FDA published a proposed rule requiring filing a PMA or Product Development Protocol (PDP) for nonroller type cardiopulmonary bypass blood pumps, and provided an opportunity to request a change in classification in the form of a reclassification petition (58 FR 36290, July 6, 1993). On July 21, 1993, FDA received a reclassification petition from manufacturers of these devices recommending reclassification to Class II (special controls). In 1995, FDA convened the Panel to review the proposed reclassification and proposed special controls for nonroller-type cardiopulmonary blood pumps for use in cardiopulmonary bypass circuits for periods of up to six hours. Micro-axial type pumps as described previously were not included in the scope of the reclassification. Reclassification to Class II with special controls was supported by the Panel for nonroller-type cardiopulmonary blood pumps for use in cardiopulmonary bypass circuits for periods of up to six hours, but FDA did not issue a regulation codifying the proposed reclassification. In 2004, the July 6, 1993 proposed rule (58 FR 36290) was withdrawn because the proposed rule was no longer considered a viable candidate for final action (69 FR 68831, November 26, 2004).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to premarket approval application [PMA]) or reclassify to class I or class II (subject to premarket notification [510(k)]), as directed by section 515(i) of the Federal Food, Drug and Cosmetic Act.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 26, 2012. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m. for session I and between 2 p.m. and 2:30 p.m. for session II. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 13, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 14, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, Conference Management Staff, at *James.Clark@fda.hhs.gov* or 301–796–5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 31, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–27068 Filed 11–6–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1075]

Minimum Clinically Important Difference: An Outcome Metric in Orthopaedic Device Science and Regulation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Minimum Clinically Important Difference: An Outcome Metric in Orthopaedic Device Science and Regulation.'' FDA is co-sponsoring this public workshop together with the Board of Regents of the University System of Georgia by and on behalf of the Georgia Institute of Technology's Translational Research Institute for Biomedical Engineering and Science