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]

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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

(TRIBES). The purpose of this public workshop is to bring together a wide variety of stakeholders to discuss key topics relating to minimum clinically important difference (MCID) for patient-reported outcome (PRO) instruments used in orthopaedic extremity device-related procedures in order to streamline evidence-based scientific rationales for regulatory guidance of clinical trials and device study design.

Date and Time: The public workshop will be held on November 27, 2012, from 7:45 a.m. to 5:30 p.m., and on November 28, 2012, from 7:45 a.m. to 1 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993, on November 27, 2012 (Day 1), and Building 66, Atrium, on November 28, 2012 (Day 2). Entrance for the public workshop participants (non-FDA employees) is through Building 1 on Day 1 and Building 66 on Day 2, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Faisal Mirza, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 1558, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6910 or 6311, FAX: 301–847–8117, email: *faisal.mirza@fda.hhs.gov.*

Registration: TRIBES will charge a registration fee for non-federal employees to cover its share of the expenses associated with the workshop. The registration fee is $230 for non-federal employees. Registration is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by November 13, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on Day 1 of the public workshop will be provided beginning at 6:45 a.m. The onsite registration fee is $275.

If you need special accommodations due to a disability, please contact Joyce Raines at 301–796–5709, email: *joyce.raines@fda.hhs.gov* no later than November 13, 2012.

To register for the public workshop, please visit the Georgia Institute of Technology's TRIBES Web site at *http://www.tribes.gatech.edu/mcid-conf-2012.* Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

For more information on the public workshop, please see FDA's Medical Devices News & Events—Workshops and Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

Streaming Webcast of the Public Workshop: This public workshop will also be available as a Webcast for registrants only. Persons interested in viewing the Webcast must register online by November 13, 2012. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after November 13, 2012. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, please visit: *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Evidence-based medicine guidelines advise the use of PRO instruments for assessing the successes of clinical treatment in practice and clinical investigations. However, the selection of a valid instrument and accurate estimation of its respective clinically meaningful differences remain challenging particularly with orthopaedic device-related procedures. The MCID approach has been proposed to overcome this problem for PRO instruments. There have been various methodological approaches to determine MCID for particular PRO instruments but consistency in the literature remains elusive in orthopaedics and, thus, is the focus of this workshop.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

1. Current high-quality validated PRO instruments used in orthopaedic extremity device-related procedures and published MCID values, if any, for the various PRO instruments.

2. The impact of variables such as gender, racial/ethnic diversity, age, body mass index, timeliness, patient expectations, and patient satisfaction on PRO response and how this affects MCID calculation within these diverse populations and particular target subgroups of interest.

3. Methodology for determining the MCID for validated PRO instruments in a consistent, reliable, and reproducible manner that is least cumbersome.

4. Current evidence on how the MCID, pertaining to a particular PRO instrument that is used in device-related orthopaedic extremity surgery, may affect patient outcomes and device regulation.

5. Potential standard metric by which to gauge patient outcomes across the spectrum of devices, target populations, and variables of interest, in order to streamline evidence-based scientific rationales for regulatory guidance of clinical trials and device study design.

Approximately 45 days after the workshop, presentation slides will be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

Dated: November 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–27147 Filed 11–6–12; 8:45 am]

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