4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-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 October 8 and 9, 2013, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

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 both days the committee will discuss, make recommendations, and vote on devices indicated for use in patients with heart failure (HF). On October 8, 2013, the committee will discuss, make recommendations, and vote on information related to the premarket approval application regarding the expansion of indications supported by the BLOCK HF trial to apply to all market-approved Medtronic Cardiac Resynchronization Therapy-Pacemaker (CRT-P) and Cardiac Resynchronization Therapy-Defibrillator (CRT-D) devices. The devices are pulse generators either without (CRT-P) or with (CRT-D) defibrillation capabilities. The devices require the implantation of at least a right ventricular (RV) and a left ventricular (LV) lead for sensing and pacing functionality. The RV lead used with a CRT-D device also has the capability to deliver high voltage energy. The implantation of a right atrial (RA) lead is left to the discretion of the clinician for both devices.

The requested expansion in indications for use was studied under the BLOCK HF trial. The trial was a prospective, multisite, randomized, double-blinded, parallel-controlled investigational device exemption (IDE) study. The primary objective of the trial was to demonstrate that the time until the first event of all-cause mortality, heart-failure-related urgent care, or a significant increase in left ventricular end systolic volume index (LVESVI) for subjects programmed to biventricular pacing is superior to that of subjects programmed to right ventricular pacing.

On October 9, 2013, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for CardioMEMS, Inc. Champion™ HF Monitoring System. The CardioMEMS HF System is a permanently implantable pressure measurement system designed to provide daily pulmonary arterial pressure measurements including systolic, diastolic, and mean pulmonary arterial (PA) pressure. These measurements are used to guide treatment of congestive heart failure. The system consists of the following:

Implantable Sensor--The Pressure Sensor consists of a three-dimensional coil and pressure-sensitive capacitor encased between two wafers of fused silica. The coil (inductor) electromagnetically couples to the Sensor and allows the remote measurement of the resonant frequency of the inductive/capacitive (LC) circuit. This allows for wireless communication with the Sensor and eliminates the need for an onboard source of energy, such as a battery.

Delivery System--The Delivery System allows the placement of the Pressure Sensor within the distal pulmonary artery. There are two versions of the Delivery System. The first includes a hydrophilic coating on the distal portion of the catheter shaft and the second has no coating on the catheter shaft. Both delivery catheters are compatible with a guidewire. The Delivery System (with HF Sensor) is introduced over a guidewire through a sheath. Tether wires connect the Sensor to the Delivery System until the physician determines that the Sensor is properly positioned within the distal pulmonary artery. Once the Sensor is in position, the tether wires are withdrawn, releasing the Sensor.

Electronics Unit (Interrogator) and database--The Electronics Unit contains hardware and software to acquire and process signals from the sensor, provides a system interface for both patients and clinicians, and transfers PA measurements to a database for review by medical

professionals. The database is a Web-based server that contains software, which receives data transmitted from the electronics unit, and presents the data for review by medical professionals.

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 September 24, 2013. On October 8 and 9, 2013, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 September 16, 2013. 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 September 18, 2013.

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 AnnMarie Williams, Conference Management Staff, at AnnMarie.Williams@fda.hhs.gov or 301-796-5966 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: September 4, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-21827 Filed 09/06/2013 at 8:45 am; Publication Date: 09/09/2013]