

time allotted for public comment, opportunity for oral presentations would be limited to the first registered requestors. All other comments may be submitted in writing.

4. Building and Security Guidelines

The Hubert H. Humphrey Building is the headquarters of the U.S. Department of Health and Human Services located at the foot of Capitol Hill at 200 Independence Avenue, SW., Washington, DC 20201. HHS headquarters is served by Metrorail and Metrobus. The closest Metrorail station is the Federal Center SW., station, which is served by the Blue and Orange lines.

The meeting is being held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, please take account of the need to clear security. All visitors must enter through the HHS Hubert H. Humphrey Building main entrance and must present government-issued photo identification (e.g., a valid federal identification badge, state driver's license, state non-driver's license, or passport). All persons entering the building must pass through a metal detector. Visitors are issued a visitor's ID wrist band in the main lobby and are escorted in groups of five to the meeting room. All items brought to HHS are subject to inspection.

Dated: October 7, 2011.

James W. Stephens,

Director, Office of Science Quality, Office of the Associate Director for Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

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 7 and 8, 2011, 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: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, james.swink@fda.hhs.gov or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 7, 2011, the committee will discuss, make recommendations, and vote on information related to a supplement to the premarket approval application (PMA) P010031, sponsored by Medtronic, Inc. Medtronic is requesting FDA approval to expand the indications for use for all commercially available Medtronic Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices covered under PMA P010031. The company has proposed the following expanded indication statement based on the results of the REVERSE and RAFT clinical studies: "Medtronic cardiac resynchronization therapy defibrillator (CRT-D) systems are indicated for heart failure patients who meet the following classification: NYHA Functional Class II who remain symptomatic despite stable, optimal medical therapy, and who have left bundle branch block (LBBB) with a QRS duration ≥ 120 ms, and left ventricular ejection fraction $\leq 30\%$."

On December 8, 2011, the committee will discuss, make recommendations, and vote on information related to the PMA for the CardioMEMS HF Pressure Measurement System (HF System) sponsored by CardioMEMS, Inc. 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 artery pressure. These measurements are used to guide treatment of congestive heart failure. The system consists of the following:

- **Implantable Sensor**—The Pressure Sensor is 15 millimeters (mm) in length, 3.41 mm in width and is 2 mm thick, consisting 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 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 have a usable length of 120 centimeters and are compatible with a 0.018" guidewire. The Delivery System (with HF Sensor) is introduced over a guidewire through an 11Fr 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 user-friendly system interface for both patients and clinicians, and transfers PA measurements to a secure 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 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 30, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on December 7 and 8, 2011. 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 22, 2011. 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 23, 2011.

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 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 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Dermatologic and Ophthalmic Drugs 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 Committees: Drug Safety and Risk Management Advisory Committee and Dermatologic and Ophthalmic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on December 1, 2011, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "Public Meetings at the FDA White Oak Campus". Please note that visitors to the White Oak Campus must enter through Bldg. 1.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: DSaRM@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about

possible modifications before coming to the meeting.

Agenda: The Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) requires FDA to bring, at least annually, one or more drugs with Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU) before its Drug Safety and Risk Management Advisory Committee (DSaRM). On December 1, 2011, the DSaRM and the Dermatologic and Ophthalmic Drugs Advisory Committees will meet in joint session to discuss REMS-related topics. During the morning session, the committees will discuss the REMS program for isotretinoin, also known as iPLEDGE, as an example of a REMS that has ETASU. During the afternoon session, the committees will discuss general issues related to the impact of REMS with ETASU on the health care system and patient access, such as how programs with ETASU can be better integrated into existing health systems.

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 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 16, 2011. Oral presentations from the public will be scheduled between approximately 9:40 a.m. and 10:10 a.m. (for comments related to iPLEDGE), and between 2:20 p.m. and 2:50 p.m. (for other REMS-related comments). 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 7, 2011. 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