

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Interagency Task Force on Antimicrobial Resistance (ITFAR): An Update on A Public Health Action Plan to Combat Antimicrobial Resistance

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of public meeting and request for comments.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and National Institutes of Health (NIH) announce an open meeting concerning antimicrobial resistance. The purpose of the meeting is to present the annual report on progress by Federal agencies in accomplishing activities outlined in *A Public Health Action Plan to Combat Antimicrobial Resistance (Action Plan)* and solicit comments from the public regarding ITFAR activities including the Annual Progress Report and the *Action Plan*. The meeting will take place at the Hubert H. Humphrey Building in Washington, DC on Tuesday, November 15, 2011 from 1 p.m.–3:30 p.m. The agenda will consist of welcome and introductory comments, a review of the *Action Plan* status and plans to update it; and reports of the progress toward implementing the *Action Plan* in each of the four focus areas: Surveillance, Prevention and Control, Research, and Product Development. The agenda is subject to change without notice. The meeting will then be open for comments from the general public. Persons wishing to participate, including those who wish to make an oral presentation, must register in advance and provide a copy of their presentation by noon Tuesday, November 8, 2011.

**DATES:** A public meeting will be held in Washington, DC, on Tuesday, November 15, 2011. The meeting will begin at 1 p.m. and end no later than 3:30 p.m.

**Deadline for Registration for all Attendees:** All attendees must register by noon, Tuesday, November 8, 2011.

**Deadline for Requests for Special Accommodation:** Requests for special accommodation should be submitted by noon, Tuesday, November 8, 2011.

**ADDRESSES:** Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, SW., Washington, DC USA 20201; <http://www.hhs.gov/about/hhhmap.html>. Toll Free: 1-877-696-6775.

Participants should be aware that the meeting is being held in a Federal government building; therefore, Federal security measures are applicable.

**FOR FURTHER INFORMATION CONTACT:**

Marsha A. Jones, Office of Antimicrobial Resistance, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop A-28, Atlanta, GA 30333; telephone 404-639-4111; E-mail [MJones@cdc.gov](mailto:MJones@cdc.gov).

**Submission of Written Comments:** Written comments and supporting documentation can be e-mailed to [ARplancomments@cdc.gov](mailto:ARplancomments@cdc.gov) or sent via regular mail to Marsha Jones, Office of Antimicrobial Resistance, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop A-28, Atlanta, GA 30333.

**Registration and Special Accommodations:** Individuals wishing to participate or who need special accommodations or both must register at [ARplancomments@cdc.gov](mailto:ARplancomments@cdc.gov) or by contacting Marsha Jones at [MJones@cdc.gov](mailto:MJones@cdc.gov). See **REGISTRATION TO ATTEND AND/OR PARTICIPATE IN THE PUBLIC HEARING** for instructions on how to submit electronic notices of participation.

**SUPPLEMENTARY INFORMATION:**

#### 1. Background

The Interagency Task Force on Antimicrobial Resistance (ITFAR) was created in 1999 to coordinate the activities of federal agencies in addressing antimicrobial resistance (AR) in recognition of the increasing importance of AR as a public health threat. The Task Force is co-chaired by the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). Other Task Force members include the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), and the HHS Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR), the Department of Agriculture (USDA), the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the Environmental Protection Agency (EPA).

In 2001, the ITFAR developed an initial *Action Plan* to combat antimicrobial resistance. In 2011, a revised version of the *Action Plan* which addresses the evolving threat of antimicrobial resistance was published. This Plan is entitled *A Public Health Action Plan to Combat Antimicrobial Resistance* and it outlines specific goals,

and implementation steps important for addressing the problem of antimicrobial resistance. Action items are organized into four focus areas: Surveillance, Prevention and Control, Research, and Product Development. The *Action Plan* and Annual Report are available at <http://www.cdc.gov/drugresistance>.

#### 2. Public Comment and Meeting

The public meeting process provides an opportunity for the public to become aware of and comment on the activities of the ITFAR to date. In addition, the ITFAR invites written comments and/or oral presentations of interested persons on the Annual Report as well as the four focus areas of the *Action Plan*: Surveillance, Prevention and Control, Research, and Product Development.

Written comments regarding ITFAR activities including the Annual Progress Report and the *Action Plan* submitted by e-mail should use the following subject line "ITFAR Comments." Written comments submitted by regular mail should clearly identify "ITFAR Comments" as the subject.

Comments and suggestions from the public for Federal agencies related to the Annual Report and/or any of the focus areas of the *Action Plan* will be taken under advisement by the Antimicrobial Resistance Interagency Task Force. The agenda does not include development of consensus positions, guidelines, or discussions or endorsement of specific commercial products.

#### 3. Registration to Attend and/or Participate in the Public Meeting

To ensure there is sufficient room we ask that you pre-register. Seating capacity is limited to 200 persons. If you wish to make an oral presentation during the open public comment period of the hearing, state your intention to present on your registration submission. To register, please send an electronic mail message to [ARplancomments@cdc.gov](mailto:ARplancomments@cdc.gov) by the deadline listed under **DATES**. Your email should include your name and email address. Please submit a written statement at the time of registration, identifying each focus area you wish to address and the approximate time requested to make your presentation. Organizations should provide this information as well as the names and e-mail addresses of all participants. Registered individuals will be notified of the approximate time scheduled for their presentation prior to the meeting. The time allotted for presentations will be limited to 5 minutes. If the number of proposed presentations exceeds the

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](mailto: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  $\geq 120$  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.