Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting Announcement (May 24, 2012)

U.S. Food & Drug Administration

Hilton Washington DC North/Gaithersburg
Montgomery Room
620 Perry Pkwy.
Gaithersburg, MD 20877
301–977–8900

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-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.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993-0002, 301-796-3063, Jamie.Waterhouse@fda.hhs.gov [1], 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 May 24, 2012, the committee will discuss current knowledge about the safety and effectiveness of the AMPLATZER ASO Device & Gore HELEX ASD Occluder as transcatheter Atrial Septal Defect (ASD) occluders used for the closure of secundum atrial septal defects. The AMPLATZER Septal Occluder (ASO) Device was the first device introduced to the US market in 2001 followed by the Gore HELEX device in 2006. With more widespread use of these devices, more information has become available regarding adverse events. These events range from rare life-threatening events to more common events that are perceived to have less severe clinical sequelae. Many of these events were evident in the premarket studies; however, rare events such as erosion were not seen. The purpose of discussion of these events is: (1) to discuss the significance of these events in the overall context of the disease and existing treatment options; (2) to discuss whether additional measures should be taken to improve protection of the public health (e.g., additional study and/or data analyses, labeling changes); and (3) to communicate to patients and physicians what is and is not known about device treatment options.

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 [2]. 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 May 16, 2012. 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 May 9, 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 May 11, 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 AnnMarie Williams, Conference Management Staff at AnnMarie.Williams@fda.hhs.gov [3] , 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 [4] 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: March 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

SOURCE [5]

Links:
[1] http://www.fda.gov/AdvisoryCommittees/Calendar/mailto:Jamie.Waterhouse@fda.hhs.gov
[2] http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm
[3] http://www.fda.gov/AdvisoryCommittees/Calendar/mailto:AnnMarie.Williams@fda.hhs.gov
[4] http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm
[5] http://www.fda.gov/AdvisoryCommittees/Calendar/ucm297470.htm