Federal Register: Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

U.S. Food & Drug Administration

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---------- DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2010-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 January 25 and 26, 2011, from 8 a.m. to 6 p.m. Location: Holiday Inn, Main Ballroom, Two Montgomery Village Ave., Gaithersburg, MD. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/default.htm [1]; under the heading ``Resources for You,'' click on ``White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings.'' Please note that visitors to the White Oak Campus must enter through Building 1. Contact Person: James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, or FDA Advisory Committee Information Line, 1-800- 741-8138 (301-443-0572 in the Washington, DC area), code 3014512625. 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 January 25, 2011, the committee will discuss and make recommendations regarding regulatory classification of Automated External Defibrillators to either reconfirm to class III (subject to premarket approval application (PMA)) or reclassify to class II (subject to premarket notification (510(k))), as directed by section 515(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360e(i)). On January 26, 2011, the committee will discuss, make recommendations and vote on information related to the PMA supplement for the RX Acculink Carotid Stent System, sponsored by Abbott Vascular. The RX Acculink is indicated for treatment of patients at high and standard risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the criteria outlined as follows: 1. Patients with neurological symptoms and >50 percent

stenosis of the common or internal carotid artery or patients without neurological symptoms and >80 percent (high risk) or >70 percent (standard risk) stenosis of the common or internal carotid artery and 2. Patients must have a reference vessel diameter within the range of 4.0 and 9.0 mm at the target lesion. 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 January 18, 2011. Oral presentations from the public will be scheduled for 1 hour at approximately 1 p.m., immediately following lunch on both days. 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 January 10, 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 January 11, 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 AnnMarie Williams, Conference Management Staff, 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 [3] 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: December 20, 2010. Leslie Kux, Acting Assistant Commissioner for Policy. [FR Doc. 2010-32367 Filed 12-23-10; 8:45 am] BILLING CODE 4160-01-P

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