4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-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, 2014, from 8 a.m. to 6 p.m. and on October 9, 2014, from 8 a.m. to 12:30 p.m.

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

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, 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 October 8, the committee will discuss, make recommendations and vote on information related to the premarket approval application regarding the Boston Scientific Corporation's WATCHMAN Left Atrial Appendage (LAA) Closure Technology. FDA is seeking committee review and recommendations regarding new clinical data and associated additional adverse events including stroke that have become available since the previous advisory committee meeting on the WATCHMAN device, which was held December 11, 2013. The WATCHMAN LAA Closure Technology is a percutaneously delivered permanent cardiac implant placed in the left atrial appendage. This device is indicated to prevent thromboembolism (TE) from the left atrial appendage. It may be considered for use in patients with non-valvular atrial fibrillation who are eligible for warfarin therapy to reduce the risk of stroke and systemic embolism based on $CHADS_2$ (congestive heart failure, hypertension, age >75 years, diabetes, and prior stroke or transient ischemic attack (TIA)) or CHA_2DS_2-VASc (congestive heart failure, hypertension, age >75 years, diabetes mellitus, stroke/TIA/TE, vascular disease, age 65-74, and sex category) scores.

On October 9, the committee will discuss and make recommendations regarding the classification of more-than-minimally manipulated allograft heart valves (MMM Allograft HVs). A MMM Allograft HV is a human valve or valved conduit that has been aseptically recovered from qualified donors, dissected free from the human heart, and then subjected to a manufacturing

process(es) that alters the original relevant characteristics of the tissue (21 CFR 1271.3(f), 21 CFR 1271.10(a)(1), and 21 CFR 1271.20). The valve is then stored until needed by a recipient. An example of such a manufacturing process is one that intentionally removes the cells and cellular debris with the goal of reducing in vivo antigenicity.

MMM Allograft HVs are considered preamendment devices because they were found substantially equivalent to devices in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. MMM Allograft HVs are currently regulated under Product Code OHA, ''Heart Valve, More than Minimally Manipulated Allograft,'' as unclassified devices and reviewed under the premarket notification, 510(k), authority (21 CFR part 807). FDA is seeking committee input on the safety and effectiveness of MMM Allograft HVs and the regulatory classification for MMM Allograft HVs.

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 30, 2014. On October 8, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. On October 9, oral presentations from the public will be scheduled between approximately 9:45 a.m. and 10:15 a.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 22, 2014. 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 24, 2014.

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, Annmarie.Williams@fda.hhs.gov 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: August 20, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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