4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Neurological 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: Neurological 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 March 23, 2012, from 8 a.m. to 7 p.m.

Location: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301-977- 8900.

Contact Person: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993-0002, 301-796-3805, Avena.Russell@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 March 23, 2012, the committee will discuss current knowledge about the safety and effectiveness of the Wingspan Stent System with Gateway PTA Balloon Catheter for the treatment of intracranial arterial stenosis. FDA is convening this committee to seek expert scientific and clinical opinion on the risks and benefits of this device based on the available premarket and postmarket data. The Wingspan Stent System with Gateway PTA Balloon Catheter is a neurovascular stent, balloon catheter, and delivery system consisting of the following components:

1. Wingspan Stent--This is a self-expanding, nitinol stent with a tubular mesh design.
2. Gateway PTA Balloon Catheter--This balloon catheter is used to predilate the lesion prior to introduction of the Wingspan Stent System into the patient.
3. Wingspan Delivery System--This delivery system is a single lumen, over-the-wire, coaxial microcatheter that is used to deliver the stent to the treatment site within the patient's artery.

The Wingspan Stent System with Gateway PTA Balloon Catheter has been approved under a humanitarian device exemption (HDE) (H050001) for the following indications: "The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with $\geq$ 50% stenosis that are accessible to the system."

Interim results and analyses of data from an ongoing randomized clinical trial, "Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis" (SAMMPRIS), published in the New England Journal of Medicine (2011;365:993-1003), will be presented for the Wingspan Stent with Gateway PTA Balloon catheter. The committee will be asked to discuss the comparability of the patient populations for the approved HDE and SAMMPRIS trial and the relevance of the SAMMPRIS trial results to the assessment of safety and probable benefit for the Wingspan Stent System with Gateway PTA Balloon Catheter HDE.

FDA recently received a citizen's petition seeking withdrawal of the HDE approval and recall of Wingspan stents currently on the market. The petitions are available for public review and comment at www.regulations.gov under docket number FDA-2011-P-0923.

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: FDA will work with affected industry and professional organizations that have an interest in the Wingspan Stent System and who wish to make a presentation separate from the general Open Public Hearing; time slots between 2 p.m. and 3 p.m. are provided. Representatives from industry and professionals organizations interested in making formal presentations to the committee should notify the contact person on or before March 1, 2012.

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 March 9, 2012. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 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 March 1, 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 March 2, 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 James Clark, 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: February 8, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012-3243 Filed 02/10/2012 at 8:45 am; Publication Date: 02/13/2012]