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. This meeting is being rescheduled due to the postponement of the November 1, 2012, meeting due to unanticipated weather conditions caused by hurricane Sandy.

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 December 10, 2012, from 8 a.m. to 6 p.m.

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

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993-0002, 301-796-5290, Natasha.Facey@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 December 10, 2012, the committee will discuss current knowledge about the safety and effectiveness of the CoAxia NeuroFlo Catheter device for the intended use of diverting cardiac output to the cerebral vasculature via partial occlusion of the descending aorta, including in patients with acute ischemic stroke within 14 hours of symptom onset.

The CoAxia NeuroFlo Catheter is a 7F multilumen device with two balloons mounted near the distal tip. The proximal end has a multiport manifold that provides access for the guidewire, monitoring of blood pressure, and independent inflation of the individual balloons. The device is placed in the descending aorta. On March 30, 2005, a humanitarian device exemption application for the CoAxia NeuroFlo Catheter was approved for the following indication for use: The CoAxia NeuroFlo Catheter is intended for the treatment of cerebral ischemia resulting from symptomatic vasospasm following aneurismal subarachnoid hemorrhage, secured by either surgical or endovascular intervention for patients who have failed maximal medical management.

Of note, the CoAxia NeuroFlo Catheter is identical in design to the CoAxia FloControl, which is currently cleared for the following general indications for use:

1. The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature (K023914).

2. The CoAxia FloControl Catheter is intended for use in selectively stopping or controlling flow in the peripheral vasculature, which includes the descending aorta (K090970).

CoAxia has submitted a de novo application for the NeuroFlo for the following indication: The CoAxia NeuroFlo Catheter is intended for use in diversion of cardiac output via partial occlusion of the descending aorta, including patients with acute ischemic stroke within 14 hours of symptom onset. The CoAxia NeuroFlo Catheter is also intended for use in selectively stopping or controlling blood flow in the peripheral vasculature, which includes the descending aorta.

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. In particular, the committee will be asked to discuss the safety and effectiveness data from the "Safety and Efficacy of NeuroFlo Technology in Ischemic Stroke" (SENTIS) clinical trial as they relate to the proposed indications for use.

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 December 4, 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 November 26, 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 November 28, 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, Committee 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 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: November 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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