4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Acute Ischemic Stroke Medical Devices Trials Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Acute Ischemic Stroke Medical Device Trials Workshop". Acute ischemic stroke medical devices are intended to remove blood clots from the cerebral neurovasculature by mechanical, laser, ultrasound, or a combination of technologies. The purpose of this workshop is to obtain public input and feedback on scientific, clinical, and regulatory considerations associated with acute ischemic stroke medical devices. Ideas generated during this workshop may facilitate further development of guidance regarding the content of premarket submissions for acute ischemic stroke emerging technologies and help to speed development and approval of future submissions.

DATES: The public workshop will be held on October 6, 2015, from 1 p.m. to 5:30 p.m. Registration to attend the meeting must be received by September 25, 2015, at 4 p.m. See the SUPPLEMENTARY INFORMATION section for instructions on how to register for the public workshop. Submit either electronic or written comments by November 3, 2015.

ADDRESSES: The public workshop will be held at the Bethesda Pooks Hill Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814. Please visit the following Web site for parking and security information: http://www.marriott.com/hotels/maps/travel/wasbt-bethesda-marriott/.

Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Hilda Scharen, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm. 3625, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6815, Hilda.Scharen@fda.hhs.gov; or Jamie Waterhouse, Project Manager, Neurointerventional and Neurosurgical Devices Branch, Division of Neurological and Physical Medicine Devices, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3063, Jamie.Waterhouse@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Acute ischemic stroke medical devices are intended to remove blood clots from the cerebral neurovasculature. This may be achieved through a variety of mechanisms, such as mechanical, laser, ultrasound, or a combination of technologies. Acute ischemic stroke medical devices can present both important safety and effectiveness questions as well as study design and data analysis challenges.

II. Purpose and Scope of the Public Workshop

The workshop seeks to involve industry and academia in addressing scientific, clinical, and regulatory considerations associated with acute ischemic stroke medical devices. By bringing together relevant stakeholders, which include scientists, patient advocates, clinicians, researchers, industry representatives, and regulators, to this workshop, we hope to facilitate the improvement of this rapidly evolving product area.

This workshop is aimed to address scientific, clinical, and regulatory considerations associated with acute ischemic stroke medical devices, including but not limited to, the following topic areas:

- Considerations for clinical study trial designs, patient populations, and patient selection methods, and
- Considerations for clinical study endpoints, e.g., clinically relevant outcome measures and related statistical analyses.

III. Attendance and Registration

Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by September 25, 2015, at 4 p.m. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 12 p.m.

If you need special accommodations due to a disability, please contact Susan Monahan, email: susan.monahan@fda.hhs.gov or phone: 301-796-5661 no later than September 25, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select

this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

IV. Comments

In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is November 3, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may also be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr.,

Element Bldg., Rockville, MD 20857. A link to the transcripts will be available approximately 45 days after the public workshop on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public workshop from the posted events list).

Dated: July 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-16774 Filed: 7/8/2015 08:45 am; Publication Date: 7/9/2015]