

Information/Guidances/  
UCM291390.pdf).<sup>3</sup>

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on labeling and safety testing requirements for heparin-containing medical devices and combination products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Device and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Heparin-Containing Medical Devices and Combination Products: Recommendations for Labeling and Safety Testing" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1817 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 211 (Current Good Manufacturing Practice for Finished Pharmaceuticals) have been approved under OMB control number 0910–0139. The collections of information in FDA's medical devices regulations in 21 CFR parts 801 (Labeling); 803 (Medical Device Reporting); 807, subpart E (Premarket Notification Procedures); 812 (Investigational Device Exemptions); 814, subparts A through E (Premarket Approval of Medical Devices); 814, subpart H (Humanitarian

Use Devices); and 820 (Quality System Regulation) have been approved under OMB control numbers 0910–0485, 0910–0437, 0910–0120, 0910–0078, 0910–0231, 0910–0332, and 0910–0073 respectively.

## V. Comments

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. 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>.

Dated: July 2, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–16775 Filed 7–8–15; 8:45 am]

**BILLING CODE 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](mailto: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](mailto: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,

<sup>3</sup> The Agency updates guidances periodically. To make sure you have the most recent version of this guidance, check the CDER guidance page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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](mailto: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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from

the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than August 10, 2015.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 594-4306.

### SUPPLEMENTARY INFORMATION:

*Information Collection Request Title:* Maternal, Infant, and Early Childhood Home Visiting (Home Visiting) Program, Competitive Funding Opportunity Announcement OMB No. 0915-0351—Extension.

*Abstract:* The Home Visiting Program, administered by the Health Resources and Services Administration (HRSA) in close partnership with the Administration for Children and Families (ACF), supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. The 50 states, District of Columbia, and 5 territories and eligible nonprofit organizations are eligible for Home Visiting Competitive Funding.

*Need and Proposed Use of the Information:* The purpose of this announcement is to solicit Fiscal Year 2016 (FY16) applications for the Home Visiting Competitive Grant program. Competitive Grants provide funds to eligible entities that are states and certain territories that continue to make significant progress toward implementing a high-quality home visiting program as part of a comprehensive, high-quality early childhood system and are ready and able to take effective programs to scale to address unmet need. This information collection is needed for eligible entities to apply for competitive funding opportunities under the MIECHV. As noted above, this program is authorized under the Social Security Act, Title V, Section 511 (42 U.S.C. 701), as amended by Section 2951 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148). A portion of funding under this program is awarded to participating states and eligible jurisdictions<sup>1</sup> by formula.

<sup>1</sup> The 50 states, the U.S. Virgin Islands, Puerto Rico, American Samoa, the Northern Marianas, District of Columbia, and Guam.