

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.

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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 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 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 jurisdictions¹ by formula.

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

However, an additional portion of funds is awarded competitively.

The information collected will be used to collect applicant information regarding proposed project plans sufficient to inform peer review and subsequent grant award and monitoring. Peer reviewers will be selected from among experts in the relevant fields to assess and score applicant proposals. On the basis of reviewer scores, applications will be ranked, and the highest scoring applications will be funded according to availability of funds. Applications approved for funding are entered into HRSA's Electronic Handbook (EHB).

Subsequent to award, the approved plans set forth in the applications in the

EHB will be monitored by Federal Project Officers to ensure implementation according to these plans, as submitted in this data collection instrument. Failure to collect this information would result in either a failure to make awards to eligible entities as required by law, or would necessitate award of all funds by formula, which is inconsistent with established program policy and implementation, as competitive awards have been made a part of this program's administration.

Likely Respondents: Applicants to FY16 Home Visiting Competitive Funding Opportunity Announcement.

Burden Statement: Burden in this context means the time expended by

persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Summary of progress on the following activities	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total burden hours
Introduction	47	1	47	10	470
Needs Assessment	47	1	47	14	658
Methodology	47	1	47	15	705
Work Plan	47	1	47	15	705
Resolution of Challenges	47	1	47	14	658
Evaluation and Technical Support	47	1	47	48	2256
Organizational Information	47	1	47	10	470
Additional Attachments	47	1	47	13	611
Total	47	8	376	139	6533

Jackie Painter,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP-2015-0019]

Advisory Committee on Commercial Operations to U.S. Customs and Border Protection (COAC)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Committee Management; notice of Federal Advisory Committee meeting.

SUMMARY: The Advisory Committee on Commercial Operations to U.S. Customs and Border Protection (COAC) will meet on July 29, 2015, in Rosemont, IL. The meeting will be open to the public.

DATES: The Advisory Committee on Commercial Operations to U.S. Customs and Border Protection (COAC) will meet on Wednesday, July 29, 2015, from 1:00 p.m. to 4:00 p.m. CDT. Please note that

the meeting may close early if the committee has completed its business.

Pre-Registration: Meeting participants may attend either in person or via webinar after pre-registering using a method indicated below:

—For members of the public who plan to attend the meeting in person, please register either online at https://apps.cbp.gov/te_reg/index.asp?w=45; by email to tradeevents@dhs.gov; or by fax to (202) 325-4290 by 5:00 p.m. EDT on July 24, 2015. You must register prior to the meeting in order to attend the meeting in person.

—For members of the public who plan to participate via webinar, please register online at https://apps.cbp.gov/te_reg/index.asp?w=45 by 5:00 p.m. EDT on July 24, 2015.

Feel free to share this information with other interested members of your organization or association.

Members of the public who are pre-registered and later require cancellation, please do so in advance of the meeting by accessing one (1) of the following links: https://apps.cbp.gov/te_reg/cancel.asp?w=45 to cancel an in person registration, or https://apps.cbp.gov/te_

[reg/cancel.asp?w=45](https://apps.cbp.gov/te_reg/cancel.asp?w=45) to cancel a webinar registration.

ADDRESSES: The meeting will be held at the Crown Plaza Chicago O'Hare, in the O'Hare Ballroom #1, 5440 North River Road, Rosemont, IL 60018. There will be signage posted directing visitors to the location of the O'Hare Ballroom #1.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection at (202) 344-1661 as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the committee prior to the formulation of recommendations as listed in the "Agenda" section below.

Comments must be submitted in writing no later than July 17, 2015, and must be identified by Docket No. USCBP-2015-0019, and may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.