

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 January 21, 2016, the Committee will meet in an open session to discuss safety and effectiveness data, including challenge study endpoints, for licensure of food allergy immunotherapy products, and the clinical development of aeroallergen immunotherapy products for the prevention of respiratory allergic disease.

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 January 6, 2016. 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 December 29, 2015. 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 December 31, 2015.

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 disabilities. If you require accommodations due to a disability, please contact Janie Kim 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: December 15, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-31894 Filed 12-18-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Risk Communication 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:** Risk Communication 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 February 16, 2016, from 9 a.m. to 5 p.m. and February 17, 2016, from 9 a.m. to 4 p.m.

**Location:** FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**Contact Person:** Lee L. Zwanziger, Risk Communication Staff, Office of Planning, Food and Drug Administration, 10903 New Hampshire

Ave., Bldg. 32, Rm. 3354, Silver Spring, MD 20993, 301-796-9151, FAX: 301-847-3540, email: [RCAC@FDA.HHS.GOV](mailto:RCAC@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 February 16 and 17, 2016, the Committee will discuss recent developments in risk communications and related sciences, and possible approaches and applications in the context of FDA communications.

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 February 9, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on February 16, 2016, and 1 p.m. and 1:30 p.m. on February 17, 2016. 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 January 25, 2016. 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 February 2, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Lee L. Zwanziger 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: December 15, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015-31893 Filed 12-18-15; 8:45 am]

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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 January 20, 2016.

**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:* The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System.

*OMB No.:* 0906-xxxx—NEW.

*Abstract:* The Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV), administered by HRSA in 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. States and territories (as well as nonprofit organizations selected to provide services in non-participating states and territories) are eligible to receive funding from the Home Visiting Program and have flexibility to tailor the program to serve the specific needs of their communities.

*Need and Proposed Use of the Information:* HRSA will use the proposed information to demonstrate program accountability and continuously monitor and provide oversight to state and territory Home Visiting Program grantees. The information will also be used to provide quality improvement guidance and technical assistance to grantees and help inform the development of early childhood systems at the national, state, and local level. HRSA is seeking to collect demographic, service utilization, and select clinical indicators for participants enrolled in home visiting services. In addition, HRSA will collect a set of standardized performance and system outcome indicators that correspond with the statutorily identified benchmark areas.

*Demographic, Service Utilization, and Clinical Indicators Data:* These data will describe the population served by the Home Visiting Program, including the unduplicated count of the number of participants and participant groups by race and ethnicity. These data will provide other socio-demographic

characteristics of program participants and their utilization of services, such as program retention. Additionally, these data will describe several select clinical indicators of program participants, such as a child's usual source of medical care. This information will be collected from participants at enrollment in home visiting services and aggregated and reported to HRSA by state/territory grantees once annually.

*Performance and System Outcome Benchmark Data:* These data constitute a discrete set of standardized performance and system outcome indicators that correspond with the statutorily identified benchmark areas. These data will provide aggregate totals, percentages, and rates for performance and system outcome indicators that are salient to the Home Visiting Program, home visiting services more generally, and the at-risk populations served. These data will be collected from participants based on the appropriate measurement period defined for each measure and aggregated and reported to HRSA by state/territory grantees once annually.

This information will be used to demonstrate accountability with legislative and programmatic requirements. It will also be used to monitor and provide continued oversight for grantee performance and to target technical assistance resources to grantees. In the future, it is anticipated that Home Visiting Program funding decisions may be allocated based on grantee performance, including on benchmark performance areas.

*Likely Respondents:* Home Visiting Program grantees.

*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.