For purposes of this extension request, we are retaining our 2012 estimates. The PRA analysis for the GRAS final rule will take into account any changes to the GRAS notification procedure as set forth in the final rule and we will revise the collection accordingly.

Dated: September 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–23334 Filed 9–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Pediatric Oncology Subcommittee of the Oncologic Drugs 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: Pediatric Oncology Subcommittee of the Oncologic Drugs 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 November 19, 2015, from 8 a.m. to 1 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. 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: Lauren D. Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *ODAC@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: Information will be presented to gauge investigator interest in exploring potential pediatric development plans for two products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) ABT–414, application submitted by AbbVie, Inc., and (2) Lenvatinib, application submitted by Eisai, Inc.

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 subcommittee. Written submissions may be made to the contact person on or before November 4, 2015. Oral presentations from the public will be scheduled between approximately 9:05 a.m. to 9:35 a.m., and 11:30 a.m. to 12 noon. 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 October 27, 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 October 28, 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 Lauren D. Tesh 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: September 14, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–23366 Filed 9–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Alliance for Innovation on Maternal and Child Health Cooperative Agreement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Single-Case Deviation from Competition Requirement for the Alliance for Innovation on Maternal and Child Health Cooperative Agreement at the Association of State and Territorial Health Officials, Grant Number UC4MC28036.

SUMMARY: HRSA announces the award of a program expansion supplement in the amount of $100,000 for the Alliance for Innovation on Maternal and Child Health (AIM) cooperative agreement. The purpose of the AIM cooperative agreement, as stated in the funding

opportunity announcement (FOA), is to expand access to care for the maternal and child health (MCH) populations through the following program focus areas: (1) Ensuring continuity of coverage and care for pregnant women and children; (2) improving systems of care for children with special health care needs; and (3) promoting the use of Bright Futures Guidelines for all children. The program expansion supplement will provide funds to the Association of State and Territorial State Health Officials (ASTHO), the cooperative agreement awardee, during the budget period of September 30, 2015, through September 29, 2016, to provide targeted technical assistance to two States at risk for rapid transmission of HIV and Hepatitis C virus (HCV) through injection drug use, to build capacity and expand access to care, document and share best practices with other State Health Officials also seeking to prevent HIV and HCV infection through injection drug use.

SUPPLEMENTARY INFORMATION: Intended Recipient of the Award: The Association of State and Territorial Health Officials
Amount of the Non-Competitive Award: $100,000
CFDA Number: 93.110
Current Project Period: 9/30/2014–9/29/2017
Period of Supplemental Funding: 9/30/2015–9/29/2016

Authority: Social Security Act, Title V, § 501(a)(2) (42 U.S.C. 701(a)(2)).

Justification: On April 24, 2015, the Governor of Indiana declared a public health disaster emergency in Scott County, Indiana, attributable to the HIV epidemic in that county. On the same day, the Centers for Disease Control and Prevention issued a Health Alert Network Advisory to inform other public health departments and healthcare providers of the possibility of HIV outbreaks among persons who inject drugs and to provide guidance to assist in the identification and prevention of such outbreaks. As of August 28, 2015, the Indiana outbreak is now 181 (177 confirmed and 4 presumptive positive) adult and adolescent HIV infections, including a small number of pregnant women. Though there are HIV prevention best practices to inform States, additional innovative practices are needed to reach women of child-bearing age, adolescents, and young adults within high risk counties, which do not routinely access health care.

As stated in the FOA, the Alliance for Innovation on Maternal and Child Health (AIM) is a Maternal and Child Health Bureau (MCHB) collaborative program of awardee organizations for the purpose of expanding access to care for the maternal and child health (MCH) populations. Per the FOA, AIM Collaborative Engagement awardees are responsible for engaging key State agencies and offices (*i.e.,* Public Health and Medicaid) in AIM activities and raising awareness of best practices.

In 2014, following objective review of its application, HRSA awarded the Association of State and Territorial Health Officials (ASTHO) cooperative agreement funding as an AIM Collaborative Engagement program. If approved, this would be the first program expansion supplement for this cooperative agreement.

ASTHO is the national nonprofit organization representing public health agencies in the United States, the U.S. Territories, the District of Columbia, and over 100,000 public health professionals these agencies employ. As part of its AIM cooperative agreement, ASTHO identifies and disseminates best practices to meet the needs of MCH populations. At the time of the FOA and application, expanding access to care among high risk populations to prevent HIV infection through injection drug use was not yet identified as a need of MCH populations. As such, the FOA and application did not address it.

To meet this emerging need, ASTHO submitted a prior approval request to expand the scope of its AIM cooperative agreement award to work with States at risk for rapid transmission of HIV and HCV through injection drug use. ASTHO, working with MCHB, would provide targeted technical assistance to two states to build capacity and expand access to care among high risk populations to prevent HIV and HCV infection through injection drug use. ASTHO would also document and share best practices and other technical assistance resources from the two targeted states to its network of State Health Officials.

FOR FURTHER INFORMATION CONTACT: Sylvia Sosa, MSc, Office of Policy and Planning, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 18W25D, Rockville, Maryland 20857; *ssosa@hrsa.gov*.

Grantee/organization name	Grant number	State	FY 2015 Authorized funding level	FY 2015 Estimated supplemental funding
The Association of State and Territorial Health Officials	UC4MC28036	VA	$350,000	$100,000

Dated: September 11, 2015.

James Macrae,

Acting Administrator.

[FR Doc. 2015–23357 Filed 9–16–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Centers of Excellence in Maternal and Child Health in Education, Science, and Practice Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Single-Case Deviation from Competition Requirements for Program Expansion Supplement Request for Centers of Excellence in Maternal and Child Health in Education, Science, and Practice program Award to the University of Washington, Grant Number T76MC00011.

SUMMARY: HRSA announces the award of a program expansion supplement in the amount of $40,000 for the Centers of Excellence in Maternal and Child Health (MCH) in Education, Science, and Practice grant. The purpose of the Centers of Excellence in MCH program is for the training of graduate and post-graduate public health professionals in an interdisciplinary MCH setting. The purpose of this notice is to award supplemental funds to conduct a rigorous evaluation of the Pediatric