

Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2016-21039 Filed 8-31-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meetings

AGENCY: Office of Head Start (OHS), Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110-134, notice is hereby given of a 1-day Tribal Consultation Session to be held between the Department of Health and Human Services (HHS), Administration for Children and Families, OHS leadership and the leadership of Tribal Governments operating Head Start (including Early Head Start) programs. The purpose of these Consultation Sessions is to discuss ways to better meet the needs of American Indian and Alaska Native children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42 U.S.C. 9835, Section 640(l)(4)].

DATES: October 19, 2016, from 8:00 a.m. to 1:00 p.m.

LOCATION: ThriveAlaska Head Start Center at 1949 Gilliam Way, Fairbanks, Alaska 99701.

FOR FURTHER INFORMATION CONTACT: Angie Godfrey, Regional Program Manager, Region XI AI/AN, OHS, email Angie.Godfrey@acf.hhs.gov, or phone (202) 205-5811. Additional information and online meeting registration is available at: <http://eclkc.ohs.acf.hhs.gov/hslc/hs/calendar/tc2016>.

SUPPLEMENTARY INFORMATION: HHS announces OHS Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs. The agenda for the scheduled OHS Tribal Consultations in Fairbanks, Alaska, will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the

needs of American Indian and Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in that geographic location. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in the 2016 OHS Tribal Consultation.

The Consultation Session will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C. 9835, Section 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the tribe. Tribal Governments must submit the designee letter at least 3 days in advance of the Consultation Session to Angie Godfrey at Angie.Godfrey@acf.hhs.gov. Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of the Consultation Session will be prepared and made available within 45 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Angie Godfrey at Angie.Godfrey@acf.hhs.gov either prior to the Consultation Session or within 30 days after the meeting. OHS will summarize oral testimony and comments from the Consultation Session in a report without attribution, along with topics of concern and recommendations.

Dated: August 26, 2016.

Blanca E. Enriquez,

Director, Office of Head Start.

[FR Doc. 2016-21047 Filed 8-31-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Announcement of the Award of Single-Source Grants Under the Wilson-Fish Alternative Program (W-F); Correction; CFDA Number: 93.583

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Notice; correction.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR), published a document in the **Federal Register** of August 22, 2016, concerning the

announcement of the award of 13 single-source grants for a total of \$35,513,938 under the W-F Alternative Program. The document contained an incorrect address and telephone number.

FOR FURTHER INFORMATION CONTACT:

Colleen Mahar-Piersma, Program Analyst, Office of Refugee Resettlement, Mary E. Switzer Building, 330 C Street SW., Washington, DC 20201. Telephone: 202-205-5266; Email: colleen.mahar-piersma@acf.hhs.gov.

Correction

In the **Federal Register** of August 22, 2016, in FR Doc. 2016-19923, on page 56655, in the third column, correct the **FOR FURTHER INFORMATION CONTACT** caption to read: Colleen Mahar-Piersma, Program Analyst, Office of Refugee Resettlement, Mary E. Switzer Building, 330 C Street SW., Washington, DC 20201. Telephone: 202-205-5266; Email: colleen.mahar-piersma@acf.hhs.gov.

Mary M. Wayland,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Advisory Committee; Cardiovascular and Renal Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Cardiovascular and Renal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Cardiovascular and Renal Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until August 27, 2018.

DATES: Authority for the Cardiovascular and Renal Drugs Advisory Committee will expire on August 27, 2016, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Jennifer Shepherd, 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, email: CRDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Cardiovascular and Renal Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Cardiovascular and Renal Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cardiovascular and renal disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of cardiology, hypertension, arrhythmia, angina, congestive heart failure, diuresis, and biostatistics. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm094743.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no

amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: August 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-21041 Filed 8-31-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

The Sentinel Post-Licensure Rapid Immunization Safety Monitoring Program; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled “The Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program.” The purpose of the workshop is to describe the Sentinel Initiative and PRISM program, illustrate how PRISM is used by FDA for regulatory responsibilities (including how it has been integrated into FDA’s regulatory review process and case examples), and discuss the future direction of PRISM in terms of expansion and further integration into the regulatory review process.

DATES: The public workshop will be held on December 7, 2016, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the National Institutes of Health, 8600 Rockville Pike, Lister Hill Center Auditorium, Building 38A, Bethesda, MD 20894.

FOR FURTHER INFORMATION CONTACT:

Chris Nguyen, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 4124, Silver Spring, MD 20993-0002; or Cynthia Whitmarsh, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 4122, Silver Spring, MD 20993-0002; For questions, email: [\[fda.hhs.gov\]\(mailto:fda.hhs.gov\) \(Subject Line: Sentinel PRISM Workshop\).](mailto:CBERPPublicEvents@</p></div><div data-bbox=)

SUPPLEMENTARY INFORMATION: The Sentinel Initiative is FDA’s national electronic surveillance system for the post-market safety monitoring of medical products. The Sentinel System was implemented as an Active Post-Market Risk Identification and Analysis program in response to section 905 of the Food and Drug Administration Amendments Act of 2007. PRISM was initiated in 2009 as one of several national vaccine safety surveillance systems deployed during the H1N1 influenza pandemic. PRISM was integrated into the FDA Sentinel Initiative in September 2010. PRISM has been used on multiple occasions to evaluate for vaccine-adverse events, such as the risk of intussusception following rotavirus vaccination, and the risk of febrile seizure among children receiving the trivalent inactivated influenza vaccine.

The PRISM distributed database covers more than 171 million individuals in a number of data partner organizations. The database is enhanced by linkages to State-wide registries and birth registries. PRISM is being used to develop broad-based signal detection tools that can be used to further evaluate vaccine safety. There are currently several active vaccine protocol-based assessments underway. More information can be found at: http://www.mini-sentinel.org/assessments/medical_events/default.aspx.

The workshop will bring together other government agencies, academia, industry, and other stakeholder participants involved in vaccine development and safety. The goal of the workshop is to present and discuss the current capabilities of PRISM. Topics include: (1) The available data infrastructure, (2) methods, and (3) tools. In addition, a few representative examples of PRISM studies will be presented to demonstrate the program’s success in safety signal refinement and evaluation and informing the regulatory process. There will also be a discussion of possible future directions for PRISM.

Registration: Please visit the following Web site to register for the workshop by November 23, 2016, midnight Eastern Standard Time: <https://www.eventbrite.com/e/the-sentinel-post-licensure-rapid-immunization-safety-monitoring-prism-system-public-workshop-tickets-22494636062>. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registrants will receive confirmation once they have been