DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Health Resources and Services Administration

Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation

AGENCY: Administration for Children and Families (ACF), HHS; Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice to announce the renewal of the Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation.

SUMMARY: ACF and HRSA announce the renewal of the Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation to provide advice and make recommendations to the Secretary of Health and Human Services, through the Assistant Secretary, ACF, and the Administrator, HRSA, with respect to the design, plan, progress, and results of the evaluation.

Authority: Sec. 511(g)(1) of Title V of the Social Security Act (42 U.S.C. 711, et seq.). The Committee is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

FOR FURTHER INFORMATION CONTACT: T’Pring Westbrook, Administration for Children and Families; tsping.westbrook@acf.hhs.gov.

SUPPLEMENTAL INFORMATION: Sec. 511(g)(1) of Title V of the Social Security Act mandates an Advisory Committee to review, and make recommendations on, the design and plan for the evaluation required under the Act. To comply with the authorizing directive and guidelines under the Federal Advisory Committee Act (FACA), a charter has been filed with the Committee Management Secretariat in the General Services Administration (GSA), the appropriate committees in the Senate and U.S. House of Representatives, and the Library of Congress to establish the Advisory Board as a non-discretionary federal advisory committee. The charter was filed on January 27, 2015.

Objectives and Scope of Activity

The purpose of the Committee is to provide advice and make recommendations to the Secretary of Health and Human Services, through the Assistant Secretary, ACF, and the Administrator, HRSA, with respect to the design, plan, progress, and results of the evaluation.

Membership and Designation

The Committee shall consist of up to 25 members appointed by the Secretary. Members shall be experts in the areas of program evaluation and research, education, and early childhood development. Members shall be appointed as Special Government Employees. The committee shall also include ex-officio members representing ACF, HRSA, and other agencies of the federal government designated by the Secretary as ex-officio members. The ACF Assistant Secretary and HRSA Administrator each shall recommend nominees for Co-Chairs of the Committee.

Members shall be invited to a 3-year term; such term is contingent upon the renewal of the Committee by appropriate action prior to its termination.

Administrative Management and Support

Coordination, management, and operational services shall be provided by ACF, with assistance from HRSA. A copy of the Committee charter can be obtained from the designated contact or by accessing the FACA database that is maintained by the GSA Committee Management Secretariat. The Web site for the FACA database is http://fido.gov/facddb/.

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, HHS.

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 three 1-day Tribal Consultation Sessions to be held between the Department of Health and Human Services, 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:

June 16, 2015, from 1:00 p.m. to 5:00 p.m.;
July 30, 2015, from 1:00 p.m. to 5:00 p.m.;
August 17, 2015, from 1:00 p.m. to 5:00 p.m.

Locations:

- June 16, 2015—National Indian Head Start Directors Association, Hyatt
Regency, 1209 L Street, Sacramento, California 95814
• July 30, 2015—Oklahoma Indian Head Start Coalition Conference
  DoubleTree at Warren Place, 6110 South Yale Avenue, Tulsa, Oklahoma 74136
• August 17, 2015—Northwest Indian Head Start Association Conference
  Holiday Inn Grand Montana, 5500 Midland Road, Billings, Montana 59101

FOR FURTHER INFORMATION CONTACT:

Ann Linehan,
Acting Director, Office of Head Start.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2014–N–0229]
Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that CHOLBAM (cholic acid), manufactured by Asklepion Pharmaceuticals, LLC, meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), added by FDASIA, FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that CHOLBAM (cholic acid), manufactured by Asklepion Pharmaceuticals, LLC, meets the criteria for a priority review voucher.