ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avgerage burden per response
Customer or Stakeholder	Online surveys	2,500	1	30/60
Customer or Stakeholder	Discussion Groups	150	1	120/60
Customer or Stakeholder	Focus groups	700	1	120/60
Customer or Stakeholder	Website/app usability testing	250	1	45/60
Customer or Stakeholder	Interviews	100	1	90/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–07840 Filed 4–6–15; 8:45 am]

BILLING CODE CODE 4163–18–P

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.

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.

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 to the Secretary of Health and Human Services (''the Secretary'') on the design, plan, progress, and findings of the evaluation required under the Act.

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

SUPPLEMENTARY 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 Activitie

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 terms are 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/facadatabase/.*

Dated: March 25, 2015.

Mary K. Wakefield,

Administrator, HRSA.

Mark H. Greenberg,

Acting Assistant Secretary, ACF.

[FR Doc. 2015–07978 Filed 4–6–15; 8:45 am]

BILLING CODE CODE 4184–01–P

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 meetings.

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: Robert Bialas, Regional Program Manager, Region XI, Office of Head Start, email *Robert.Bialas@acf.hhs.gov* or phone (202) 205–9497. Additional information and online meeting registration is available at *http://eclkc.ohs.acf.hhs.gov/hslc/hs/calendar/tc2015*.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (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 Sacramento, California, Tulsa, Oklahoma, and Billings, Montana, will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian/Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2014 OHS Tribal Consultations.

The Consultation Sessions 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 prior to the Consultation Sessions. Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of the Consultation Sessions will be prepared and made available within 45 days of the Consultation Sessions 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 Robert Bialas at *Robert.Bialas@acf.hhs.gov* either prior to the Consultation Sessions or within 30 days after the meeting.

OHS will summarize oral testimony and comments from each Consultation Session in the report without attribution, along with topics of concern and recommendations. OHS has sent hotel and logistical information for the California, Oklahoma, and Montana Consultation Sessions to tribal leaders via email and posted information on the Early Childhood Learning and Knowledge Center Web site at *http://eclkc.ohs.acf.hhs.gov/hslc/hs/calendar/tc2015*.

Dated: March 26, 2015.

Ann Linehan,

Acting Director, Office of Head Start.

[FR Doc. 2015–07958 Filed 4–6–15; 8:45 am]

BILLING CODE CODE 4184–40–P

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: Larry Bauer, Rare Diseases Program, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Silver Spring, MD 20993–0002, 301–796–4842, FAX: 301–796–9858, email: *larry.bauer@fda.hhs.gov*.

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. CHOLBAM (cholic acid) is a bile acid indicated for the treatment of bile acid synthesis disorders due to single enzyme defects and as adjunctive treatment of peroxisomal disorders, including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease or steatorrhea or complications from decreased fat soluble vitamin absorption. Bile acid synthesis disorders is a group of rare congenital disorders caused by the absence or malfunction of an enzyme involved in an important metabolic pathway, leading to a failure to produce normal bile acids.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *http://www.fda.gov/ForIndustry/DevelopingProductsforRare DiseasesConditions/RarePediatric DiseasePriorityVoucherProgram/default.htm.*

For further information about CHOLBAM (cholic acid), go to the *Drugs@FDA* Web site at *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.*

Dated: April 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08016 Filed 4–6–15; 8:45 am]

BILLING CODE CODE 4164–01–P

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 UNITUXIN (dinutuximab), manufactured by United Therapeutics Corporation, meets the criteria for a priority review voucher.