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/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/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]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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