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 will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives. Designees must have a letter from the Tribal Government authorizing them to represent the tribe prior to the consultation. 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.

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 (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. 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.