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]

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

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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 UNITUXIN (dinutuximab), manufactured by United Therapeutics Corporation, meets the criteria for a priority review voucher. UNITUXIN (dinutuximab) is indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM–CSF), interleukin-2 (IL–2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy. Neuroblastoma is the most common pediatric solid tumor occurring outside the brain, and it is the most common cancer in infants.

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 UNITUXIN (dinutuximab), 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. 2015–08014 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–D–1747]

Risk Evaluation and Mitigation Strategies: Modifications and Revisions; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Risk Evaluation and Mitigation Strategies: Modifications and Revisions.'' This guidance provides information on how FDA will define and process submissions for modifications and revisions to risk evaluation and mitigation strategies (REMS), as well as information on what types of changes to approved REMS will be considered modifications of the REMS and what types of changes will be considered revisions of the REMS. There are different procedures for submission of REMS modifications and revisions to FDA as well as different timeframes for FDA review and action of such changes. In addition, this guidance provides information on how REMS modifications and revisions should be submitted to FDA and how FDA intends to review and act on these submissions. The definitions of REMS modifications and revisions apply to all types of REMS.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the guidance by June 8, 2015. Submit either electronic or written comments concerning the proposed collection of information by June 8, 2015.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave. Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristen Everett, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0453; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Risk Evaluation and Mitigation Strategies: Modifications and Revisions.'' This guidance provides information on what types of changes to approved REMS will be considered modifications and what types of changes will be considered revisions. See section 505–1(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355–1(h)). This guidance also provides information on how REMS modifications and revisions should be submitted to FDA and how FDA intends to review and act on these submissions.

If FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh its risks, FDA is authorized to require a REMS for such drugs under section 505–1 of the FD&C Act,[1] added by section 901 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85).[2] Section 505–1(g) and (h) of the FD&C Act include provisions for the assessment and modification of an approved REMS.

In 2009, FDA issued draft guidance on the format and content of REMS, REMS assessments, and proposed REMS modifications. In that guidance, based on the language of section 505–1(g) and (h) of the FD&C Act before the amendments made by the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA), FDA stated that any proposed modification to an approved REMS, including proposed changes to materials that are appended to the REMS document, must be submitted as a proposed REMS modification in the form of a prior approval supplement and must include a REMS assessment. The guidance stated that the proposed

[1] Section 505–1 of the FD&C Act applies to applications for prescription drugs submitted under subsection 505(b) (*i.e.*, new drug applications) or (j) (*i.e.*, abbreviated new drug applications) of the FD&C Act (21 U.S.C. 355) and applications under section 351 of the Public Health Service Act (*i.e.*, biologics license applications).

[2] See *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm.*