The State Plan is a comprehensive narrative description of the nature and scope of a States programs and provides assurances that the programs will be administered in conformity with the specific requirements stipulated in 45 CFR 400.4–400.9. The State Plan must include all applicable State procedures, designations, and certifications for each requirement as well as supporting documentation. The plan assures ORR that the State is capable of administering refugee assistance and coordinating employment and other social services for eligible caseloads in conformity with specific requirements. Implementation of the Affordable Care Act has significant impacts on States' administration of Refugee Medical Assistance and requires information to ensure accountability and compliance with regulations. Also, Revised Medical Screening Guidelines for Newly Arriving Refugees policy (State Letter #12–09) requires assurances that medical screening is conducted in compliance with regulations and policies. The increasing complexity of the Unaccompanied Refugee Minor program, impacted by changes in federal child welfare legislation as well as state child welfare statutes, regulations and IV–B and IV–E plans, necessitates information and assurances for review of State Plans for URM programs against requirements and mandatory standards under 45 CFR Part 400, subpart H and associated State Letters and ORR guidance. Information and assurances address administrative structure and state oversight, legal responsibility, eligibility, services and case review/planning, and interstate movement.

States must use a pre-print format for required components of State Plans for ORR- funded refugee resettlement services and benefits prepared by the Office of Refugee Resettlement (ORR) of the Administration for Children and Families (ACF).

States must submit by August 15 each year new or amended State Plan for the next Federal fiscal year. For previously approved plan, States must certify no later than October 31 each year that the approved State plan is current and continues in effect.

Respondents: State Agencies, Replacement Designees under 45 CFR 400.301(c), and Wilson-Fish Grantees (State 2 Agencies) administering or supervising the administration of programs under Title IV of the Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Title IV State Plan	50	1	15	750

Estimated Total Annual Burden Hours: 750.

Additional Information

Copies of the proposed collection can be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–23288 Filed 9–30–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Tribal Consultation Meeting

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 one 1-day Tribal Consultation Session to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal Governments operating Head Start (including Early Head Start) programs. The purpose of this Consultation Session 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: October 22, 2014, from 1:00 p.m. to 5:00 p.m.

Location: Aleutian Pribilof Islands Association, 1131 East International Airport Road, Anchorage, Alaska 99518.

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/tc2014.*

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) announces Office of Head Start (OHS) Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs.

The agenda for the scheduled OHS Tribal Consultation in Anchorage, Alaska, 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 2013 OHS Tribal Consultations.

The Consultation Session 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. The letter should be submitted at least 3 days in advance of the Consultation Session to Robert Bialas at *Robert.Bialas@acf.hhs.gov.* Other representatives of tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of the Consultation Session will be prepared and made available within 45 days of the Consultation Session 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 Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Session will be summarized in each report without attribution, along with topics of concern and recommendations. OHS has sent hotel and logistical information for the Alaska Consultation Session 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/tc2014.*

Dated: September 24, 2014.

Ann Linehan,

Acting Director, Office of Head Start.

[FR Doc. 2014–23342 Filed 9–30–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0007]

Fee for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a rare pediatric disease priority review voucher for fiscal year (FY) 2015. 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 determine and collect rare pediatric disease priority review user fees for certain applications for review of human drug or biological products when those applications use a rare pediatric disease priority review voucher. These vouchers are awarded to the sponsors of certain rare pediatric disease product applications, submitted 90 days or more after July 9, 2012, upon FDA approval of such applications. The amount of the fee for using a rare pediatric disease priority review voucher is determined each FY based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year, and the average cost incurred in the review of an application that is not subject to priority review in the previous fiscal year. This notice establishes the rare pediatric disease priority review fee rate for FY 2015 and outlines the payment procedures for such fees.

FOR FURTHER INFORMATION CONTACT: Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202F, Silver Spring, MD 20993–0002, 301–796–7223.

SUPPLEMENTARY INFORMATION:

I. Background

Section 908 of FDASIA (Pub. L. 112–144) added section 529 to the FD&C Act (21 U.S.C. 360ff). In section 529, Congress encouraged development of new human drugs and biological products for prevention and treatment of certain rare pediatric diseases by offering additional incentives for obtaining FDA approval of such products. Under section 529, the sponsor of an eligible human drug application submitted 90 days or more after July 9, 2012, for a rare pediatric disease (as defined in section 529(a)(3) of the FD&C Act) shall receive a priority review voucher upon approval of the rare pediatric disease product application. The recipient of a rare pediatric disease priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or transfer (including by sale) the voucher to another party that may then use it for a human drug application. A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending on the type of application. Information regarding the PDUFA goals is available at: *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

The applicant that uses a rare pediatric disease priority review voucher is entitled to a priority review of its eligible human drug application but must pay FDA a rare pediatric disease priority review user fee in addition to any fee required by PDUFA for the application. Information regarding the rare pediatric disease priority review voucher program is available at: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm375479.htm.*

This notice establishes the rare pediatric disease priority review fee rate for FY 2015 at $2,562,000 and outlines FDA's procedures for payment of rare pediatric disease priority review user fees. This rate is effective on October 1, 2014, and will remain in effect through September 30, 2015.

II. Priority Review User Fee for FY 2015

Under section 529(c)(2) of the FD&C Act, the amount of the rare pediatric disease priority review user fee is determined each fiscal year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year, and the average cost incurred by FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year. The rare pediatric disease priority review voucher fee is intended to cover the incremental costs for FDA to do a priority review on a human drug application that would otherwise get a standard review. The formula provides the Agency with the added resources to conduct a priority review while still ensuring a robust rare pediatric disease priority review voucher program that is consistent with the Agency's public health goal of encouraging the development of new human drugs and biological products for rare pediatric diseases.

A priority review is a review conducted with a PDUFA goal date of 6 months after the receipt or filing date, depending on the type of application. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of the applications granted priority review status within this expedited timeframe. Normally, an application for a human drug or biological product will qualify for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or