

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](mailto: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](mailto: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.*

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## 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](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

effectiveness. An application that does not receive a priority designation will receive a standard review. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of standard applications within 10 months of the receipt or filing date depending on the type of application. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

Section 529 of the FD&C Act specifies that the rare pediatric disease priority review voucher fee amount must be based on the difference between the average cost incurred by the Agency in the review of a human drug application subject to a priority review in the previous fiscal year, and the average cost incurred by the Agency in the review of a human drug application not subject to a priority review in the previous fiscal year. FDA is setting a fee for FY 2015, which is to be based on standard cost data from the previous fiscal year, FY 2014. However, the FY 2014 submission cohort has not been closed out yet, thus the cost data for FY 2014 are not complete. The latest year for which FDA has complete cost data is FY 2013. Furthermore, because FDA has never tracked the cost of reviewing applications that get priority review as a separate cost subset, FDA estimated this cost based on other data that the Agency has tracked. FDA uses data that the Agency estimates and publishes on its Web site each year—standard costs for review. FDA does not publish a standard cost for “the review of a human drug application subject to priority review in the previous fiscal year.” However, we expect all such applications would contain clinical data. The standard cost application categories with clinical data that FDA publishes each year are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs) with clinical data.

The standard cost worksheets for FY 2013 show standard costs (rounded to the nearest thousand dollars) of \$5,122,000 for a NME NDA, and \$4,090,000 for a BLA. Based on these standard costs, the total cost to review the 53 applications in these two categories in FY 2013 (31 NME NDAs and 22 BLAs with clinical data) was \$248,762,000. (Note: These numbers exclude the President’s Emergency Plan for AIDS Relief NDAs; no investigational new drug (IND) review costs are included in this amount.) Twenty of these applications (12 NDAs and 8 BLAs) received priority review, which would mean that the remaining 33 received standard reviews. Because a

priority review compresses a review schedule that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject. In the article “Developing Drugs for Developing Countries,” published in *Health Affairs*, Volume 25, Number 2, in 2006, the comparison of historical average review times by David B. Ridley, Henry G. Grabowski, and Jeffrey L. Moe supports a priority review multiplier in the range of 1.48 to 2.35. The multiplier derived by FDA falls well below the mid-point of this range. Using FY 2013 figures, the costs of a priority and standard review are estimated using the following formula:

$$(20 \alpha \times 1.67) + (33 \alpha) = \$248,762,000$$

Where “ $\alpha$ ” is the cost of a standard review and “ $\alpha$  times 1.67” is the cost of a priority review. Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be \$3,746,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or \$6,256,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or \$2,510,000, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2015 fee, FDA will need to adjust the FY 2013 incremental cost by the average amount by which FDA’s average costs increased in the 3 years prior to FY 2014, to adjust the FY 2013 amount for cost increases in FY 2014. That adjustment, published in the **Federal Register** on August 1, 2014 (see 79 FR 44807 at 44809), is 2.0813 percent for the most recent year, not compounded. Increasing the FY 2013 incremental priority review cost of \$2,510,000 by 2.0813 percent results in an estimated cost of \$2,562,000 (rounded to the nearest thousand dollars). This is the rare pediatric disease priority review user fee amount for FY 2015 that must be submitted with a priority review voucher for a human drug application in FY 2015, in addition to any PDUFA fee that is required for such an application.

### III. Fee Schedule for FY 2015

The fee rate for FY 2015 is set out in Table 1 of this document:

TABLE 1—RARE PEDIATRIC DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2015

Fee category	Fee rate for FY 2015
Applications Submitted With a Rare Pediatric Disease Priority Review Voucher in Addition to the Normal PDUFA Fee .....	\$2,562,000

### IV. Payment Procedures for Rare Pediatric Disease Priority Review Voucher Fees Incurred in FY 2015

Under section 529(c)(4)(A) of the FD&C Act, the priority review voucher user fee is due (i.e., the obligation to pay the fee is incurred) when a sponsor notifies FDA of its intent to use the voucher. In order to comply with this section the sponsor must contact FDA before providing official notification of its intent to use the voucher.

Rare pediatric disease priority review voucher fees incurred for FY 2015 will be payable after Congress provides an appropriation of these fees. Accordingly, FDA will issue an invoice to the sponsor who has incurred a rare pediatric disease priority review voucher fee when it receives the sponsor’s notification of intent to use the voucher or, if an appropriation of rare pediatric disease priority review voucher fees has not been enacted at that time, after the appropriation has been enacted. The invoice will include instructions on how to pay the fee via wire transfer or check.

As noted above, if a sponsor uses a rare pediatric disease priority review voucher for a human drug application, the sponsor would incur the rare pediatric disease priority review voucher fee in addition to any PDUFA fee that is required for the application. The sponsor would need to follow FDA’s normal procedures for timely payment of the PDUFA fee for the human drug application.

Dated: September 26, 2014.

**Peter Lurie,**

*Associate Commissioner for Policy and Planning.*

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