

FDA issued a document entitled “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products, Guidance for Industry” dated December 2015 (<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf>) which changed the blood donor criterion for men who have sex with men (MSM) from an indefinite (permanent) deferral to a 12-month deferral since last MSM contact. The impact of this change in the deferral criteria requires a national monitoring effort as part of TTIMS to assess if the relative proportions of risk factors for infection in blood donors have changed following the adoption of the 12-month donor deferral for MSM. TTIMS will use similar procedures as the ones used in the REDS-II study to monitor and evaluate risk factors among HIV-positive donors and recently HCV or HBV infected donors as well as controls.

This study will help identify the specific risk factors for TTI and their prevalence in blood donors, and help inform FDA on the proportion of incident (new) infections among all HIV positive blood donors. Donations with incident infections have the greatest potential transmission risk because they could be missed during routine blood screening. The study will help FDA evaluate the effectiveness of screening strategies in reducing the risk of HIV transmission from at-risk donors and to evaluate if there are unexpected consequences associated with the recent change in donor deferral policy such as an increase in HIV incidence among

donors. These data also will inform FDA regarding future blood donor deferral policy options to reduce the risk of HIV transmission, including the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options, such as the use of individual risk assessments, and to inform the design of potential studies to evaluate the feasibility and effectiveness of such alternative deferral options.

TTIMS will include a comprehensive interview-based epidemiological study of risk factor information for viral infection-positive blood donors at the American Red Cross (ARC), Blood Systems, Inc. (BSI), New York Blood Center (NYBC), and OneBlood that will identify the current predominant risk factors and reasons for virus-positive donations. The TTIMS program establishes a new, ongoing donor hemovigilance capacity that currently does not exist in the United States. Using procedures developed by the REDS-II study, TTIMS will establish this capacity in greater than 50 percent of all blood donations collected in the country.

As part of the TTIMS project, a comprehensive hemovigilance database will be created that integrates the risk factor information collected through donor interviews of blood donor with the resulting data from disease marker testing and blood components collected by participating organizations into a research database. Following successful initiation of the risk factor interviews, the TTIMS network is poised to be expanded to include additional blood centers and/or re-focused on other safety threats as warranted. In this way,

the TTIMS program will maintain standardized, statistically and scientifically robust processes for applying hemovigilance information across blood collection organizations.

The specific objectives are to:

- Determine current behavioral risk factors associated with all HIV infections, incident HBV, and incident HCV infections in blood donors (including parenteral and sexual risks) across the participating blood collection organizations using a case-control study design.

- Determine infectious disease marker prevalence and incidence for HIV, HBV, and HCV overall and by demographic characteristics of donors in the majority of blood donations collected in the country. This will be accomplished by forming epidemiological databases consisting of harmonized operational data from ARC, BSI, NYBC, and OneBlood.

- Analyze integrated risk factor and infectious marker testing data concurrently because when taken together these may suggest that blood centers are not achieving the same degree of success in educational efforts to prevent donation by donors with risk behaviors across all demographic groups.

The respondents will be persons who donated blood in the United States and these participants will be defined as cases and controls. The estimated number of respondents is based on an overall expected participation in the risk factor survey. We estimate a case to control ratio of 1:2 (200 to 400) with a 50 percent case enrollment.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Questionnaire/survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cases and controls. ²	600	1	600	0.75 (45 minutes)	450

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Cases consist of virus-positive donations, and controls represent uninfected donors.

Dated: September 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0007]

Fee for Using a Rare Pediatric Disease Priority Review Voucher in Fiscal Year 2017

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) 2017. 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 rare pediatric disease product applications that meet all of the requirements of this program, are submitted 90 days or more after July 9, 2012, and 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 FY, and the average cost incurred in the review of an application that is not subject to priority review in the previous FY. This notice establishes the rare pediatric disease priority review fee rate for FY 2017 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 of the FD&C Act, 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 of the FD&C Act, 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)) 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. The voucher may be transferred (including by sale) repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act. 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 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 user 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 2017 at \$2,706,000 and outlines FDA's procedures for payment of rare pediatric disease priority review user fees. This rate is effective on October 1, 2016, and will remain in effect through September 30, 2017.

II. Rare Pediatric Priority Review User Fee for FY 2017

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.

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 2017, which is to be based on standard cost data from the previous fiscal year, FY 2016. However, the FY 2016 submission cohort has not been closed out yet, thus the cost data for FY 2016 are not complete. The latest year for which FDA has complete cost data is FY 2015. 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 2015 show standard costs (rounded to the nearest thousand dollars) of \$5,251,000 for an NME NDA, and \$5,055,000 for a BLA. Based on these standard costs, the total cost to review the 56 applications in these two categories in FY 2015 (32 NME NDAs and 24 BLAs with clinical data) was \$289,352,000. (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-five of these applications (18 NDAs and 7 BLAs) received priority review, which would mean that the remaining 31 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 which supports a priority review multiplier in the range of 1.48 to 2.35 (Ref. 1). Using FY 2015 figures, the costs of a priority and standard review are estimated using the following formula:

$$(25 \alpha \times 1.67) + (31 \alpha) = \$289,352,000$$

Where “ α ” is the cost of a standard review and “ α 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 \$3,977,000 (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 \$6,642,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or \$2,665,000, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2017 fee, FDA will need to adjust the FY 2015 incremental cost by the average amount by which FDA’s average costs increased in the 3 years prior to FY 2016, to adjust the FY 2015 amount for cost increases in FY 2016. That adjustment, published in the **Federal Register** on July 28, 2016 (see 81 FR 49674 at 49676), setting the FY 2017 PDUFA fee, is 1.5468 percent for the most recent year, not compounded. Increasing the FY 2015 incremental priority review cost of \$2,665,000 by 1.5468 percent results in an estimated cost of \$2,706,000 (rounded to the nearest thousand dollars). This is the rare pediatric disease priority review user fee amount for FY 2017 that must be submitted with a priority review voucher for a human drug application in FY 2017, in addition to any PDUFA fee that is required for such an application.

III. Fee Schedule for FY 2017

The fee rate for FY 2017 is set out in table 1:

TABLE 1—RARE PEDIATRIC DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2017

Fee category	Fee rate for FY 2017
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA fee	\$2,706,000

IV. Implementation of Rare Pediatric Disease Priority Review User Fee

Under section 529(c)(4)(A) of the FD&C Act, the priority review 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. Section 529(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, section 529(c)(4)(C) specifies that FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act. Beginning with FDA’s appropriation for FY 2015, the annual appropriation language states specifically that “priority review user fees authorized by 21 U.S.C. 360n and 360ff (section 529 of the FD&C Act) shall be credited to this account, to remain available until expended.” (Pub. L. 113–235, Section 5, Division A, Title VI).

The rare pediatric disease priority review fee established in the new fee schedule must be paid for any application that is received on or after October 1, 2016. In order to comply with this requirement, the sponsor must notify FDA 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application.

Upon receipt of this notification, FDA will issue an invoice to the sponsor who has incurred a rare pediatric disease priority review voucher fee. The invoice will include instructions on how to pay the fee via wire transfer or check.

As noted in section II, 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.

V. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

- Ridley, D.B., H.G. Grabowski, and J.L. Moe, “Developing Drugs for Developing Countries,” *Health Affairs*, vol. 25, no. 2, pp. 313–324, 2006.

Dated: September 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

State Health Departments Coordinating Center of the Jurisdictional Approach To Curing Hepatitis C Among HIV/HCV Coinfected People of Color Demonstration Project Supported by the Secretary’s Minority AIDS Initiative Fund

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of a deviation from competition requirements to make a single-source award related to the Jurisdictional Approach to Curing Hepatitis C (HCV) among HIV/HCV Coinfected People of Color demonstration project.

SUMMARY: HRSA’s HIV/AIDS Bureau (HAB) awarded a non-competitive single source cooperative agreement to National Alliance of State and Territorial AIDS Directors (NASTAD) for approximately \$977,400 in the Secretary’s Minority AIDS Initiative Funds (SMAIF) as authorized under the Consolidated Appropriations Act, 2016 (Pub L. 114–113), Division H, Title II. Subject to the availability of funds and NASTAD’s satisfactory performance, HAB will also issue non-competitive, single-source awards of approximately \$750,000 each in fiscal years (FY) 2017 and 2018. This will allow NASTAD to facilitate the participation of up to two Ryan White HIV/AIDS Program Part B recipients in the Jurisdictional Approach to Curing Hepatitis C among HIV/HCV Coinfected People of Color demonstration project over its 3-year project period.

FOR FURTHER INFORMATION CONTACT: Harold J. Phillips, Director, Office of Training and Capacity Development, HAB/HRSA, 5600 Fishers Lane, Room 9N–114, Rockville, MD 20857, by email at hphillips@hrsa.gov or by phone at (301) 443–8109.

SUPPLEMENTARY INFORMATION: *Recipient of the Award:* National Alliance of State and Territorial AIDS Directors.

Period of Supplemental Funding: September 30, 2016–September 29, 2019.