support programs to use federally-approved forms in intergovernmental IV–D cases unless a country has provided alternative forms as a part of its chapter in a Caseworker's Guide to Processing Cases with Foreign Reciprocating Countries.

Respondents: State agencies administering a child support program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Annex I: Transmittal form under Article 12(2)	54	46	1	2,484
Annex II: Acknowledgment form under Article 12(3)	54	93	.5	2,511
Annex A: Application for Recognition and Enforcement, including restricted information on the applicant	54	19	.5	513
Annex A: Abstract of Decision	54	5	1	270
Annex A: Statement of Enforceability of Decision	54	19	0.17	174
Annex A: Statement of Proper Notice	54	5	.5	135
Annex A: Status of Application Report	54	37	.33	659
Annex B: Application for Enforcement of a Decision Made or Recognized in the Requested State, including restricted information on the applicant	54	19	.5	513
Annex B: Status of Application Report, Article 12	54	37	.33	659
Annex C: Application for Establishment of a Decision, including restricted information on the Applicant	54	5	.5	135
Annex C: Status of Application Report—Article 12	54	9	.33	160
Annex D: Application for Modification of a Decision, including Restricted Information on the Applicant	54	5	.5	135
Annex D: Status of Application Report—Article 12	54	9	.33	160
Annex E: Financial Circumstances Form	54	46	2	4,968
Estimated Total Annual Burden Hours				13,478

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–23722 Filed 9–29–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Fee for Using a Tropical 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 rates for using a tropical 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 Amendments Act of 2007 (FDAAA), authorizes FDA to determine and collect priority review user fees for certain applications for approval of drug or biological products when those applications use a tropical disease priority review voucher awarded by the Secretary of Health and Human Services. These vouchers are awarded to the sponsors of certain tropical disease product applications, submitted after September 27, 2007, upon FDA approval of such applications. The amount of the fee submitted to FDA with applications using a tropical disease priority review voucher 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 in the review of an application that is not subject to priority review in the previous fiscal year. This notice establishes the tropical disease priority review fee rate for FY 2017.

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 1102 of FDAAA (Pub. L. 110–85) added section 524 to the FD&C Act (21 U.S.C. 360n). In section 524, Congress encouraged development of new drug and biological products for prevention and treatment of certain tropical diseases by offering additional incentives for obtaining FDA approval

of such products. Under section 524, the sponsor of an eligible human drug application submitted after September 27, 2007, for a tropical disease (as defined in section 524(a)(3) of the FD&C Act), shall receive a priority review voucher upon approval of the tropical disease product application. The recipient of a tropical disease priority review voucher may either use the voucher with a future submission to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (42 U.S.C. 262), 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 upon 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 priority review voucher is entitled to a priority review but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA published draft guidance on its Web site about how this tropical disease priority review voucher program operates (available at: *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080599.pdf*).

This notice establishes the tropical disease priority review fee rate for FY 2017 as $2,706,000 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2016, and will remain in effect through September 30, 2017, for applications submitted with a tropical disease priority review voucher. The payment of this priority review user fee is required in addition to the payment of any other fee that would normally apply to such an application under PDUFA before FDA will consider the application complete and acceptable for filing.

II. Tropical Disease Priority Review User Fee for FY 2017

FDA interprets section 524(c)(2) of the FD&C Act as requiring that FDA determine the amount of the tropical disease priority review user fee 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 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.

As interpreted by FDA, section 524(c)(2) of the FD&C Act requires that the fee amount should 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 FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year. FDA is setting fees for FY 2017, and the previous fiscal year is FY 2016. However, the FY 2016 submission cohort has not been closed out yet, and 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 does publish each year are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).

The worksheets for standard costs for FY 2015, show a standard cost (rounded to the nearest thousand dollars) of $5,251,000 for a 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 with clinical data and 24 BLAs) was $289,352,000. (Note: These numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.) 25 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 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 three 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 FY 2017 PDUFA fees, 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

tropical 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—TROPICAL DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2017

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

IV. Implementation of Tropical Disease Priority Review User Fee

Under section 524(c)(4)(A) of the FD&C Act, the priority review user fee is due upon submission of a human drug application for which the priority review voucher is used. Section 524(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, FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act and FDA may not collect priority review voucher fees ''except to the extent provided in advance in appropriation Acts.'' Section 524(c)(4)(C) and 524(c)(5)(B). Beginning with FDA's appropriation for FY 2009, the annual appropriation language states specifically that ''priority review user fees authorized by 21 U.S.C. 360n (section 524 of the FD&C Act) may be credited to this account, to remain available until expended.'' (Pub. L. 111–8, Section 5, Division A, Title VI).

The tropical 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, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, credit card, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* Once you search for your invoice, click ''Pay Now'' to be redirected to *Pay.gov.* Note that electronic payment options are based on the balance due. Payments must be drawn on U.S bank accounts.

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a Web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA Web site after the user fee ID number is generated.

The user fee identification (ID) number should be included on the check, followed by the words ''Tropical Disease Priority Review.'' Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.) The FDA post office box number (P.O. Box 979107) must be written on the check. The tax identification number of FDA is 53–0196965.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002.

Paying by credit card (Discover, VISA, MasterCard, American Express) is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S. credit cards.

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.

1. 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.

[FR Doc. 2016–23623 Filed 9–29–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2836]

Agency Information Collection Activities; Proposed Collection; Comment Request; Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on an information collection request regarding risk factors associated with transfusion-transmissible infections (TTI) in blood donors.

DATES: Submit either electronic or written comments on the collection of information by November 29, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or