DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Fee for Using a Tropical Disease Priority Review Voucher in Fiscal Year 2018

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) 2018. 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 2018.

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/ucm511438.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 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 2018 as $2,830,579 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2017, and will remain in effect through September 30, 2018, 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 2018

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.

FDA is setting fees for FY 2018, and the previous fiscal year is FY 2017. However, the FY 2017 submission cohort has not been closed out yet, and the cost data for FY 2017 are not complete. The latest year for which FDA has complete cost data is FY 2016. 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 2016, show a standard cost (rounded to the nearest hundred dollars) of $5,929,100 for a NME NDA and $4,887,100 for a BLA. Based on these standard costs, the total cost to review the 49 applications in these two categories in FY 2016 (27 NME NDAs with clinical data and 22 BLAs) was $267,601,900. (**Note:** These numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no

investigational new drug review costs are included in this amount.) Twenty-three of these applications (14 NDAs and 9 BLAs) received priority review, which would mean that the remaining 26 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 2016 figures, the costs of a priority and standard review are estimated using the following formula:

$(23\ \alpha \times 1.67) + (26\ \alpha) = \$267{,}601{,}900$

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 $4,154,664 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $6,938,289 (rounded to the nearest dollar). The difference between these two cost estimates, or $2,783,625, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2018 fee, FDA will need to adjust the FY 2016 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2017, to adjust the FY 2016 amount for cost increases in FY 2017. That adjustment, published in the **Federal Register** on July 28, 2016 (see 81 FR 49674 at 49676), setting FY 2018 PDUFA fees, is 1.6868 percent for the most recent year, not compounded. Increasing the FY 2016 incremental priority review cost of $2,783,625 by 1.6868 percent (or 0.016868) results in an estimated cost of $2,830,579 (rounded to the nearest dollar). This is the tropical disease priority review user fee amount for FY 2018 that must be submitted with a priority review voucher for a human drug application in FY 2018, in addition to any PDUFA fee that is required for such an application.

III. Fee Schedule for FY 2018

The fee rate for FY 2018 is set out in table 1:

TABLE 1—TROPICAL DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2018

Fee category	Fee rate for FY 2018
Application submitted with a tropical disease priority review voucher in addition to the normal PDUFA fee	$2,830,579

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 section 524 of the FD&C Act (see section 524(c)(4)(C)) and FDA may not collect priority review voucher fees ''except to the extent provided in advance in appropriation Acts.'' (Section 524(c)(5)(B) of the FD&C Act.) 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 [*i.e.,* 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, 2017, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA. Payment should 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.* (**NOTE:** Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov*. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments should be made using U.S bank accounts as well as U.S. credit cards.

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.

If paying with a paper check the user fee identification (ID) number should be included on the check, followed by the words ''Tropical Disease Priority Review.'' All paper checks should be in U.S. currency from a U.S. bank made payable and 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. If needed, FDA's tax identification number 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. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. 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.

V. Reference

The following reference is on display in the Dockets Management Staff (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 22, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20799 Filed 9–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Request for Nominations on Public Advisory Panels of the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on certain panels of the Medical Devices Advisory Committee (MDAC or Committee) in the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on certain device panels of the MDAC in the CDRH. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current and upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by October 30, 2017 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by October 30, 2017.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's Web site at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Division of Workforce Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5264, Silver Spring, MD 20993, 301–796–5960, Fax: 301–847–8505, email: *margaret.ames@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency is requesting nominations for nonvoting industry representatives to the panels listed in the table in this document.

I. Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (the FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the FD&C Act; advises on the necessity to ban a device; and responds to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Committee also provides recommendations to the Commissioner or designee on complexity categorization of in vitro diagnostics under the Clinical Laboratory Improvement Amendments of 1988.

Panels	Function
Circulatory System Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in the circulatory and vascular systems and makes appropriate recommendations to the Commissioner of Food and Drugs.
Clinical Chemistry and Clinical Toxicology Devices Panel.	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine including clinical toxicology, clinical chemistry, endocrinology, and oncology and makes appropriate recommendations to the Commissioner of Food and Drugs.
Gastroenterology and Urology Devices Panel.	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational gastroenterology, urology, and nephrology devices and makes appropriate recommendations to the Commissioner of Food and Drugs.
General Hospital and Personal Use Devices Panel.	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational general hospital, infection control, and personal use devices and makes appropriate recommendations to the Commissioner of Food and Drugs.
Obstetrics and Gynecology Devices Panel.	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in obstetrics and gynecology and makes appropriate recommendations to the Commissioner of Food and Drugs.