development of a draft guidance on benefit-risk assessments for new drugs and biologics, to further the Agency's implementation of structured benefit-risk assessment, including the incorporation of the patient's voice in drug development and decision making, in the human drug review program.

III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001 as follows: (1) The content and format of investigational new drugs applications, (2) expanded access uses and treatment of patients with immediately life-threatening conditions or serious diseases or conditions, (3) regulatory requirements pertaining to postmarketing study commitments, and (4) risk evaluation and mitigation strategies pertaining to benefit-risk assessments. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014 as follows: (1) The content and format of NDAs, (2) the submission of the patient population, (3) the submission of clinical trial data, and (4) benefit-risk planning, including early consultations with FDA meetings in end-of-phase 2 and pre-NDA meetings. The collections of information for good laboratory practices for nonclinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information for the submission of postmarketing adverse drug experience reporting have been approved under OMB control number 0910–0230. The collections of information in 21 CFR 201.56 and 201.57 for the content and format requirements for labeling of drugs and biologics have been approved under OMB control number 0910–0572. The collections of information in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765. The collections of information in the guidance for industry entitled ''Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)'' have been approved under OMB control number 0910–0771.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–21194 Filed 9–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0981]

Fee Rate for Using a Tropical Disease Priority Review Voucher in Fiscal Year 2022

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) 2022. The Federal Food, Drug, and Cosmetic Act (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 review of drug and biological products when those applications use a tropical disease priority review voucher. These vouchers are awarded to the sponsors of certain tropical disease product applications submitted after September 27, 2007, the enactment date of FDAAA, 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 to review a human drug application designated as 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 2022 and outlines the payment procedures for such fees.

FOR FURTHER INFORMATION CONTACT: Andrew Bank, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 62019A, Beltsville, MD, 20705–4304, 301–796–0292.

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 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 (as defined in section 524(a)(4) of the FD&C Act), assuming other criteria are met. The recipient of a tropical 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 (PHS Act) (42 U.S.C. 262), or transfer (including by sale) the voucher to another party. The voucher may be transferred 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 PHS 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: *https://www.fda.gov/media/99140/download.*

The sponsor 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 website about how this tropical disease priority review voucher program operates (available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tropical-disease-priority-review-vouchers*).

This notice establishes the tropical disease priority review fee rate for FY 2022 as $1,266,651 and outlines FDA's process for implementing the collection of the priority review user fees. This rate is effective on October 1, 2021, and will remain in effect through September 30,

2022, for applications submitted with a tropical disease priority review voucher.

II. Tropical Disease Priority Review User Fee Rate for FY 2022

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. As described in 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 receives a standard review. As described in 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.

FDA is setting a fee for FY 2022, which is to be based on standard cost data from the previous fiscal year, FY 2021. However, the FY 2021 submission cohort has not been closed out yet, thus the cost data for FY 2021 are not complete. The latest year for which FDA has complete cost data is FY 2020. 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. The Agency expects all applications that received priority review would contain clinical data. The application categories with clinical data for which FDA tracks the cost of review are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).

The total cost for FDA to review NME NDAs with clinical data and BLAs in FY 2020 was $227,248,467. There was a total of 86 applications in these two categories (53 NME NDAs with clinical data and 33 BLAs). (Note: these numbers exclude the President's Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.) Of these applications 55 (35 NDAs and 20 BLAs) received priority review and the remaining 31 (18 NDAs and 13 BLAs) 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 2020 figures, the costs of a priority and standard review are estimated using the following formula:

$$(55\ \alpha \times 1.67) + (31\ \alpha) = \$227{,}248{,}467$$

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 $1,849,804 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $3,089,173 (rounded to the nearest dollar). The difference between these two cost estimates, or $1,239,369, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2022 fee, FDA will need to adjust the FY 2020 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2021, to adjust the FY 2020 amount for cost increases in FY 2021. That adjustment, published in the **Federal Register** on August 16, 2021 (see 86 FR 45732), setting FY 2022 PDUFA fees, is 2.2013 percent for the most recent year, not compounded. Increasing the FY 2020 incremental priority review cost of $1,239,369 by 2.2013 percent (or 0.022013) results in an estimated cost of $1,266,651 (rounded to the nearest dollar). This is the tropical disease priority review user fee amount for FY 2022 that must be submitted with a priority review voucher for a human drug application in FY 2022, in addition to any PDUFA fee that is required for such an application.

III. Fee Rate Schedule for FY 2022

The fee rate for FY 2022 is set out in table 1:

TABLE 1—TROPICAL DISEASE PRIORITY REVIEW SCHEDULE FOR FY 2022

Fee category	Priority review fee rate for FY 2022
Application submitted with a tropical disease priority review voucher in addition to the normal PDUFA fee	$1,266,651

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.)

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, 2021, and is 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 website after the user fee identification (ID) number is generated.

If paying by paper check, the user fee 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 the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33.

V. Reference

The following reference is on display with the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852, 240–402–7500, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is not available electronically at *https://www.regulations.gov* as this reference is copyright protected. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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, available at: *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.25.2.313.*

Dated: September 24, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0983]

Fee Rate for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2022

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 material threat medical countermeasure (MCM) priority review voucher for fiscal year (FY) 2022. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to determine and collect material threat MCM priority review user fees for certain applications for review of human drug products when those applications use a material threat MCM priority review voucher. These vouchers are awarded to the sponsors of material threat MCM applications that meet all the requirements of this program and upon FDA approval of such applications. The amount of the fee for using a material threat MCM priority review voucher is determined each FY based on the difference between the average cost incurred by FDA to review a human drug application designated as 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 material threat MCM priority review fee rate for FY 2022 and outlines the payment procedures for such fees.

FOR FURTHER INFORMATION CONTACT: Lola Olajide, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61077B, Beltsville, MD 20705–4304, 240–402–4244.

SUPPLEMENTARY INFORMATION:

I. Background

Section 3086 of the Cures Act (Pub. L. 114–255) added section 565A to the FD&C Act (21 U.S.C. 360bbb–4a). In section 565A of the FD&C Act, Congress encouraged development of material threat MCMs by offering additional incentives for obtaining FDA approval of such products. Under section 565A of the FD&C Act, the sponsor of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the material threat MCM application. The recipient of a material threat MCM 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 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: *https://www.fda.gov/media/99140/download.*

The sponsor that uses a material threat MCM priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a material threat MCM priority review user fee in addition to any user fee required by PDUFA for the application. Information regarding the material threat MCM priority review voucher program is available at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions.*

This notice establishes the material threat MCM priority review fee rate for FY 2022 at $1,266,651 and outlines FDA's payment procedures for material threat MCM priority review user fees.