

an intent to submit the human drug application, including the estimated submission date.

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

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.

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> (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 must be made using U.S. bank accounts as well as U.S. credit cards.

If paying by paper check the invoice number should be included on the check, followed by the words "Rare Pediatric Disease Priority Review." All paper checks must 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 invoice 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 at 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; 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.

- 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: October 2, 2020.

**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-2020-N-1987]

#### Fee Rate for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2021

**AGENCY:** Food and Drug Administration, Health and Human Services (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) 2021. 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 2021 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 2021 at \$1,360,879 and outlines FDA's payment procedures for material threat MCM priority review user fees. This rate is effective on October 1, 2020, and will remain in effect through September 30, 2021.

**II. Material Threat Medical Countermeasure Priority Review User Fee Rate for FY 2021**

FDA interprets section 565A(c)(2) of the FD&C Act as requiring that FDA determine the amount of the material threat MCM 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 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 2021, which is to be based on standard cost data from the previous fiscal year, FY 2020. However, the FY 2020 submission cohort has not been closed out yet, thus the cost data for FY 2020 are not complete. The latest year for which FDA has complete cost data is FY 2019. 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 that 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 2019 was \$199,369,923. There was a total of 70 applications in these two categories (49 NME NDAs with clinical data and 21 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 44 (32 NDAs and 12 BLAs) received priority review and the remaining 26 (17 NDAs and 9 BLAs) 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 ÷ 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 2019 figures, the costs of a priority and standard review are estimated using the following formula:

$$(44 \alpha \times 1.67) + (26 \alpha) = \$199,369,923$$

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 \$2,004,121 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or \$3,346,882 (rounded to the nearest dollar). The difference between these two cost estimates, or \$1,342,761, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2021 fee, FDA will need to adjust the FY 2019 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2020, to adjust the FY 2019 amount for cost increases in FY 2020. That adjustment, published in the **Federal Register** on August 3, 2020 (see 85 FR 46651), setting FY 2021 PDUFA fees, is 1.3493 percent for the most recent year, not compounded.

Increasing the FY 2019 incremental priority review cost of \$1,342,761 by 1.3493 percent (or 0.013493) results in an estimated cost of \$1,360,879 (rounded to the nearest dollar). This is the material threat MCM priority review user fee amount for FY 2021 that must be submitted with a priority review voucher for a human drug application in FY 2021, in addition to any PDUFA fee that is required for such an application.

**III. Fee Rate Schedule for FY 2021**

The fee rate for FY 2021 is set out in table 1:

TABLE 1—MATERIAL THREAT MEDICAL COUNTERMEASURE PRIORITY REVIEW SCHEDULE FOR FY 2021

Fee category	Priority review fee rate for FY 2021
Application submitted with a material threat MCM priority review voucher in addition to the normal PDUFA fee .....	\$1,360,879

**IV. Implementation of Material Threat Medical Countermeasure Priority Review User Fee**

Under section 565A(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 565A(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 565A(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.

The material threat MCM priority review fee established in the new fee schedule must be paid for any application with a priority review voucher that is received on or after October 1, 2020. 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>. (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](https://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 must 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](https://pay.gov), a web-based payment application, for online electronic payment. The [Pay.gov](https://pay.gov) feature is available on the FDA website after the user fee ID number is generated.

If paying by paper check, the user fee identification (ID) number should be included on the check, followed by the words "Material Threat Medical Countermeasure Priority Review." All paper checks must 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

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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: October 2, 2020.

**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-2020-N-2014]

#### Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice, establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide

advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on November 2, 2020, from 9 a.m. to 1 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2020-N-2014. The docket will close on October 30, 2020. Submit either electronic or written comments on this public meeting by October 30, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 30, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 30, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before October 19, 2020, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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,