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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-9047]

Fee Rate for Using a Priority Review Voucher in Fiscal Year 2027

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 priority review voucher for fiscal year (FY) 2027. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, authorizes FDA to determine and collect priority review user fees for certain applications for review of human drug or biological products when those applications use a tropical disease, rare pediatric disease, or material threat medical countermeasure (MCM) priority review voucher. These vouchers are awarded to the sponsors of tropical disease, rare pediatric disease, or material threat MCM product applications, respectively, that meet the requirements of the FD&C Act, upon FDA approval of such applications. The amount of the fee for using a 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 FY 2027 priority review fee rate applicable to submission of eligible applications for review of human drug or biological products using a tropical disease, rare pediatric disease, or material threat MCM priority review voucher and outlines the payment procedures for such fees.

DATES: This rate is effective on October 1, 2026, and will remain in effect through September 30, 2027.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 301-796-7900; or FDAUserFees@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Establishment of the Tropical Disease Priority Review Voucher

Section 1102 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) added section 524 to the FD&C Act (21 U.S.C. 360n). In section 524 of the FD&C Act, Congress encouraged development of new human 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 of the FD&C Act, the sponsor of an eligible human drug application 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).

B. Establishment of the Rare Pediatric Disease Priority Review Voucher

Section 908 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) added section 529 of 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 for a rare pediatric disease (as defined in section 529(a)(3) of the FD&C Act) shall receive a priority review voucher upon approval of the rare pediatric disease product application (as defined in section 529(a)(4) of the FD&C Act).[1]

C. Establishment of the Material Threat MCM Priority Review Voucher

[1] The FD&C Act includes a sunset of authority to award rare pediatric disease priority review vouchers. Section 529(b)(5) of the FD&C Act provides that after September 30, 2029, FDA may not award any rare pediatric disease priority review vouchers. This limit of FDA's authority to award rare pediatric disease priority review vouchers does not affect the ability to use rare pediatric disease priority review vouchers issued by FDA.

Section 3086 of the 21st Century 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) of the FD&C Act) shall receive a priority review voucher upon approval of the material threat MCM application.[2]

A priority review involves a more intensive level of effort and a higher level of resources than a standard review.[3] A priority review is a review conducted within a timeframe prescribed in FDA commitments for such reviews made in connection with PDUFA reauthorization for FYs 2023-2027, known as PDUFA VII. For the FYs 2023 through 2027, FDA has committed to a goal date to review and act on 90 percent of the applications granted priority review status within the expedited timeframe of 6 months after receipt or filing date (filing date for new molecular entity (NME), new drug application (NDA), and original biologics license application (BLA) submissions; receipt date for priority non-NME original NDA submissions).

D. Transferability of the Priority Review Voucher

The recipient of a 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(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 PHS Act. As further described below, 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.

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[2] Although under section 565A(g) of the FD&C Act, material threat MCM priority review vouchers may not be awarded after October 1, 2023, this "sunset" of authority to award vouchers does not affect the ability to use material threat MCM priority review vouchers that have already been issued.

[3] For more information on priority review designation, see FDA's May 2014 guidance entitled *Expedited Programs for Serious Conditions—Drugs and Biologics*, available at: https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf.

Information regarding review goals for FY 2027 is available at: https://www.fda.gov/media/151712/download.

The sponsor that uses a priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a priority review user fee in addition to any other fee required by PDUFA. FDA published information on its website about how the priority review voucher program operates.[4, 5, 6]

This notice establishes the FY 2027 priority review fee rate for use of tropical disease, rare pediatric disease, and material threat MCM priority review vouchers at $1,798,596 and outlines FDA's process for implementing the collection of priority review user fees. This rate is effective on October 1, 2026, and will remain in effect through September 30, 2027.

II. Priority Review User Fee Rate for FY 2027

FDA interprets section 524(c)(2) (tropical disease priority review user fee), section 529(c)(2) (rare pediatric disease priority review user fee), and section 565A(c)(2) (material threat MCM priority review user fee) of the FD&C Act as requiring that FDA determine the amount of each priority review user fee for 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.

FDA is setting a fee for FY 2027, which is to be based on standard cost data from the previous fiscal year, FY 2026. However, the FY 2026 submission cohort has not been closed out yet, thus the cost data for FY 2026 are not complete. The latest year for which FDA has

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[4] Information regarding the tropical disease priority review voucher program is available at: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/tropical-disease-priority-review-voucher-program.

[5] Information regarding the rare pediatric disease priority review voucher program is available at: https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/rare-pediatric-disease-designation-and-priority-review-voucher-programs.

[6] 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.

complete cost data is FY 2025. 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) NDAs for an NME with clinical data and (2) BLAs.

The total cost for FDA to review NME NDAs with clinical data and BLAs in FY 2025 was $259,267,306. There was a total of 73 applications in these 2 categories (44 NME NDAs with clinical data and 29 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, 42 (24 NDAs and 18 BLAs) received priority reviews and the remaining 31 (20 NDAs and 11 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 nonpriority 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 2025 figures, the costs of a priority and standard review are estimated using the following formula:

$$(42\ \alpha \times 1.67) + (31\ \alpha) = \$259{,}267{,}306$$

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 $2,563,450 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $4,280,962 (rounded to the nearest dollar). The difference between these two cost estimates, or $1,717,512, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2027 fee, FDA will need to adjust the FY 2025 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2026, to adjust the FY 2025 amount for cost increases in FY 2026. That adjustment, published in the *Federal Register* setting the FY 2027 PDUFA fees, is 4.7210 percent for the most recent year,

not compounded. Increasing the FY 2025 incremental priority review cost of $1,717,512 by 4.7210 percent (or 0.047210) results in an estimated cost of $1,798,596 (rounded to the nearest dollar). This is the priority review user fee amount for FY 2027 that must be submitted in connection with a priority review voucher for a human drug application in FY 2027, in addition to any PDUFA fee that is required for such an application.

III. Fee Rate Schedule for FY 2027

The fee rate for FY 2027 is set in Table 1:

Table 1.--Priority Review Fee Schedule for FY 2027

Fee Category	Priority Review Fee Rate for FY 2027
Application submitted with a tropical disease priority review voucher in addition to the normal PDUFA fee	$1,798,596
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA fee	$1,798,596
Application submitted with a material threat MCM priority review voucher in addition to the normal PDUFA fee	$1,798,596

IV. Implementation of Priority Review User Fee

Sections 524(c)(4)(B), 529(c)(4)(B), and 565A(c)(4)(B) of the FD&C Act specify that the human drug application for which the sponsor requests the use of a priority review voucher 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 these sections of the FD&C Act (see sections 524(c)(4)(C), 529(c)(4)(C), and 565A(c)(4)(C)). FDA may not collect priority review voucher fees for any fiscal year "except to the extent provided in advance in appropriation Acts." (Section 524(c)(5)(B), 529(c)(5)(B), and 565A(c)(6) of the FD&C Act.)

The priority review fee established in the new fee schedule must be paid for any application received on or after October 1, 2026, submitted with a priority review voucher. As noted in section II, this fee must be paid in addition to any PDUFA fee that is required for the application. The sponsor would need to follow normal requirements for timely payment of any

PDUFA fee for the human drug application. For more information regarding payment of PDUFA application fees generally, please see section 736(a)(1) of the FD&C Act.[7]

A. Priority Review Voucher Notification of Intent Requirement

All three priority review vouchers have a notification requirement. To comply with this requirement, the sponsor must notify FDA not later than 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 estimated submission date. See sections 524(b)(4), 529(b)(4)(B)(i), and 565A(b)(3)(A) of the FD&C Act.

B. Priority Review Voucher User Fee Due Date

Under sections 524(c)(4)(A) (tropical disease priority review user fee), 529(c)(4)(A) (rare pediatric disease priority review user fee), and 565A(c)(4)(A) (material threat MCM priority review user fee) of the FD&C Act, the priority review user fee is due (i.e., the obligation to pay the fee is incurred) upon submission of a human drug application for which the priority review voucher is used.[8]

V. Fee Payment Options and Procedures

Payments made to FDA must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred method for payments to FDA is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a web-based payment application, for online

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[7] Additional information is also available in the guidance for industry entitled *Assessing User Fees Under the Prescription Drug User Fee Amendments of 2022*. FDA updates guidance periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[8] In the case of a "rolling review" application (as discussed in FDA's May 2014 guidance entitled *Expedited Programs for Serious Conditions--Drugs and Biologics*, available at: https://www.fda.gov/files/drugs/published/Expedited-Programs-for-Serious-Conditions-Drugs-and-Biologics.pdf) for which a tropical disease priority review voucher, rare pediatric disease priority review voucher, or material threat MCM priority review voucher is redeemed, FDA considers the application to be submitted on the date FDA receives the final portion of the application that the applicant identifies as complete. Also see section 506(d) of the FD&C Act, relating to review of incomplete applications for approval of a fast track product.

electronic payment. The Pay.gov feature is available on the FDA website upon receipt of an invoice.

Secure electronic payments to FDA 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 an invoice is located, "Pay Now" should be selected to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available for balances 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.

For payments made by wire transfer, include the invoice number to ensure that the payment is applied to the correct fee(s). Without the invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53-0196965. If a fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see 45 CFR Part 30), meaning the invoice balance due amount is referred to collections.

VI. 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

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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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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