Statutory Authority: 42 U.S.C. 8626(b).

Anthony Petruccelli,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4246]

Fee Rate for Using a Priority Review Voucher in Fiscal Year 2025

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) 2025. 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 2025 priority review fee rate applicable to submission of eligible applications for review of human drug or biological products using a rare pediatric disease, material threat MCM, or tropical disease priority review voucher and outlines the payment procedures for such fees.

DATES: This rate is effective on October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., 6th Floor, Beltsville, MD 20705–4304, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@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 for a rare pediatric disease (as defined in section 529(a)(3)) 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

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)) shall receive a priority review voucher upon approval of the material threat MCM application.[2]

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. Information regarding review goals for FY 2025 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.[3] [4] [5]

This notice establishes the FY 2025 priority review fee rate for use of

[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, 2024, FDA may not award any rare pediatric disease priority review vouchers unless a rare pediatric disease product application: (1) is for a drug that, not later than September 30, 2024, is designated under section 529(d) of the Act as a drug for a rare pediatric disease, and (2) is, not later than September 30, 2026, approved under section 505(b)(1) of the FD&C Act or section 351(a) of the PHS Act. This limit of FDA's authority to award rare pediatric disease vouchers does not affect the ability to use rare pediatric disease priority review vouchers issued by FDA.

[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] Information regarding the tropical disease priority review voucher program is available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tropical-disease-priority-review-vouchers.*

[4] Information regarding the rare pediatric disease priority review voucher program is available at: *https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm375479.htm.*

[5] 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.*

tropical disease, rare pediatric disease, and material threat MCM priority review vouchers at $2,482,446 and outlines FDA's process for implementing the collection of priority review user fees. This rate is effective on October 1, 2024, and will remain in effect through September 30, 2025.

II. Priority Review User Fee Rate for FY 2025

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.

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). 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. 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 2025, which is to be based on standard cost data from the previous fiscal year, FY 2024. However, the FY 2024 submission cohort has not been closed out yet, thus the cost data for FY 2024 are not complete. The latest year for which FDA has complete cost data is FY 2023. 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) 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 2023 was $305,296,115. There was a total of 61 applications in these 2 categories (34 NME NDAs with clinical data and 27 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, 37 (19 NDAs and 18 BLAs) received priority review and the remaining 24 (15 NDAs and 9 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 2023 figures, the costs of a priority and standard review are estimated using the following formula:

$$(37\ \alpha \times 1.67) + (24\ \alpha) = \$305{,}296{,}115$$

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 $3,558,645 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $5,942,937 (rounded to the nearest dollar). The difference between these two cost estimates, or $2,384,292, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2025 fee, FDA will need to adjust the FY 2023 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2024, to adjust the FY 2023 amount for cost increases in FY 2024. That adjustment, published in the **Federal Register** setting the FY 2025 PDUFA fees, is 4.1167 percent for the most recent year, not compounded. Increasing the FY 2023 incremental priority review cost of $2,384,292 by 4.1167 percent (or 0.041167) results in an estimated cost of $2,482,446 (rounded to the nearest dollar). This is the priority review user fee amount for FY 2025 that must be submitted with a priority review voucher for a human drug application in FY 2025, in addition to any PDUFA fee that is required for such an application.

III. Fee Rate Schedule for FY 2025

The fee rate for FY 2025 is set in table 1:

TABLE 1—PRIORITY REVIEW FEE SCHEDULE FOR FY 2025

Fee category	Priority review fee rate for FY 2025
Application submitted with a tropical disease priority review voucher in addition to the normal PDUFA fee	$2,482,446
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA fee	2,482,446
Application submitted with a material threat MCM priority review voucher in addition to the normal PDUFA fee	2,482,446

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, 2024, 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.[6]

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 or biological 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), 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) 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.[7]

Under section 529(c)(4)(A) (rare pediatric disease 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) when a sponsor notifies FDA of its intent to use the voucher. 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.

V. Fee Payment Options and Procedures

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.

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.

A. Paper Check Payment Process

If paying by paper check, the sponsor should include on the check the appropriate reference number and the type of review requested. For rare pediatric disease priority review, please use the invoice number issued by FDA. The invoice number is issued by FDA upon receipt of the rare pediatric disease priority review notification (see section IV.A). For tropical disease priority review and for material threat MCM priority review, please use the user fee ID number generated for the *Pay.gov* feature.

Tropical disease priority review: A paper check for a tropical disease priority review fee should include the user fee ID number and the words: ''Tropical Disease Priority Review''.

Rare pediatric disease priority review: A paper check for a rare pediatric disease priority review fee should include the invoice number followed by the words: ''Rare Pediatric Disease Priority Review''.

Material threat MCM priority review: A paper check for a material threat MCM priority review fee should include the user fee ID number and the words: ''Material Threat Medical Countermeasure Priority Review'' (or ''MCMPR'').

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, 3180 Rider Trail S, Earth City, MO 63045. (*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 855–259–3064. 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.

B. Wire Transfer Payment Process

If paying by wire transfer, please reference your invoice number/unique user fee ID number when completing your transfer. (For rare pediatric disease priority review, please use your invoice number issued by FDA upon receipt of notification. For all other priority reviews, please use the unique user fee ID number generated for the *Pay.gov* feature.) 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.

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 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://*

[6] 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.*

[7] In the case of ''rolling review'' of an 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 (PRV) or material threat MCM PRV is redeemed, the PRV fee is due upon submission of the final portion of the application, given that the Agency generally views ''submission of a human drug application'' (including as used in sections 524(c)(4)(A) and 565A(c)(4)(A)) to mean the submission of a complete application. Also see section 506(d) of the FD&C Act, relating to review of incomplete applications for approval of a fast track product.

www.healthaffairs.org/doi/full/10.1377/hlthaff.25.2.313.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21433 Filed 9–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4289]

Allergan, Inc., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of nine abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of October 21, 2024.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 062452	Gentamicin Sulfate solution/drop, Equivalent to (EQ) 0.3% base.	Allergan, Inc., 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92612.
ANDA 064124	Cefuroxime Sodium injectable, EQ 7.5 grams (g) base/vial ...	ACS Dobfar S.p.A., U.S. Agent Interchem Corp., 120 Route 17 North, Paramus, NJ 07652.
ANDA 077151	Milrinone Lactate injectable, EQ 40 milligrams (mg) base/200 milliliters (mL) (EQ 0.2 mg base/mL) EQ 20 mg base/100 mL (EQ 0.2 mg base/mL).	Woodward Pharma Services, LLC, 47220 Cartier Dr., Suite A, Wixom, MI 48393.
ANDA 079032	Ondansetron Hydrochloride preservative free injectable, EQ 2 mg base/mL.	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 079075	Fentanyl Citrate tablet, EQ 0.1 mg base, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base.	Watson Laboratories, Inc., (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Parsippany, NJ 07054.
ANDA 206155	Olanzapine tablet, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg.	Indoco Remedies Ltd., U.S. Agent RegCon Solutions, LLC, 9920 Pacific Heights Blvd., Suite 250, San Diego, CA 92121.
ANDA 206204	Piperacillin Sodium and Tazobactam Sodium injectable, EQ 12 gm base/vial, EQ 1.5 gm base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 207919	Acyclovir Sodium injectable, EQ 50 mg base/mL	Dr. Reddy's Laboratories, Inc., 107 College Rd. East, Princeton, NJ 08540.
ANDA 209708	Mivacurium Chloride solution, EQ 10 mg base/5 mL (EQ 2 mg base/mL) and EQ 20 mg base/10 mL (EQ 2 mg base/mL).	Woodward Pharma Services, LLC.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of October 21, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on October 21, 2024 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: September 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21432 Filed 9–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4189]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments: Strain Selection for Influenza Vaccines

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 Vaccines and Related