that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than October 3, 2025.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414. Comments can also be sent electronically to *Comments.applications@chi.frb.org:*

1. *Richard A. Griffin, Dysart, Iowa;* to join the Griffin Family Group, a group acting in concert, to acquire voting shares of Dysart Bancshares, Inc., and thereby indirectly acquire voting shares of Dysart State Bank, both of Dysart, Iowa.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2025–18084 Filed 9–17–25; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–3406]

Fee Rate for Using a Priority Review Voucher in Fiscal Year 2026

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) 2026. 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 2026 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, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at *UFSS@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

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

[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 December 20, 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 December 20, 2024, is designated under section 529(d) of the FD&C 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 priority review vouchers does not affect the ability to use rare pediatric disease priority review vouchers issued by FDA.

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 2026 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 2026 priority review fee rate for use of tropical disease, rare pediatric disease, and material threat MCM priority review vouchers at $1,962,472 and outlines FDA's process for implementing the collection of priority review user fees. This rate is effective on October 1, 2025, and will remain in effect through September 30, 2026.

[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*.

II. Priority Review User Fee Rate for FY 2026

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 2026, which is to be based on standard cost data from the previous fiscal year, FY 2025. However, the FY 2025 submission cohort has not been closed out yet, thus the cost data for FY 2025 are not complete. The latest year for which FDA has complete cost data is FY 2024. 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 2024 was $290,420,610. There was a total of 76 applications in these 2 categories (38 NME NDAs with clinical data and 38 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 (19 NDAs and 23 BLAs) received priority review and the remaining 34 (19 NDAs and 15 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 2024 figures, the costs of a priority and standard review are estimated using the following formula:

$$(42\ \alpha \times 1.67) + (34\ \alpha) = \$290{,}420{,}610$$

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 $2,788,752 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $4,657,216 (rounded to the nearest dollar). The difference between these two cost estimates, or $1,868,464, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2026 fee, FDA will need to adjust the FY 2024 incremental cost by the average amount by which FDA's average costs increased in the 3 years prior to FY 2025, to adjust the FY 2024 amount for cost increases in FY 2025. That adjustment, published in the **Federal Register** setting the FY 2026 PDUFA fees, is 5.0313 percent for the most recent year, not compounded. Increasing the FY 2024 incremental priority review cost of $1,868,464 by 5.0313 percent (or 0.050313) results in an estimated cost of $1,962,472 (rounded to the nearest dollar). This is the priority review user fee amount for FY 2026 that must be submitted in connection with a priority review voucher for a human drug application in FY 2026, in addition to any PDUFA fee that is required for such an application.

III. Fee Rate Schedule for FY 2026

The fee rate for FY 2026 is set in Table 1:

TABLE 1—PRIORITY REVIEW FEE SCHEDULE FOR FY 2026

Fee category	Priority review fee rate for FY 2026
Application submitted with a tropical disease priority review voucher in addition to the normal PDUFA fee	$1,962,472
Application submitted with a rare pediatric disease priority review voucher in addition to the normal PDUFA fee	1,962,472
Application submitted with a material threat MCM priority review voucher in addition to the normal PDUFA fee	1,962,472

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, 2025, 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 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) 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, electronic check, or online payments.

V. Fee Payment Options and Procedures

A. Fee Payment Procedures

Payment must be made in U.S. currency by electronic check, wire transfer, or credit card.[8] The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). 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.

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. If needed, FDA's tax identification number is 53–0196965.

VI. Reference

The following reference is on display with the Dockets Management Staff

[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 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 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.

[8] *See* ''Change in Federal Payment and Collection Options'' announcement published in the **Federal Register** on June 27, 2025 (90 FR 27639).

(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*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18075 Filed 9–17–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Library of Medicine Board of Scientific Counselors, October 15–16, 2025, 9:00 a.m. to 4:00 p.m., which was published in the **Federal Register** on August 26, 2025, 90 FR 163, Page Number 415876.

This notice is being amended to announce that the meeting will be changed from an In-Person Meeting to a Hybrid Meeting.

Dated: September 15, 2025.

Denise M. Santeufemio,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–18037 Filed 9–17–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2025 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting an administrative supplement in scope of the parent award for the one (1) eligible grant recipients funded in FY 2024 under the National Anti-Drug Coalitions Training and Workforce Development Cooperative Agreement (Short Title: Coalitions Training Cooperative Agreement), Notice of Funding Opportunity (NOFO) SP–24–003. The recipient may receive up to $300,000. This recipient has a project end date of September 29, 2029. The supplemental funding will be used to leverage existing resources to expand SAMHSA's youth-focused substance use prevention capacity to provide training and technical assistance to youth leaders who are members of anti-drug community coalitions from around the country and who are committed to addressing the evolving needs of the behavioral health field, thereby promoting youth engagement in substance use prevention workforce development opportunities. The recipient will use the funds to support development and implementation of a Substance Use Prevention Youth Summit in 2025–2026.

FOR FURTHER INFORMATION CONTACT: David Wilson, Public Health Analyst, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone 240–276–2588; email: *david.wilson@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: FY 2024 National Anti-Drug Coalitions Training and Workforce Development Cooperative Agreement (Short Title: Coalitions Training Cooperative Agreement), Notice of Funding Opportunity (NOFO) SP–24–003.

Assistance Listing Number: 93.243.

Authority: Sections 509, 516, and 520A of the Public Health Service Act, as amended.

Justification: CADCA is the only national organization that provides training and technical assistance solely focused on community anti-drug coalitions annually through their national leadership conference and mid-year training institute. CADCA's reach of more than 5,000 community coalitions and long-history of training and technical assistance to thousands of members of community coalitions dedicated to preventing substance use means they are uniquely positioned to carry out the activities included in this supplemental funding. This is not a formal request for application. Assistance will only be provided to the one (1) Coalitions Training Cooperative Agreement grant recipient funded in FY 2024.

Dated: September 15, 2025.

Ann Ferrero,

Public Health Analyst.

[FR Doc. 2025–18029 Filed 9–17–25; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2025 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting an administrative supplement in scope of the parent award for the one eligible grant recipient funded in FY 2023 under the Historically Black Colleges and Universities Center for Excellence (HBCU–CFE) grant, Notice of Funding Opportunity (NOFO) (TI–23–015). The recipient may receive up to $350,000 total funding. This recipient has a project end date of September 29, 2026. The supplement expands SAMHSA's engagement with Historically Black Colleges and Universities (HBCUs) by supporting a series of strategic initiatives that promote behavioral health career exploration and student wellness. These efforts are aligned with Executive Order 14283, *The White House Initiative to Promote Excellence and Innovation at Historically Black Colleges and Universities* and focus on building active public-private sector and philanthropic partnerships to advance shared goals related to student success and retention and creating professional development opportunities for HBCU students to help build America's workforce in behavioral health. The initiative will include the formation of a planning committee and a national convening of HBCU educators and behavioral health professionals to co-develop a shared vision and strategy. A key deliverable will be the creation of a behavioral health career exploration curriculum tailored to high school, community college, and early college students, with plans for national