[3] Numbers may be rounded.

This information collection reflects program changes and adjustments. We propose to revise data elements in Form FDA 3926 and to reevaluate the burden of EA submissions reported in Table 1, as described. We also report a decrease in submissions since the last OMB review and approval of the information collection. As a result of these cumulative changes and adjustments, the information collection reflects an overall decrease of 11,767 responses and 236,308 burden hours.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15148 Filed 7–27–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1377]

Cancer Clinical Trial Eligibility Criteria: Performance Status; Guidance for Industry, Institutional Review Boards, and Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for industry entitled ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation Research (CBER) for the treatment of cancer. Specifically, this guidance includes recommendations regarding expanding eligibility criteria to include patients with a wider range of performance status. This guidance finalizes the draft guidance of the same title issued on April 26, 2024.

DATES: The announcement of the guidance is published in the **Federal Register** on July 28, 2026.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–1377 for ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: LCDR Michael Gu, Oncology Center of Excellence, Food and Drug

Administration, 301–796–2031, *OCE-Guidances@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, Institutional Review Boards (IRBs), and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' The purposes of eligibility criteria are to select the intended patient population and reduce potential risks to trial participants. The Agency recognizes that some eligibility criteria may have become commonly accepted over time or used as a template across trials, but such criteria should be carefully considered and be appropriate for a specific trial context. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug. This guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by CDER and CBER for the treatment of cancer. Specifically, this guidance includes recommendations regarding expanding eligibility criteria to include patients with a wider range of performance status, and is intended to assist interested parties, including sponsors and IRBs, who are responsible for the development and oversight of clinical trials.

This guidance finalizes the draft guidance entitled ''Cancer Clinical Trial Eligibility Criteria: Performance Status'' issued on April 26, 2024 (89 FR 32442). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include updates on additional considerations for sponsors (*i.e.,* impact of including patients with lower performance status on trial retention and sample size) and minor revisions for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is also being issued consistent with FDA regulations in 21 CFR 312.145, 314.445, and 601.29, which provide that FDA will make guidance documents available to facilitate compliance with certain requirements in 21 CFR parts 312, 314, and 601, respectively.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15185 Filed 7–27–26; 8:45 am]

BILLING CODE 4164–01–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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is amending a notice entitled ''Fee Rate for Using a Priority Review Voucher in Fiscal Year 2026'' that appeared in the **Federal Register** on September 18, 2025. The notice established 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 medical countermeasure, or tropical disease priority review voucher and outlined the payment procedures for such fees. This amendment is being made to reflect that on February 3, 2026, Congress amended section 529 of the FD&C Act, including to require a sponsor of a human drug application that is the subject of a rare pediatric disease priority review voucher to submit a priority review user fee ''upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used.''

FOR FURTHER INFORMATION CONTACT: Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5324, Silver Spring, MD 20993–0002, 301–796–2771, *CDER_ARC_Program@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 18, 2025 (90 FR 45041), in FR Doc. 2025–18075, the following corrections are made:

1. On page 45041, in the third column, the second sentence in footnote #1 is revised to state only the following: ''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.''

2. On page 45043, in the second column, in section IV.B titled ''Priority Review Voucher User Fee Due Date,'' the first sentence is revised to state, ''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.'' The second paragraph in section IV.B is removed. A new paragraph is inserted: ''Given the recent amendment to section 529, FDA is updating the electronic Form FDA 3397, Prescription Drug User Fee Coversheet to allow sponsors the option to select for use of a rare pediatric disease priority review voucher. Generally, if a sponsor selects for use of a tropical disease, material threat MCM, or rare pediatric disease priority review voucher on Form FDA 3397, the form will be placed on hold while FDA completes its review of the priority review voucher redemption. Once the hold is lifted, a sponsor can proceed with submission of the completed Form FDA 3397 and payment of the applicable fees.'' Footnote #7 is revised to state, ''In the case of a ''rolling review'' application (as discussed in FDA's May 2014 guidance entitled Expedited Programs for Serious