

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 the appropriate use of washout periods and concomitant medication exclusions 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This guidance finalizes the draft guidance entitled "Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications" issued on April 26, 2024 (89 FR 32440). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include minor revisions for clarification.

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: Washout Periods and Concomitant Medications." 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7426]

Agency Information Collection Activities; Proposed Collection; Comment Request; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with expanded access to investigational drugs for treatment use.

DATES: Either electronic or written comments on the collection of information must be submitted by September 28, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 28, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be

considered timely if they are received on or before that date.

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–2026–N–7426 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Expanded Access to Investigational Drugs for Treatment Use." Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-402-5683, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910-0814—Revision

This information collection supports Agency regulations in 21 CFR part 312, subpart I, Expanded Access to Investigational Drugs for Treatment Use; associated guidance; and Form FDA 3926, Individual Patient Expanded Access Investigational New Drug Application (IND). The regulations govern the use of investigational new drugs, biologics, and approved drugs, when the primary purpose is to diagnose, monitor, or treat a patient's disease or condition. The goal of the expanded access program is to facilitate the availability of such products to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition.

Sometimes called "compassionate use," expanded access (EA) is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Agency regulations in 21 CFR part 312 provide for individual patient EA and associated procedures for those submitting EA requests to FDA. We provide resource information on our website at <https://www.fda.gov/news-events/public-health-focus/expanded-access> regarding our EA program, including information for patients, physicians, and industry. We also provide information pertaining to forms and processes for submitting EA requests to FDA.

This information collection accounts for burden associated with the submission of expanded access requests for individual patients and other expanded access submissions, including INDs that involve large groups of patients enrolled for treatment use of the investigational drug (§§ 312.300 through 312.320 (21 CFR 312.300 through 312.320)).

We developed electronic Form FDA 3926 to assist respondents with the information collection. Upon accessing the online form, users may need to follow certain technical instructions to save the document in a portable document format (PDF). Form FDA 3926 requires the completion of data fields that enable us to uniformly collect the minimum information necessary from licensed physicians who want to request EA as prescribed in the applicable regulations. To supplement the form instructions, we issued guidance, most recently updated in April 2026, titled "Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expanded-access-investigational-drugs-treatment-use-questions-and-answers>. As discussed in the guidance, § 312.310(b) contains additional submission requirements for individual patient expanded access requests. These respondents may continue to use either Form FDA 3926 or Form FDA 1571, Investigational New Drug Application (IND), for all types of IND submissions to satisfy requirements in 21 CFR 312.23(a) (approved under OMB control number 0910-0014). FDA considers a completed Form FDA 3926 signed by the physician and checked in the box in Field 10.a (Request for Authorization to use Form FDA 3926) to be a waiver request in accordance with 21 CFR 312.10.

For additional clarity, we have proposed several revisions to Table 1, including adding rows and more complete descriptive text to more accurately represent the submissions we receive and, in some cases, reducing our estimate of the hours per response to more accurately reflect the time we expect it will take to prepare and submit individual patient expanded access requests.

We also are proposing the following revisions to data elements in Form FDA 3926. In Field 6, "Treatment

Information,” delete the data element “Investigational Drug Name” and replace it with “Planned Date of Treatment Initiation” and revise the data element “FDA Review Division (if known)” to read “FDA Office/Review Division (if known)”. We will make corresponding revisions to the form instructions. In Field 9, replace the

heading “Contents of Submission” with “Contents of Submission (follow-up/ additional submissions only)” to correspond with the text in the instructions.

Data elements in §§ 312.315 and 312.320 continue to be reported in Form FDA 1571 (approved under OMB control number 0910–0014).

Description of Respondents: Respondents to the collection of information are licensed physicians who request patient access to investigational drugs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—CENTER FOR DRUG EVALUATION AND RESEARCH^{1 2 3}

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 312.310(b) and 312.305(b); submissions related to expanded access and treatment of an individual patient: Form FDA 3926.	752	1.3484	1,014	0.75 (45 minutes)	761
§§ 312.310(b) and 312.305(b); submissions related to expanded access and treatment of an individual patient: Form FDA 1571.	10	10.8	108	3	324
§ 312.310(d); submissions related to expanded access and treatment of an individual patient for emergency use: Form FDA 3926.	394	1.1371	448	0.75 (45 minutes)	336
§ 312.310(d); submissions related to expanded access and treatment of an individual patient for emergency use: Form FDA 1571.	7	3.2857	23	3	69
§§ 312.315(c) and 312.305(b); submissions related to expanded access and treatment of an intermediate-size patient population: Form FDA 1571.	37	1.0541	39	120	4,680
§ 312.320(b) and 312.305(b); submissions related to a treatment IND or treatment protocol Form FDA 1571.	18	1.0555	19	300	5,700
Total			1,651		11,870

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Form FDA 1571 is approved under OMB control number 0910–0014.

³ Numbers may be rounded.

We have reevaluated the burden of EA submissions reported in Table 1. We reevaluated our estimate of the average burden per response in row 3 for submissions for expanded access and treatment of an individual patient on Form FDA 3926. We estimate the time needed to complete Form FDA 3926 (0.75 hour or 45 minutes) should be the

same irrespective of whether it is submitted for emergency or non-emergency single patient IND. In doing so, we corrected an overreporting. We also revised Table 1 to add rows 2 and 4. These rows reflect our estimates for EA submissions for expanded access and treatment of an individual patient on Form FDA 1571. We estimate that

preparing Form FDA 1571 for an individual patient will take a provider about four times as long as preparing Form FDA 3926, or 3 hours. As with the use of Form FDA 3926, we estimate the time needed to complete Form FDA 1571 will be the same whether the submission is for emergency or non-emergency single patient IND.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN—CENTER FOR BIOLOGICS EVALUATION AND RESEARCH^{1 2 3}

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 312.310(b) and 312.305(b); number of submissions related to expanded access and treatment of an individual patient: Form FDA 3926	256	1.4804	379	8	3,032
§ 312.310(d); number of submissions related to emergency use of an investigational new drug: Form FDA 3926	80	1.2	96	16	1,536
§§ 312.315(c) and 312.305(b); number of submissions related to expanded access and treatment of an intermediate-size patient population: Form FDA 1571	14	1	14	120	1,680
§ 312.320(b) and 312.305(b); number of submissions related to a treatment IND or treatment protocol: Form FDA 1571	3	1	3	300	900
Total			492		7,148

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Form FDA 1571 is approved under OMB control number 0910–0014.

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]

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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