

regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

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; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 9, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0814. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910–0814—Revision

This information collection helps support implementation of Food and Drug Administration (FDA, agency, us, or we) regulations, as well as agency forms and associated guidance. Provisions in section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) set forth general requirements relating to expanded access to unapproved therapies and diagnostics. Sometimes called “*compassionate use*,” expanded access (EA) is a potential pathway for a patient with an immediately life-threatening condition, or serious 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. To facilitate expanded access to investigational drugs by patients, regulations in 21 CFR part 312, subpart I; *Expanded Access to Investigational Drugs for Treatment Use* (21 CFR 312.300–21 CFR 312.320), establish submission requirements that include demonstrating certain criteria have been met, and that content and format requirements have been satisfied. Information collection associated with all other provisions in 21 CFR 312 are included in OMB control no. 0910–0014 unless specifically noted.

The information collection utilizes Form FDA 3926 entitled, “Individual Patient Expanded Access—Investigational New Drug Application (IND).” Form FDA 3926 requires the completion of data fields that enable us to uniformly collect the minimum information necessary from licensed physicians or industry who want to request expanded access as prescribed in the applicable regulations. We are revising Form FDA 3926 as follows:

- 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).”
- In Field 9, replace the heading “Contents of Submission” with “Contents of Submission (follow-up/additional submissions only).”

Upon OMB approval of these modifications, we will revise accompanying instructions. Respondents may continue to use either Form FDA 3926 or Form FDA 1571, Investigational New Drug Application

(IND) (approved under OMB control number 0910–0014), for all types of IND submissions to satisfy requirements in 21 CFR 312.23(a). 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.

We continue to maintain an expanded access website (www.fda.gov/news-events/public-health-focus/expanded-access), including associated guidance documents. Regulations in 21 CFR 312.145 (approved in control. 0910–0014) provide for the issuance of guidance documents by FDA to assist respondents in complying with applicable regulations in 21 CFR 312. The guidance document “Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers,” (April 2026), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expanded-access-investigational-drugs-treatment-use-questions-and-answers>, supplements reporting instructions applicable to Form FDA 3926.

Description of Respondents:

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

In the **Federal Register** of July 28, 2026 (91 FR 47248), we published a 60-day notice requesting public comment on the proposed collection of information. One comment letter was received, containing multiple comments.

One comment was supportive of the proposed revisions to Form FDA 3926, stating that the changes to the form were appropriate and should make it easier to access investigational therapies efficiently. Other comments stated that the information collected through expanded access should not merely satisfy administrative requirements and suggested that the information collection should be used to facilitate the collection of meaningful and standardized information, including safety data, patient-reported outcomes, biomarker information, and other real-world clinical observations. We appreciate the comment and will take the concerns raised into consideration in future evaluations. No changes were made to the information collection or burden estimates as a result of the comment.

We estimate the burden of the collections of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING 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 Numbers may be rounded.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING 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.

³ Numbers may be rounded.

Burden estimates we attribute to the recordkeeping requirements established by the applicable regulations have been updated to include the reporting of data elements using Form FDA 1571. We have characterized the collection activity as recordkeeping, consistent with 5 CFR 1320.3(m) which defines a recordkeeping requirement to include the task of reporting the records to the Federal government. Upon our most recent review, the information collections reflect a cumulative decrease of 11,767 responses and 236,308 burden hours annually.

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 Nos. FDA–2020–E–1882 and FDA–2020–E–1892]

Determination of Regulatory Review Period for Purposes of Patent Extension; MONOFERRIC

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MONOFERRIC and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are

incorrect may submit either electronic or written comments and ask for a redetermination by December 8, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 7, 2027. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

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 December 8, 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.