

UNITED STATES FOOD & DRUG ADMINISTRATION

Expanded Access to Investigational Drugs for Treatment Use

OMB Control No. 0910-0814 – Revision

We are proposing revisions to Form FDA 3926 as discussed at Q. 15.

SUPPORTING STATEMENT **Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

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. Different types of expanded access include:

- Expanded access for individual patients, including for emergency use
- Expanded access for intermediate-size patient groups
- Expanded access for widespread treatment use

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.

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 made available to assist respondents in complying with applicable regulations in 21 CFR 312. We also continue to utilize **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 therefore requesting approval of collection provisions in 21 CFR part 312, subpart I, and revisions to Form FDA 3926, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

This ICR collects information from licensed physicians who submit requests for expanded access to investigational drugs on behalf of individual patients. Physicians may use Form FDA 3926 instead of Form FDA 1571 for the submission of information as described in the regulations (e.g., the rationale for the intended use of the drug and the physician's qualifications). We use the information to determine whether the access request can be granted. Form FDA 3926 may also be used for certain follow-up submissions to existing individual patient expanded access INDs as described in FDA regulations (e.g., to submit an annual report or summary of expanded access use (treatment completed)).

3. Use of Improved Information Technology and Burden Reduction

Form FDA 3926 is available as a fillable PDF document for expanded access sponsors and can be used as an alternative cover sheet to completion of Form FDA 1571 - Investigational New Drug Application. We encourage all respondents to utilize the fillable features of Form FDA 3926. We also continue to consider additional ways to facilitate submission of the information, including direct electronic submissions and possible developments of mobile applications.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

In most cases, respondents to the information collection are licensed physicians submitting requests on behalf of individual patients who have met specific criteria, as set forth in the applicable regulations. Commercial entities or research facilities may submit emergency applications, or expanded access applications for treatment INDs, or treatment protocols provided the product meets the expanded access criteria in the regulations. There is no undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with regulatory requirements and intended to be most beneficial to respondents. Submissions are made on behalf of patients by their licensed physicians, research facilities, or commercial entities. We are unaware of any legal obstacles to reducing burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances relating to this information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice soliciting public comment on the information collection in the *Federal Register* of July 28, 2026 (91 FR 47248). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3926 (Individual Patient Expanded Access Investigational New Drug Application (IND)) is name, address, email address, telephone number, fax number, and physician IND number. FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature applicable to this collection of information.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Recordkeeping Burden--Center for Drug Evaluation and Research^{1, 2, 3}

21 CFR Section; Activity	No. of Respondents	No. 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 Data elements are reported in Forms FDA 1571 and/or 1572, approved under OMB control number 0910-0014.

Table 2.--Estimated Annual Recordkeeping Burden--Center for Biologics Evaluation and Research^{1, 2, 3}

21 CFR Section; Activity	No. of Respondents	No. 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.

12b. Annualized Cost Burden Estimate

We assume industry labor costs by physicians using an hourly wage rate from U.S. Department of Labor, Bureau of Labor Statistics, as below:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Physicians	19,018	\$103.06	\$1,959,995.08

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

Review, processing, and responding to applications requires scientific expertise across various disciplines. Our estimate is based on the submissions we have received since establishing the information collection and the number of burden hours allotted for review of expanded access submissions. FDA estimates that 67.4 FTEs are required. Where the cost of each FTE is approximately \$175,000 (fully loaded), the total cost burden to the Federal Government is estimated at \$11,795,000.

15. Explanation for Program Changes or Adjustments

We have adjusted our burden estimate downward based upon our most recent review of the information collection. Over the past three years we have received fewer submissions from fewer respondents and have reduced our estimate by 11,767 responses and 236,308 burden hours annually. Upon OMB approval, we are also revising **Form FDA 3926** as follows, and as discussed in our *Federal Register* notices:

- In **Field 6**, “*Treatment Information*,” we are deleting the data element “*Investigational Drug Name*” and replacing it with “*Planned Date of Treatment Initiation*.” We are also revising the data element “*FDA Review Division (if known)*” to read “*FDA Office/Review Division (if known)*.”
- In **Field 9**, we are replacing the heading “*Contents of Submission*” with “*Contents of Submission (follow-up/additional submissions only)*.”

16. Plans for Tabulation and Publication and Project Time Schedule

There is no plan to tabulate or publish data from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of the OMB expiration date is appropriate and included on Form FDA 3926.

Consistent with established practice, FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with all guidance documents and will display in that notice both the OMB control number and the current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.