

UNITED STATES FOOD & DRUG ADMINISTRATION

Expanded Access to Investigational Drugs for Treatment Use

OMB Control No. 0910-0814

**SUPPORTING STATEMENT Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection supports 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 (as codified in 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*) establish submission requirements that include demonstrating certain criteria have been met, and that content and format requirements have been satisfied. This ICR revision consolidates the burden associated with the expanded access guidances for industry, Form FDA 3926 and the expanded access programs covered under FDA regulations 21 CFR 312.300 – 21 CFR 312.320, previously included under OMB control number 0910-0014.

We have developed an expanded access website ([www.fda.gov/news-events/public-health-focus/expanded-access](http://www.fda.gov/news-events/public-health-focus/expanded-access)) and a Form FDA 3926 entitled, “Individual Patient Expanded Access -- Investigational New Drug Application (IND) to assist respondents with the information collection, .” The 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.

Under § 312.310(d), in an emergency situation requiring a patient to be treated before a written submission for FDA approval can be made, a request to use an investigational drug for individual patient expanded access may be made by telephone (or other rapid means of communication) to the appropriate FDA review division. Authorization of the emergency use may be given by an FDA official by telephone, provided the requesting physician explains how the expanded access use will meet the requirements of §§ 312.305 and 312.310 and agrees to submit an expanded access application within 15 working days of FDA’s initial authorization of the expanded access use (§ 312.310(d)(2)). The requesting physician may choose to use Form FDA 3926 for the expanded access application or the Form FDA 1571 for submission of INDs.

A physician requesting individual patient expanded access may satisfy some of the submission requirements by referring to information in an existing IND, ordinarily one held by the investigational drug's manufacturer, if the physician obtains permission from that IND holder (e.g., the drug manufacturer or pharmaceutical company) (§ 312.305(b)(1)). If permission is obtained, the physician should then provide us with a letter of authorization (LOA) from the existing IND holder permitting us to reference that IND. Information collection associated with other provisions of Investigational New Drugs and Form FDA 1571 ("*Investigational New Drug Application (IND)*") and Form FDA 1572 ("*Statement of Investigator*") is currently approved under OMB Control No. 0910-0014.

We are requesting continued approval of the revised information collection associated with expanded access applications including Form FDA 3926, associated guidances, the FDA website for expanded access programs, and expanded access information collection as required by our regulations in 21 CFR 312; subpart I (§§312.300 – 312.320).

## 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)).

Under expanded access to investigational drugs for treatment use regulations, 21 CFR 312.300-312.320, this collection covers the information pertaining to expanded access programs, including individual patient access requirements, emergency use of investigational new drugs, expanded access and treatment for intermediate-sized patient populations, treatment INDs and treatment protocols as summarized in 21 CFR 312, Subpart I – Expanded Access to Investigational Drugs for Treatment Use. By collecting only the information necessary for processing an expanded access request, Form FDA 3926 streamlines the application process for physicians and reduces time that might otherwise be spent on patient care.

This ICR also includes the following associated GUIDANCES FOR INDUSTRY:

- *Individual Patient Expanded Access Applications: Form FDA 3926*
- *Expanded Access to Investigational Drugs for Treatment Use - Questions and Answers; Guidance for Industry*

- *Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency*

These guidances are available at <https://www.fda.gov/regulatory-information/Search-FDA-Guidance-Documents#guidancesearch>

### 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. This ICR revision consolidates the burden associated with the expanded access guidances for industry, Form FDA 3926 and the expanded access programs covered under FDA regulations 21 CFR 312.300 – 21 CFR 312.320, previously included under OMB control number 0910-0014. By collecting only the information necessary for processing an expanded access request, Form FDA 3926 streamlines the process for sponsors (usually licensed physicians requesting compassionate use of investigational drug or biologic products) and reduces the time that would otherwise be spent on completing other information elements included in Form FDA 1571 that are unnecessary for an expanded access application.

### 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 December 14, 2021, *Federal Register* (86 FR 71069). Although one comment was received, it was not responsive to the four collection of information topics solicited.

#### 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

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (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 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.

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

We estimate the burden of the information collection as follows:

### *12a. Annualized Hour Burden Estimate*

As indicated in table 1, the total annual estimated burden for the information collection is 140,205.75 hours.

Table 1.--Estimated Annual Reporting Burden--Center for Drug Evaluation and Research<sup>1</sup>

21 CFR part 312, subpart I; Information Collection 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	1,204	2.5	3,010	0.75	2,258
§ 312.310(d); submissions related to emergency use of an investigational new drug	1,265	2.8	3,542	16	56,672
§§ 312.315(c) and 312.305(b); submissions related to expanded access and treatment of an intermediate-size patient population	88	3.6	317	120	38,040
§ 312.320(b); submissions related to a treatment IND or treatment protocol	20	7	140	300	42,000
Total					138,970

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

<sup>2</sup> Data elements are reported in Forms FDA 1571 and 1572, approved under OMB control number 0910-0014.

Table 2.--Estimated Annual Reporting Burden--Center for Biologics Evaluation and Research<sup>1</sup>

Part 312, subpart I; 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	118	1.305	154	8	1,232
§ 312.310(d); submissions related to emergency use of an investigational new drug: Form FDA 3926	1,591	4.2137	6,704	16	107,264
§§ 312.315(c) and 312.305(b); submissions related to expanded access and treatment of an intermediate-size patient population <sup>2</sup>	28	1	28	120	3,360
§ 312.320(b); submissions related to a treatment IND or treatment protocol <sup>2</sup>	15	1	15	300	4,500

Total			6,901		116,356
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<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Data elements are reported in Forms FDA 1571 and 1572, approved under OMB control number 0910-0014.

### *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	255,326	\$103.06	\$26,313,897.56

### 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 made no program changes, however, on our own initiative, and for efficiency Agency operations, we are revising the information collection to consolidate all of the expanded access programs from 0910-0014 into 0910-0814. The change of the reported burden in OMB Control No. 0910-0014 will be adjusted as appropriate. The information collection reflects an increase in 253,530 burden hours and 11,516 responses annually.

### 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](http://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.