UNITED STATES FOOD & DRUG ADMINISTRATION

Individual Patient Expanded Access Applications

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 unaapproved 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.

To assist respondents to the information collection, we developed 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 who want to request expanded access as prescribed in the applicable regulations. To supplement the form instructions, we issued guidance entitled, "*Individual Patient Expanded Access Applications: Form FDA 3926*," available from our website at – https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm432717.pdf As discussed in the guidance, 21 CFR 312.310(b) contains additional submission requirements for individual patient expanded access requests.

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.

Under § 312.310(d), in an emergency situation requiring a patient to be treated before a written submission 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 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 physician may choose to use Form FDA 3926 for the expanded access application.

Accordingly, we are requesting continued approval of the information collection associated with individual patient expanded access applications included in Form FDA 3926, discussed in the associated guidance, and covered 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)).

3. Use of Improved Information Technology and Burden Reduction

Form FDA 3926 is available as a fillable PDF document. We estimate 95 percent of respondents will use the fillable features of this form. We continue to consider additional ways to facilitate submission of the information including direct electronic submissions and possible development of a mobile application. FDA's Oncology Center for Excellence is also planning a pilot project ("Project Facilitate") that will operate a call center to assist oncologists with applying for expanded access to oncology products on behalf of their patients. Project Facilitate will enable oncologists to ask questions of FDA staff in real time and provide information verbally over the phone rather than filling out a form directly. Project Facilitate staff will also assist respondents in locating resources for IRB review and information about IND sponsors' expanded access policies, which will reduce the respondent's burden associated for obtaining approval of an expanded access use.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Although information collection associated with IND regulations under part 312 are included under OMB Control No. 0910-0014, this collection covers only that information pertaining to individual patient access requirements found in subpart I. By collecting only the information necessary for processing

an access request, Form FDA 3926 streamlines the process and reduces time that might otherwise be spent on other elements included in Form FDA 1571.

5. Impact on Small Businesses or Other Small Entities

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. 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. 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 November 7, 2018 (83 FR 55723). No comments were received. Additionally, as part of our commitment to continuous operational improvement of the EA program, we commissioned an independent assessment that considered stakeholder perspectives from across the healthcare ecosystem. The assessment's key goals were to better understand the current EA program's performance and identify ways to improve it. The assessment is available from our website at:

https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM618903.pdf[1]

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

Information submitted is protected under 21 CFR 314.430 directly, or as incorporated by reference (see 21 CFR 314.430(a)), as well as subject to 21 CFR part 20. Although patient initials are provided in the collection instrument, this field is not use for any retrieval purposes and thus this identifier has been minimized to protect the privacy of individuals.

[1] On or about April 26, 2019, we will launch a redesigned website, however we expect the link to remain active.

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 1,795 hours.

Table 1 – Estimated Annual Reporting Burden[1]

Information Collection Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Form FDA 3926	790	1.46	1,153	0.75 (45 mins.)	865
Follow-up submissions	790	1.57	1,241	0.75 (45 mins.)	930
TOTAL			2,394		1795

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

We estimate 790 physicians will submit Form FDA 3926; 1,153 individual patient expanded access INDs and approximately 1,241 follow-up submissions, for a total of 2,394 annual responses. Because different fields of the form are completed depending on whether the submission is an initial or follow up submission, we assume an overall average burden 45 minutes per response, for a total of 1,795 annual hours.

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	1,795	$93.74	$168,263

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

We assume annuals costs of $134,159.76. Review, processing, and responding to applications requires scientific expertise across various disciplines. Our estimate is based on submissions we have received since establishing the information collection.

15. Explanation for Program Changes or Adjustments

We have made no program changes or adjustments to the information collection since last OMB review and approval. At the same time, we have modified Form FDA 3926 (approved by OMB July 25, 2017) and anticipate potential future modifications. Specifically, we are searching for ways to employ burden-reducing measures that will assist respondents in submitting expanded access requests, including the capacity for direct electronic submissions and/or a mobile application that will enable reporting by phone. We discuss this more fully at *Question 3* of this supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

As discussed in *Question 8* above, since last OMB review we sponsored an evaluation of the EA program and prepared a report based on stakeholder engagement. However, we have no current plans to repeat this evaluation, nor plans for tabulation of the data from the information collection.

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

Display of the OMB expiration date is appropriate and included on both Form FDA 3629 and the associated guidance.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.