One additional State has enrolled in the program since 2016. The total estimated burden of this collection has increased to 41,667 hours among 43 respondents, from a previous total of 15,792 hours among 42 respondents. This increase is due to a change in the self-reported response times provided by the respondents. Because this is a long-term program, we believe this change is the result of more precise documentation by participating agencies as they have grown more experienced over time.

Dated: April 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–07706 Filed 4–16–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3758]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Individual Patient Expanded Access Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by May 17, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0814. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@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.

Guidance for Industry on Individual Patient Expanded Access Applications: Form FDA 3926

OMB Control Number 0910–0814—Extension

This information collection supports Agency regulations, associated guidance, and Form FDA 3926 concerning individual patient expanded access. Individual patient expanded access allows an individual patient who has a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition, the use of an investigational new drug (IND) outside of a clinical investigation, or the use of an approved drug where availability is limited by a risk evaluation and mitigation strategy. When applicable criteria in § 312.305(a) (21 CFR 312.305(a)) (which apply to all types of expanded access) and the criteria in § 312.310(a) (21 CFR 312.310(a)) (which apply specifically to individual patient expanded access, including for emergency use) are met, FDA may permit expanded access.

Section 312.305(b) sets forth the submission requirements for all types of expanded access requests. To assist respondents with requirements in § 312.305, we developed Form FDA 3926 (Individual Patient Expanded Access Investigational New Drug Application) and the guidance document entitled, ''Individual Patient Expanded Access Applications: Form FDA 3926,'' which are available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm* and *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm432717.pdf,* respectively.

The physician may satisfy some of the submission requirements by referring to information in an existing IND, ordinarily the one held by the investigational drug's manufacturer, if the physician obtains permission from that IND holder. If permission is obtained, the physician should then provide to FDA a letter of authorization (LOA) from the existing IND holder that permits FDA to reference that IND.

One of the requirements under § 312.305(b)(2) is that a ''cover sheet'' must be included ''meeting the requirements of § 312.23(a).'' This provision applies to several types of submissions under part 312 (21 CFR part 312), ranging from commercial INDs under § 312.23 that involve large groups of patients enrolled in clinical trials to requests from physicians to use an investigational drug for an individual patient. Sponsors currently use Form FDA 1571 for all types of IND submissions to meet the requirements in § 312.23(a).

Concerned that physicians requesting expanded access for an individual patient may encounter difficulty in completing Form FDA 1571 and the associated documents because the form is not tailored to requests for individual patient expanded access, we developed Form FDA 3926 to comply with the IND submission requirements in §§ 312.23, 312.305(b), and 312.310(b). Form FDA 3926 provides a streamlined means to request expanded access and is available for licensed physicians. FDA considers a completed Form FDA 3926 with the box in Field 10 checked and the form signed by the physician to be a request in accordance with § 312.10 for a waiver of any additional requirements in part 312 for an IND submission, including additional information currently provided in Form FDA 1571 and Form FDA 1572 (Statement of Investigator, which provides the identity and qualifications of the investigator conducting the clinical investigation).

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

As explained in the instructions for Form FDA 3926 and discussed in the guidance document, the following information is submitted to FDA:

- Initials for the patient and date of submission.
- Type of submission (initial or followup submission).
- Clinical information, including indication, brief clinical history of the patient (age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy), and the reason for

requesting the proposed treatment, including an explanation of why the patient lacks other therapeutic options.

- Treatment information, including the investigational drug's name and the name of the entity supplying the drug (generally the manufacturer), the applicable FDA review division (if known), and the treatment plan. This should include the planned dose, route and schedule of administration, planned duration of treatment, monitoring procedures, and planned modifications to the treatment plan in the event of toxicity.
- LOA, generally obtained from the entity that is the sponsor of the IND (*e.g.,* commercial sponsor/drug manufacturer) being referenced, if applicable.
- Physician's qualification statement. An appropriate statement includes medical school attended, year of graduation, medical specialty, State medical license number, current employment, and job title. Alternatively, the relevant portion of the physician's curriculum vitae may be attached.
- Physician's contact information, including name, physical address, email address, telephone number, facsimile number, and physician's IND number, if previously issued by FDA.
- Contents of submission (for followup/additional submissions), including the type of submission being made. FDA accepts Form FDA 3926 for certain followup/additional submissions, which include the following: Initial written IND safety report (§ 312.32(c)); followup to a written IND safety report (§ 312.32(d)); annual report (§ 312.33); summary of expanded access use (treatment completed) (§ 312.310(c)(2)); change in treatment plan (§ 312.30); general correspondence or response to FDA request for information (§ 312.41); and response to clinical hold (§ 312.42(e)).
- Request for authorization to use Form FDA 3926 for individual patient expanded access application.
- Signature of the physician certifying that treatment will not begin until 30 days after FDA receives the completed application and all required material unless the submitting physician receives earlier notification from FDA that the treatment may proceed. The physician agrees not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold. The physician also certifies that informed consent will be obtained in compliance with Federal requirements (including FDA's regulations in 21 CFR part 50) and that an institutional review board (IRB) that complies with all Federal requirements (including FDA's regulations in 21 CFR part 56) will be responsible for initial and continuing review and approval of the expanded access use. The physician also acknowledges that in the case of an emergency request, treatment may begin without prior IRB approval, provided the IRB is notified of the emergency treatment within 5 working days of treatment. The physician agrees to conduct the investigation in accordance with all other applicable regulatory requirements.

In the **Federal Register** of November 7, 2018 (83 FR 55723), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance on individual patient expanded access applications: Form FDA 3926	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Expanded access submission elements included in Form FDA 3926	790	3.03	2,394	0.75 (45 mins.)	1,795

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

Based on a review of the information collection, we are retaining the currently approved burden estimate. The estimates for ''number of respondents,'' ''number of responses per respondent,'' and ''total annual responses'' were obtained from reports and data management systems from the Center for Drug Evaluation and Research (CDER) and from other sources familiar with the number of submissions received for individual patient expanded access use under part 312. The estimates for ''average burden per response'' were based on information CDER provided and personnel of the U.S. Department of Health and Human Services familiar with preparing and reviewing expanded access submissions by practicing physicians.

Based on data from the Document Archiving, Reporting, and Regulatory Tracking System for the number of submissions to FDA using FDA Form 3926 during fiscal years 2015, 2016, and 2017, we estimate that approximately 790 licensed physicians would use FDA Form 3926 to submit 1.46 requests per physician (respondent) for individual patient expanded access, for a total of 1,153 responses annually. Based on these estimates, FDA calculates the total annual responses to be 2,394 (1,153 requests for individual patient expanded access and 1,241 followup submissions) by 790 physicians for an average of 3.03 responses per respondent. FDA estimates the average burden per response to be 45 minutes (0.75 hour). Based on this estimate, FDA calculates the total burden to be 1,795 hours.

Dated: April 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0001]

Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Advancing the Development and Implementation of Analysis Data Standards: Key Challenges and Opportunities.'' Convened by the Duke-Robert J. Margolis Center for Health Policy at Duke University in partnership with the Critical Path Institute and supported by a cooperative agreement