DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1661]

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 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, 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.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910-0814--Revision

Sometimes called "compassionate use," expanded access (EA) is a potential pathway for a patient with a serious or immediately life-threatening 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. Agency regulations in 21 CFR part 312 provide for individual patient EA and associated procedures for those submitting EA requests to FDA. We provide resource information on our website at https://www.fda.gov/news-events/public-health-focus/expanded-access regarding our EA program, including information for patients, physicians, and industry. We also provide information pertaining to forms and processes for submitting EA requests to FDA. Specifically, we have developed electronic Form FDA 3926 "Individual Patient Expanded Access Investigational New Drug Application (IND)." Upon accessing the online form, users may need to follow certain technical instructions to save the document in a portable document format (PDF). Form FDA 3926 requires the completion of data fields that enable FDA to uniformly collect the minimum information necessary from licensed physicians who want to request EA as prescribed in the applicable regulations.

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

In the *Federal Register* of December 14, 2021 (86 FR 71069), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. However, on our own initiative, we are proposing the following revisions to associated Form FDA 3926:

Table 1.--Summary of Proposed Data Field Changes to Form FDA 3926

Current Field:	Includes Proposed Changes to:	Becoming New Field:	With Accompanying Instruction to:

8. Physician Name, Address, and Contact Information	Delete “Physician’s IND number, if known” from this field and move to proposed Field 4.a. Add “Name of Institution or Clinical Practice” to the title of the field.	1. Physician Name, Name of Institution or Clinical Practice, Address, and Contact Information Remaining fields become renumbered.	Enter the physician’s name, name of institution or clinical practice, and the physician’s contact information, including the physical address, email address, telephone number, and facsimile (FAX) number.
3.a. Initial Submission	Add “enter the Physician’s IND Number, if previously issued by FDA,”	4.a. Initial Submission ☐Select this box if this form is an initial submission for an individual patient expanded access IND, enter the Physician’s IND Number, if previously issued by FDA, and complete only fields 5 through 8, and fields 10 and 11	If the submission is an initial (original) submission for an individual patient expanded access IND (including for emergency use), select the box provided in field 4.a., enter the physician’s IND number, if previously issued by FDA, and complete only fields 5 through 8, and fields 10 and 11. Do not include commercial sponsor’s IND number.
4. Clinical Information Brief Clinical History (Patient’s age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy, reason for request, including an explanation of why the patient lacks other therapeutic options)	Add “or sensitivities, race and ethnicity (optional)” after allergies Add “Ethnicity (check one)” and list choice options (Hispanic/Latino or Not Hispanic/Latino) Add “Race (check all that apply)” and list choice options (American Indian/Alaska Native or Asian or Black/African American or Native Hawaiian/Other Pacific Islander or White)	5. Clinical Information Brief Clinical History (Patient’s age, gender, weight, allergies or sensitivities, race and ethnicity (optional), diagnosis, prior therapy, response to prior therapy, reason for request, including an explanation of why the patient lacks other therapeutic options) Ethnicity (check one) ☐Hispanic/Latino ☐Not Hispanic/Latino Race (check all that apply) ☐American Indian/Alaska Native ☐Asian ☐Black or African American ☐Native Hawaiian/Other Pacific Islander ☐White	Provide the indication (proposed treatment use) and a brief clinical history of the patient. The clinical history includes age, gender, weight, allergies or sensitivities (general (e.g. soy) and drug specific) and other optional demographic and clinical information (e.g. race (as reported by the patient; you may choose multiple answers) and ethnicity (choose only one response)), diagnosis (e.g. a brief summary (with dates) of relevant past medical and surgical history, diagnostic procedures, current stage/severity of disease, and functional status), prior therapy, response to prior therapy (e.g. patient was treated with drug X and subsequently developed lung metastasis), and the reason for requesting the proposed treatment, including an explanation of why the patient lacks other therapeutic options (e.g. patient has failed or is intolerant to currently available therapy, or is not eligible for any clinical trials registered at ClinicalTrials.gov).

5: Treatment Information	Add "(including rationale for dose)" Add "(e.g. assessment criteria/procedure(s) for monitoring and frequency)" Add "(e.g. criteria for adjusting dose if dose reduction or escalation is planned, criteria for stopping the treatment)," Add "(e.g. concomitant medication)" Add "You may choose to attach an Investigator Brochure, scientific publication(s), or other supporting documents, if needed."	Field 6.	Provide 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 a concise statement regarding the treatment plan. This includes the planned dose, route and schedule of administration of the investigational drug (including rationale for dose), planned duration of treatment, monitoring procedures (e.g. assessment criteria/procedure(s) for monitoring and frequency), planned modifications to the treatment plan in the event of toxicity (e.g. criteria for adjusting dose if dose reduction or escalation is planned, criteria for stopping the treatment), and other relevant information (e.g. concomitant medication). The information should be entered within the space provided. You may choose to attach an Investigator Brochure, scientific publication(s), or other supporting documents, if needed.
None	Add a box option for "Request for Withdrawal" under "Summary of Expanded Access Use (treatment completed)"	9. Contents of Submission ☐ Request for Withdrawal	Field 9: Contents of Submission (Follow-up/Additional Submissions Only) *Request for Withdrawal*: A submission describing the intent to withdraw an effective IND (21 CFR 312.38)
None	Add "When a waiver is requested in this manner, the physician does not receive notice from FDA indicating that the waiver is granted."	Field 10.b.: Request for Authorization to Use Alternative IRB Review Procedures	Select this box to request under 21 CFR 56.105, authorization to obtain concurrence by the IRB chairperson or by a designated IRB member, instead of at a convened IRB meeting, before the treatment use begins, in order to comply with FDA's requirements for IRB review and approval. When a waiver is requested in this manner, the physician does not receive notice from FDA indicating that the waiver is granted.
None	Add "Information on where and how to submit this form is available at Expanded Access – How to Submit"	Field 11: Certification Statement and Signature of the Physician	Field 11: Certification Statement and Signature of the Physician Information on where and how to submit this form is available at Expanded Access – How to Submit

[General Instruction?]	Insert a statement "Information on where and how to submit this form is available at Expanded Access – How to Submit a Request (Forms)" under "Signature of Physician" after Field 11	[General Instruction?]	Information on where and how to submit this form is available at Expanded Access – How to Submit a Request (Forms)

We retain the currently approved burden estimate of 13,910 responses and 255,326 hours annually for the information collection. We anticipate no adjustment as a result of the proposed form updates and have posted a draft of revised Form FDA 3926 to the docket, available for public inspection through https://www.regulations.gov.

Dated: May 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-09982 Filed: 5/9/2023 8:45 am; Publication Date: 5/10/2023]