

# UNITED STATES FOOD & DRUG ADMINISTRATION

## Individual Patient Expanded Access Applications

OMB Control No. 0910-0814

Non-substantive Change Request to an existing information collection:

### **I. Background:**

This information collection supports FDA 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 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. 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. Because of FDA’s long history of facilitating expanded access to investigational drugs for treatment use for patients with serious or immediately life-threatening diseases or conditions, our efforts in this regard are ongoing. Form FDA 3926, entitled, “*Individual Patient Expanded Access – Investigational New Drug Application (IND)*” was developed to assist respondents to the information collection. 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, most recently updated in October of 2017, entitled, “*Individual Patient Expanded Access Applications: Form FDA 3926*,” available at – <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/individual-patient-expanded-access-applications-form-fda-3926>. As discussed in the guidance, 21 CFR 312.310(b) contains additional submission requirements for individual patient expanded access requests.

Form FDA 3926 is available as a fillable PDF document on FDA’s website. Form FDA 3926 and accompanying instructions may be found at FDA’s website at <https://www.fda.gov/about-fda/reports-manuals-forms/forms>. Once it is filled out, FDA currently requires Form FDA 3926 to be mailed, emailed, or faxed by the physician to the Agency together with a letter of authorization and any other relevant information the clinician submits in support of the expanded access application.

### **II. Proposed change:**

FDA is seeking to revise a method used in collecting Form FDA 3926 and does not intend to change any of the information collected under the already approved ICR. The Reagan-Udall Foundation for the Food and Drug Administration (RUF) is an independent 501(c)(3)

organization created by Congress “to advance the mission of the FDA to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.” RUF is independent of the FDA, but FDA and RUF staff often work together, particularly with respect to the expanded access program. A new web-based interface that is available on a mobile device or desktop will be hosted by RUF on their website to guide physicians seeking authorization of expanded access use on behalf of patients through a series of webpages to fill out FDA Form 3926. The system will also allow them to upload their letter of authorization and any other information that they believe will support their application and then either:

- eSubmit the form (the portal generates a secure email to FDA); *or*
- Download the now completed PDF form and submit it to FDA through mail, email, or fax.

RUF does not retain any of the expanded access IND information that is submitted through the web-based program. RUF hosts the software on their website that enables simplification of the process. Only the same information as previously approved by OMB is collected, and the submission of that information to the Agency is via a secure email. Use of this web-based method is voluntary, and physicians wishing to initiate an expanded access IND request have the option of using the fillable PDF version of form FDA 3926 and then submitting that form to the Agency via mail, email, or fax rather than using the RUF web application. No changes or alterations have been made to Form FDA 3926 in the process of developing the RUF web application. This web-based method removes barriers to physicians seeking to file expanded access requests on behalf of their patients by streamlining the completion and submission of the form in a convenient web application that can be easily accessed by medical providers. While we hope this submission mechanism will help to increase efficiency and reduce burden, we currently are making no change in our estimate.