estimates of the average burden per response on our experience with NADAs and related submissions.

Dated: *May 27, 2016.*

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–D–0268]**

### Individual Patient Expanded Access Applications: Form FDA 3926; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Individual Patient Expanded Access Applications: Form FDA 3926.'' The guidance describes Form FDA 3926 (Individual Patient Expanded Access—Investigational New Drug Application (IND)), which is available for licensed physicians to use for expanded access requests for individual patient INDs. Individual patient expanded access allows for the use of an investigational new drug outside of a clinical investigation, or the use of an approved drug where availability is limited by a risk evaluation and mitigation strategy (REMS), for an individual patient who has a serious or immediately life-threatening disease or condition when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition. Form FDA 3926 provides a streamlined alternative for submitting an IND for use in cases of individual patient expanded access, including for emergency use. This guidance finalizes the draft guidance issued in February 2015.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2015–D–0268 for ''Individual Patient Expanded Access Applications: Form FDA 3926; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Larry Lim, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., Rm. 4134, Silver Spring, MD 20993, 301–796–3146; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a guidance for industry entitled

''Individual Patient Expanded Access Applications: Form FDA 3926.'' The guidance describes Form FDA 3926, which is available for licensed physicians to use for expanded access requests for individual patient INDs. FDA's current expanded access regulations (21 CFR part 312, subpart I) went into effect on October 13, 2009 (74 FR 40900). Expanded access refers to the use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient rather than to obtain the kind of information about the drug that is generally derived from clinical trials. Under the regulations, there are three categories of expanded access: (1) Expanded access for individual patients, including for emergency use; (2) expanded access for intermediate-size patient populations (generally smaller than those typical of a treatment IND or treatment protocol—a treatment protocol is submitted as a protocol amendment to an existing IND by the sponsor of the existing IND); and (3) expanded access for widespread treatment use through a treatment protocol or treatment IND (designed for use in larger patient populations). The regulations are intended to facilitate the availability of investigational new drugs outside of a clinical investigation, or approved drugs where availability is limited by a REMS, to patients with serious or immediately life-threatening diseases or conditions when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.

Elsewhere in this issue of the **Federal Register,** FDA is announcing the availability of a guidance for industry entitled ''Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers,'' which provides answers to questions concerning the implementation of FDA's regulations on expanded access to investigational drugs for treatment use (21 CFR part 312, subpart I). (FDA's guidance documents are available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* FDA has verified the Web site addresses throughout this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

Additionally, in this issue of the **Federal Register**, FDA is announcing the availability of a guidance for industry entitled ''Charging for Investigational Drugs Under an IND—Questions and Answers,'' which provides information about the implementation of FDA's regulation on charging for investigational drugs under an IND, including investigational drugs made available for expanded access use.

FDA may permit expanded access to an investigational new drug outside of a clinical investigation, or to an approved drug where availability is limited by a REMS, for an individual patient when the applicable criteria in § 312.305(a) (which apply to all types of expanded access) and in § 312.310(a) (which apply specifically to individual patient expanded access, including for emergency use) are met. In addition, § 312.305(b) sets forth the submission requirements for all types of expanded access use requests. 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, 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. Form FDA 1571 is currently used by sponsors for all types of IND submissions. However, FDA is concerned that physicians requesting expanded access for an individual patient may have encountered difficulty in completing Form FDA 1571 and providing the associated documents because Form FDA 1571 is not tailored to requests for individual patient expanded access.

To streamline the submission process for individual patient expanded access INDs, FDA developed Form FDA 3926, which is available for licensed physicians to use to request expanded access to an investigational drug outside of a clinical investigation, or to an approved drug where availability is limited by a REMS, for an individual patient who has a serious or immediately life-threatening disease or condition when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.

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 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 request 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.

In the **Federal Register** of February 10, 2015 (80 FR 7318), FDA announced the availability of the draft guidance. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Both the guidance and Form FDA 3926 were revised based on public comments and editorial changes were made primarily for clarification. One notable change includes the ability to use Form FDA 3926 for subsequent submissions to an existing individual patient expanded access IND.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the use of Form FDA 3926 by licensed physicians to submit requests for individual patient expanded access INDs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0814.

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

## III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: May 31, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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