DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–3452]

Institutional Review Board Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products; Guidance for Institutional Review Boards and Clinical Investigators; 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 final guidance for institutional review boards (IRBs) and clinical investigators entitled ''Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products.'' FDA is issuing this final guidance to provide recommendations regarding the key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions, including for reviews conducted by a single member of the IRB, to fulfill its obligations under FDA regulations. Although FDA has issued guidance on expanded access requests, including expanded access for individual patients, the Agency is aware that IRBs seek further clarity on this topic.

DATES: The announcement of the guidance is published in the **Federal Register** on September 11, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2023–D–3452 for ''Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this final 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 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: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–5683.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for IRBs and clinical investigators entitled ''Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products.'' FDA is issuing this guidance to provide recommendations regarding the key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions, including for reviews conducted by a single member of the IRB, to fulfill its obligations under 21 CFR part 56.

Although FDA has issued guidance on expanded access requests, including expanded access for individual patients, the Agency is aware that IRBs seek further clarity on this topic.

Under FDA regulations, there are three categories of expanded access: individual (also known as single) patient, including for emergency use; intermediate-size for intermediate-size patient populations; and ''treatment'' for larger populations. This guidance only applies to IRB review of individual patient expanded access submissions, as outlined in 21 CFR 312.310. The recommendations in this guidance are intended to provide additional clarity to assist IRBs in conducting efficient reviews of individual patient expanded access requests.

In the **Federal Register** of June 9, 2020 (85 FR 35311), FDA announced the availability of a guidance for IRBs and investigators entitled ''Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID–19 Public Health Emergency: Guidance for IRBs and Clinical Investigators'' (2020 COVID–19 guidance) to support public health efforts following a determination, under section 319 of the Public Health Service (PHS) Act (42 U.S.C. 247d), by the Secretary of Health and Human Services that a public health emergency existed related to Coronavirus Disease 2019 (COVID–19 public health emergency). The 2020 COVID–19 guidance focused on addressing the COVID–19 public health emergency and was intended to remain in effect only for the duration of the COVID–19 public health emergency. However, the 2020 COVID–19 guidance explained we expected the recommendations would assist the Agency more broadly in its continued efforts to facilitate access to drugs through expanded access for individual patients beyond the COVID–19 public health emergency and that FDA would replace the 2020 COVID–19 guidance with any appropriate changes based on comments received and the Agency's experience with implementation. FDA continues to believe that many of the recommendations set forth in the 2020 COVID–19 guidance are applicable outside the context of the COVID–19 public health emergency and are applicable to key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions. In addition, in the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed the 2020 COVID–19 guidance as one of the guidances FDA was revising to continue in effect for 180 days after the COVID–19 PHE declaration issued under the PHS Act expired on May 11, 2023, during which time FDA planned to further revise those guidances. Consistent with what we said in the **Federal Register** of March 13, 2023, FDA is therefore issuing this revised final guidance, which supersedes the 2020 COVID–19 guidance. FDA revised the guidance to remove references to the COVID–19 public health emergency and made editorial changes to improve clarity. FDA also clarified recommendations on IRB procedures and factors to consider for individual patient expanded access submissions.

FDA is issuing this guidance for immediate implementation in accordance with our good guidance practices regulation (21 CFR 10.115(g)(3)) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see 21 CFR 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because public health emergencies (PHEs) and the need to address individual patient expanded access submissions for patient access to investigational drugs for diagnosing, monitoring, or treating diseases or conditions related to PHEs may occur without notice and, as we have learned from experience during the COVID–19 PHE, may hinder physicians seeking to treat their patients in a timely manner. It is thus important to public health to provide recommendations regarding the key factors and procedures IRBs should consider when reviewing requests. Interested parties had an opportunity to comment on the recommendations in the 2020 COVID–19 guidance, and FDA considered those comments when revising the guidance. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's good guidance practices regulation (§ 10.115(g)(3)(D)).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 and Form FDA 1571 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 relating to the protection of human subjects, informed consent, and IRBs have been approved under OMB control number 0910–0130. The collections of information in 21 CFR 312.300 through 312.320 relating to expanded access to investigational drugs for treatment use and Form FDA 3926 have been approved under OMB control number 0910–0814. The collections of information in 21 CFR part 11 relating to electronic records and signatures have been approved under OMB control number 0910–0303.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19501 Filed 9–8–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis and