guidance addresses major (*i.e.,* pivotal) studies used to support safety and efficacy claims in BLAs and NDAs regulated by CBER, as well as certain supplemental applications containing new clinical study reports.

To meet its review performance goals in accordance with CBER good review management principles and practices for products covered by the Prescription Drug User Fee Act, CBER generally initiates inspection planning early in the application review process (*i.e.,* during the filing determination and review planning phase). CBER's inspection planning includes the selection of clinical investigator sites and other regulated entities for onsite inspections, and the preparation of assignment memos and background packages that CBER provides to FDA's ORA, which performs FDA's BIMO inspections. CBER uses the data and information described in this guidance to plan BIMO inspections, including: (1) to facilitate the timely identification of sites for inspection and (2) to ensure the availability of information needed to conduct BIMO inspections by ORA investigators.

This draft guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (21 CFR 10.115). However, in section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1(a)), Congress granted explicit authorization to FDA to specify, in guidance, the electronic format for submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), (i), or (j)) and submissions under section 351(a) or (k) of the Public Health Service Act (42 U.S.C. 262(a) or (k)). Accordingly, to the extent that this guidance, when finalized, provides such requirements, as indicated by the use of the words ''must'' or ''required'', this guidance will not be subject to the usual restrictions in FDA's GGP regulations, such as the requirement that guidances not establish legally enforceable responsibilities (see 21 CFR 10.115(d); see also the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act,'' available at *https://www.fda.gov/Drugs//GuidanceCompliance/Regulatory/Information/Guidances/default.htm.*

To comply with GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidance documents should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance document because it is not an accurate description of this guidance. Insofar as this guidance specifies the format for electronic submissions pursuant to section 745A(a) of the FD&C Act, when finalized, it will have binding effect.

The draft guidance, when finalized, and the BIMO Technical Conformance Guide will represent the current thinking of FDA on standardized format for electronic submission of BLA and NDA content for the planning of BIMO inspections for CBER submissions.

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 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

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

Dated: May 31, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12354 Filed 6–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5021]

Processes and Practices Applicable to Bioresearch Monitoring Inspections; Draft 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 draft guidance for industry entitled ''Processes and Practices Applicable to Bioresearch Monitoring Inspections.'' The draft guidance is being issued to comply with the Food and Drug Omnibus Reform Act of 2022, which directs the Agency to issue guidance describing the processes and practices applicable to inspections of sites and facilities inspected under FDA's Bioresearch Monitoring inspection program, to the extent not specified in existing publicly available FDA guides and manuals. The draft guidance is intended to cover the following: the types of records and information required to be provided, best practices for communication between FDA and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct.

DATES: Submit either electronic or written comments on the draft guidance by August 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–5021 for ''Processes and Practices Applicable to Bioresearch Monitoring Inspections.'' 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.

- 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.

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

Submit written requests for single copies of the draft guidance to the Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by emailing ORA at *orapolicystaffs@fda.hhs.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Darby Hull, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993–0002, *Darby.Hull@fda.hhs.gov,* 301–796–5949.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Processes and Practices Applicable to Bioresearch Monitoring Inspections.''

FDA is issuing this draft guidance to comply with section 3612(b)(2) of the Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted as part of the Consolidated Appropriations Act, 2023.

This section of FDORA directs FDA to issue guidance describing the processes and practices applicable to inspections of certain sites and facilities, to the extent not specified in existing publicly available FDA guides and manuals for such inspections. These sites and facilities are inspected under FDA's Bioresearch Monitoring (BIMO) inspection program. Specifically, this draft guidance addresses the following (to the extent not publicly available in FDA guides and manuals): the types of records and information required to be provided, best practices for communication between FDA and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct.

FDA's BIMO program is a comprehensive portfolio of programs designed to assess and monitor all aspects of the conduct and reporting of FDA-regulated research as well as certain postmarketing activities through on-site inspections, investigations, and Remote Regulatory Assessments. The BIMO program was established to assess the quality and integrity of data submitted to the Agency in support of regulatory decision-making, as well as to provide for protection of the rights, safety, and welfare of human trial participants and animal subjects involved in FDA-regulated research. The program assesses compliance with statutory requirements and FDA's regulations governing the conduct of nonclinical and clinical studies, and applicable postmarketing activities.

FDA also is announcing that the following two guidances will be withdrawn upon finalization of this guidance, as their substance is superseded by this draft guidance and other guidances and related documents described in this draft guidance: the 2010 ''Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators,'' and the 2006 ''Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: FDA Institutional Review Board Inspections.''

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Processes and Practices Applicable to Bioresearch Monitoring Inspections.''

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

FDA tentatively concludes that this revised draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.regulations.gov.*

Dated: May 31, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12319 Filed 6–4–24; 8:45 am]

BILLING CODE 4164–01–P