DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4416]

Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities.'' FDA is issuing this draft guidance to describe how we request and conduct voluntary remote interactive evaluations at facilities where drugs are manufactured, processed, packed, compounded, or held, and at facilities covered under FDA's bioresearch monitoring program. FDA may consider the use of a remote interactive evaluation for any of the inspection program areas described in the guidance. FDA is also announcing the withdrawal of the guidance entitled ''Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID–19 Public Health Emergency.''

DATES: Submit either electronic or written comments on the draft guidance by December 26, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–4416 for ''Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities.'' 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 the draft 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; 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; or the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Tina Kiang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4374, Silver Spring, MD 20993–0002, 301–796–6487; 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, 240–402–7911; or CVM at *AskCVM@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities.'' FDA is issuing this draft guidance to describe how we request and conduct voluntary remote interactive evaluations at: (1) facilities where drugs are manufactured, processed, packed, or held; (2) facilities covered under FDA's bioresearch

monitoring program; and (3) outsourcing facilities registered under section 503B (21 U.S.C. 356b) of the FD&C Act. FDA may consider the use of a remote interactive evaluation for any of the inspection program areas described in the draft guidance.

During the Coronavirus Disease 2019 (COVID–19) pandemic, FDA expanded our use of alternative tools for evaluating drug manufacturing facilities to support regulatory decision-making. When an inspection was not feasible or practical because of the public health emergency (PHE), FDA used other available tools and information to support regulatory decisions and oversight of facilities. FDA announced its policy for using these alternative tools in a guidance entitled ''Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID–19 Public Health Emergency'' posted in April 2021 and announced in the **Federal Register** on May 27, 2021 (86 FR 28627) (''2021 COVID–19 Remote Interactive Evaluations Guidance''). FDA issued the guidance to communicate its policy for the duration of the COVID–19 PHE declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). Furthermore, in the **Federal Register** of March 13, 2023 (88 FR 15417) FDA listed the: (1) guidances that will no longer be effective with the expiration of the PHE declaration, (2) guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration to provide a period for stakeholder transition and then would no longer be in effect, and (3) guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration during which time FDA planned to further revise the guidances. The 2021 COVID–19 Remote Interactive Evaluations Guidance is included in the latter category and was revised to remain in effect for 180 days post expiration of the PHE declaration. Although the HHS Secretary of has announced that the COVID–19 public health emergency declaration has ended and FDA has largely resumed inspections, FDA has determined that continued use of alternative tools, including remote interactive evaluations, based on risk and program needs, will enhance our ability to assess facilities.

This draft guidance describes the various remote interactive tools we may request to use to conduct an evaluation. In this draft guidance, we refer to our use of any combination of these interactive tools as a *remote interactive evaluation.* FDA may request to conduct a remote interactive evaluation prior to or following other types of regulatory oversight activities (*e.g.,* an inspection or a request for records or other information). In preparing this draft guidance, FDA considered comments received on the 2021 COVID–19 Remote Interactive Evaluations Guidance.

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 ''Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities.'' 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.

FDA also is announcing that the 2021 COVID–19 Remote Interactive Evaluations Guidance will be withdrawn upon publication of this draft guidance. FDA has determined that the 2021 COVID–19 Remote Interactive Evaluations Guidance is no longer needed because this new draft guidance is available and its recommendations, when finalized, will be applicable outside the context of the COVID–19 public health emergency.

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). 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. The collections of information in 21 CFR part 58 pertaining to good laboratory practices have been approved under OMB control number 0910–0119. The collection of information pertaining to current good manufacturing practices have been approved under OMB control number 0910–0139. The collections of information relating to the registration of human drug compounding outsourcing facilities under section 503B of the FD&C Act and associated fees under section 744K of the FD&C Act (21 U.S.C. 379j–62) have been approved under OMB control number 0910–0776. The collections of information pertaining to human drug compounding under sections 503A (21 U.S.C. 356a) and 503B of the FD&C Act have been approved under OMB control number 0910–0800. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130.

III. Electronic Access

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

Dated: October 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: November 15, 2023.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F58, Rockville, MD 20892 (Virtual Meeting).