Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency

Guidance for Industry

This guidance is intended to remain in effect until November 7, 2023, unless superseded by a revised final guidance before that date. For further information, refer to 88 FR 15417, March 13, 2023, available at https://www.federalregister.gov/documents/2023/03/13/2023-05094/guidance-documents-related-to-coronavirus-disease-2019-covid-19.

Contains Nonbinding Recommendations

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Guidance for Industry

April 2021

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research
Center for Veterinary Medicine

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA web page titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, and the FDA web page titled "Search for FDA Guidance Documents," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents. You may also send an e-mail request to druginfo@fda.hhs.gov or ocod@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number FDA-2020-D-1136 and complete title of the guidance in the request.

Questions

For questions about this document, contact the Center for Drug Evaluation and Research at CDER-OPQ-Inquiries@fda.hhs.gov, the Center for Biologics Evaluation and Research at ocod@fda.hhs.gov, the Center for Veterinary Medicine at AskCVM@fda.hhs.gov, or the Office of Regulatory Affairs at ORAPolicyStaffs@fda.hhs.gov.

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Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency

Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to describe how we will request and conduct voluntary remote interactive evaluations at facilities[2] where drugs[3] are manufactured, processed, packed, or held; facilities covered under FDA's bioresearch monitoring (BIMO) program; and outsourcing facilities registered under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the duration of the COVID-19 public health emergency.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

[1] This guidance has been prepared by the Center for Drug Evaluation and Research in cooperation with the Center for Biologics Evaluation and Research, the Center for Veterinary Medicine, and the Office of Regulatory Affairs at the Food and Drug Administration.

[2] In this guidance, the term *facility* covers persons, sites, and establishments subject to FDA drug manufacturing and bioresearch monitoring regulations and statutory authority.

[3] In this guidance, the term *drug* includes biologics.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," *available at* https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[4] In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.[5]

During the COVID-19 public health emergency, FDA is limiting unnecessary contact by only conducting prioritized domestic facility inspections and those that are deemed mission-critical.[6] When an upcoming inspection is not mission-critical, is not a prioritized domestic inspection, or is impacted by travel restrictions resulting from the public health emergency, we are using other available tools and information to support regulatory decisions and oversight of facilities. FDA may also supplement a planned inspection with other available tools. Therefore, FDA has developed this guidance to describe various remote interactive tools we may request to use to

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[4] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

[5] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/. On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID-19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic (February 24, 2021), available at https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic

[6] See the guidance for industry *Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers* (January 2021) for further information on FDA's criteria for deeming inspections mission-critical during the COVID-19 public health emergency. (We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.)

conduct an evaluation. In this 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).[7]

III. Planning a Remote Interactive Evaluation

FDA may request to conduct a remote interactive evaluation whenever a program office determines it is appropriate based on mission needs and any travel limitations. FDA conducts inspections for many purposes and programs, and we will consider each of those inspection program areas as possible candidates for a remote interactive evaluation. This policy applies to all drug inspection programs including, but not limited to:

- *Pre-Approval Inspections (PAIs) and Pre-License Inspections (PLIs)*: FDA may perform a PAI or PLI to assess a marketing application. FDA uses these inspections to ensure that any facility named or referenced in support of an application can perform the proposed manufacturing operations in conformance with current good manufacturing practice (CGMP) requirements, to verify conformance with the application, and to confirm that data submitted in the application are accurate and complete.
- *Post-Approval Inspections (PoAIs)*: PoAIs focus on a specific drug and changes to its manufacturing operations, the evaluation of process validation, any changes submitted to the application, and the execution of supporting activities according to application commitments and CGMP requirements.
- *Surveillance Inspections*: Surveillance drug quality inspections examine overall operations, including controls that ensure manufacturing processes produce quality drugs, thereby reducing the risk of adulterated or misbranded drugs reaching consumers and patients. FDA uses surveillance inspections to evaluate the CGMP compliance of manufacturing operations. Surveillance inspections are performed at active pharmaceutical ingredient and drug product manufacturing facilities, as well as outsourcing facilities that have registered with FDA under section 503B of the FD&C Act.
- *Follow-Up and Compliance Inspections*: When a specific drug quality problem or facility issue comes to FDA's attention, we may initiate a follow-up or compliance drug quality inspection. For example, FDA may conduct an inspection to investigate: (1) product safety, effectiveness, or quality concerns arising from defect reports; (2) information provided by an informant about a facility; (3) violative activities involving

[7] A remote interactive evaluation is not the same as an inspection as described in section 704(a)(1) of the FD&C Act or a request for records or other information in advance of or in lieu of an inspection, as described in section 704(a)(4) of the FD&C Act. Similarly, a remote interactive evaluation or a request under section 704(a)(4) does not constitute an inspection for purposes of section 510(h)(3) of the FD&C Act. Section 704(a)(4) does not apply to every inspection program covered by this guidance (e.g., section 704(a)(4) does not apply to the BIMO inspection program). Failure to cooperate with either an inspection or a 704(a)(4) request for records or other information may constitute a limiting of inspection and as a result, FDA may deem the relevant drugs manufactured at these establishments adulterated. See the guidance for industry *Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection* (October 2014) for further information.

a facility that were discovered during the inspection of another facility; or (4) corrective actions undertaken by a facility in response to, for example, a warning letter or regulatory meeting.

- *Bioresearch Monitoring (BIMO) Inspections*: The BIMO program is a comprehensive, Agency-wide program of inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA-regulated research. The goals of the BIMO program are to protect the rights, safety, and welfare of research subjects; to verify the accuracy, reliability, and integrity of clinical and nonclinical trial data submitted to FDA; and to assess compliance with FDA's regulations governing the conduct of clinical and nonclinical trials, including regulations for informed consent and ethical review, and certain postmarketing requirements.

A. Selecting and Notifying the Facility

FDA will apply risk management methods and tools to determine when to request a facility's participation in a remote interactive evaluation. In some cases, FDA may request records or request that a facility participate in a remote interactive evaluation prior to an inspection; this approach could minimize risk associated with conducting inspections during the pandemic by reducing the number of FDA staff who have to travel and by reducing time spent on-site for the inspection. We will not accept requests from applicants or facilities for FDA to perform a remote interactive evaluation. Such decisions depend on many factors and information not always known to applicants or facilities, and it would be too burdensome on all parties to establish a request-based program.

Once FDA determines that a remote interactive evaluation is appropriate for a particular facility or drug, we will notify the facility and applicant (when appropriate) by electronic correspondence or phone call. We will use the facility's registration or application information to identify the facility point of contact or U.S. agent. Correspondence or phone contact will include a request for confirmation of the facility's willingness and ability to participate in a remote interactive evaluation, including the use of teleconference, livestream video, and screen sharing of data and documents. The request will indicate the name and address of the facility to be evaluated, the reason for the use of a remote interactive evaluation, and the names of FDA participants, if known.

Following a facility's agreement to be evaluated remotely, FDA will contact the facility to confirm the point of contact for the remote interactive evaluation, facilitate planning, and determine a facility's ability to transfer records and perform remote interactions with FDA staff. FDA will identify the FDA lead for the remote interactive evaluation. FDA will also work with facilities to procure information necessary to plan and coordinate the activities for a remote interactive evaluation. The facility should meet these requests or inform FDA of any challenges in meeting these requests as soon as possible.

Declining FDA's request to perform a remote interactive evaluation could impede our ability to make a timely regulatory decision (e.g., regarding adequacy of a clinical trial used in support of a pending application or adequacy of a drug manufacturing operation described in the application).

1. Specific Considerations for Pre-Approval and Pre-License Inspections

When FDA cannot perform a PAI or PLI, or when we determine it would be useful to supplement a planned inspection, we will consider using tools other than inspection, selecting the most appropriate method to address the specific risks that justify the need for the PAI or PLI. FDA may request a remote interactive evaluation to support an application action if we determine that: (1) remote interaction with the facility will help us assess risks identified during application review; and (2) there are no data integrity or other issues that FDA determines require an inspection.

Generally, FDA intends to request records and other information under section 704(a)(4) of the FD&C Act, before initiating a remote interactive evaluation.

2. Specific Considerations for Post-Approval Inspections

When FDA cannot perform a PoAI, or when we determine it would be useful to supplement a planned inspection, we will consider using tools other than inspection to address the specific risks that justify the need for the PoAI; we may determine that requesting a remote interactive evaluation is an appropriate alternative to conducting an inspection. FDA may request a remote interactive evaluation for PoAIs when: (1) a facility has an acceptable inspection history with no data integrity or other concerns that FDA determines require an inspection; and (2) specific application considerations and CGMP manufacturing risks that warrant a PoAI can be sufficiently assessed through a remote interactive evaluation.

3. Specific Considerations for Surveillance Inspections

The prioritization of facilities, domestic and foreign, for remote interactive evaluations will follow the same risk-based approach currently used by FDA for surveillance inspections.[8]

A remote interactive evaluation does not constitute an inspection for purposes of section 510(h)(3) of the FD&C Act. However, FDA will use information gathered via a remote interactive evaluation to determine the scope, depth, and timing of a future inspection.

4. Specific Considerations for Follow-Up and Compliance Inspections

A follow-up or compliance inspection examines operations, records, and other information that relate to the specific issue being addressed (e.g., drug quality control, facility, or manufacturing problem). FDA will determine whether a remote interactive evaluation is appropriate, such as when an inspection cannot be performed due to travel restrictions or to supplement a planned inspection. The use of a remote interactive evaluation will depend on the nature of the facility and the reason for the assignment, including, but not limited to, inspection history and any data integrity concerns.

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[8] See, for example, the risk-based approach described in MAPP 5014.1 *Understanding CDER's Risk-Based Site Selection Model*, *available at* https://www.fda.gov/media/118214/download.

After issuance of a warning letter, holding a regulatory meeting, or following an enforcement action (e.g., seizure or injunction), FDA usually will conduct an inspection to confirm that corrective actions have been implemented.

To evaluate defect reports (e.g., Field Alert Reports or Biological Product Deviation Reports), FDA may request a remote interactive evaluation and/or make a request under section 704(a)(4) of the FD&C Act.

5. Specific Considerations for Bioresearch Monitoring Inspections

Selection of facilities for BIMO inspections is risk based. While some facility selection factors such as inspection history and time since last inspection may be common across BIMO programs, other factors are unique to each BIMO program.

FDA will consider BIMO facilities for remote interactive evaluation according to existing risk-based facility selection methodologies when there are no data integrity or other concerns that FDA determines require an inspection, and information to be evaluated can be accessed remotely. Generally, the information obtained from a remote interactive evaluation will be used to assess the facility's conduct, including data reliability and human subject protections to determine the acceptability of BIMO studies for FDA's application decision-making.

B. Preparing for a Remote Interactive Evaluation

Once the facility confirms its willingness and ability to participate in a remote interactive evaluation, FDA will schedule a brief virtual meeting to discuss logistics, responsibilities, and expectations. Discussion topics may include, but are not limited to, the following:

- Objectives and scope of the remote interactive evaluation.
- Introduction of the FDA remote interactive evaluation team and the remote interactive evaluation lead.
- Identification of the facility point of contact and all other participants (e.g., sponsor or contract research organization, monitor, remote ancillary operations).
- Schedule of virtual interactions and the anticipated duration of the remote interactive evaluation.
- FDA's expectations during the livestreaming walkthroughs of the facility.
- Time zone differences and translation services (i.e., spoken and written translation), if applicable. Virtual interactions, including remote observation of manufacturing operations or livestream assessment of data, usually will occur during the facility's normal business hours.
- Methods for sharing requested information, including sharing documents and the use of video-streaming technology.
- Technological limitations that could impair or prevent FDA's remote interactive evaluation of the facility.

- Check of the internet connection throughout the facility to verify that the signal strength is adequate to support livestreaming video and audio during the actual remote interactive evaluation.

IV. Conducting a Remote Interactive Evaluation

When facilities agree to participate in a remote interactive evaluation, FDA expects them to cooperate with the same level of transparency as they would during an FDA inspection. We expect appropriate staff to be available at scheduled times for interviews and other virtual interactions, and we expect the facility to be operational to the extent possible for FDA to evaluate areas and operations of interest (e.g., manufacturing, laboratory, packaging). If a facility is unable to support video or other virtual interactions, or if FDA determines that the video or any other virtual interaction during the remote interactive evaluation does not permit a sufficient examination of the facility or of a corrective action, FDA may terminate the remote interactive evaluation and instead perform an inspection or use other available tools.

As part of a remote interactive evaluation, FDA may:

- Request and review documents, records, and other information (electronic systems).[9]
- Use livestream and/or pre-recorded video to examine facilities, operations, and data and other information.[10]
- Through the facility's point of contact, schedule interviews and meetings to address any questions or concerns.
- Evaluate a facility's corrective actions (e.g., in response to a previous inspection or evaluation, or to the current remote interactive evaluation). An inspection instead of a remote interactive evaluation may be necessary to verify the adequacy of some corrective actions, or if evaluating the corrective actions remotely would unreasonably extend the duration of the remote interactive evaluation.
- Provide verbal updates to the facility on observations and outstanding issues, whenever feasible.

FDA will not issue a Form FDA 482, Notice of Inspection, to announce or open a remote interactive evaluation.

A. Technological Requirements

The quality of the remote connection (e.g., connectivity, image quality, cameras used) should be adequate for FDA to remotely review, observe, examine, and evaluate the information requested. To the extent practicable, technologies employed also should allow access for remotely viewing

[9] Some remote interactive evaluations will be preceded by a request for records and other information for those facilities covered by FDA's authority under section 704(a)(4) of the FD&C Act, when appropriate. FDA requests, including requests for records, during a remote interactive evaluation are considered voluntary unless a section 704(a)(4) request is sent to the facility.

[10] For a remote interactive evaluation supporting a pending biologics license application, FDA usually will expect a facility to provide for livestream video of the manufacturing operations described in the application.

and evaluating operations at the facility, as necessary (e.g., aseptic practices, equipment cleaning and set up, material weighing and dispensing, instrument set up, sampling, testing). FDA understands that there may be temporary connection issues during the virtual interaction, and we expect either party to resolve the issue in a timely manner.

For security reasons, FDA will use its own IT platforms and equipment[11] to host virtual interactions during remote interactive evaluations (e.g., videoconferences, livestreaming video of the facility and operations in the facility). FDA currently uses the following conferencing platforms:

- FDA Microsoft Teams
- FDA Zoom for Government
- FDA Adobe Connect

B. Remote Interactive Evaluation of Documents and Records

FDA will usually request and review documents and other information in advance of a remote interactive evaluation[12] to ensure the livestream interactions are as efficient as possible. However, we may request additional documents and other information, including video recordings, at any time during the remote interactive evaluation to address questions and to explain observations. Documents and other information requested during a remote interactive evaluation are expected to be provided within a reasonable timeframe, similar to requests for documents or other information made during an inspection.

FDA expects all documents requested during the remote interactive evaluation to be provided in electronic format or accessible by screen sharing during a live interaction so that the documents can be assessed efficiently. FDA will provide a secure means to send requested information during a remote interactive evaluation. For electronic documents and other information, facilities should identify any limitations and ensure that encrypted and password-protected files can be accessed by FDA. Documents submitted during a remote interactive evaluation should be in English. However, if translation is needed during a livestream interaction, the facility may need to provide a translator.

FDA recognizes that some facilities maintain documents in paper format and not all electronic systems will be accessible for direct viewing. Thus, when such a facility agrees to participate in a remote interactive evaluation, they should consider taking steps to enable FDA's remote viewing and verification of the facility's documents, procedures, and electronic systems. Requested documents maintained in paper format should be scanned as searchable Portable Document Format (PDF) files when possible.

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[11] FDA is not able to supply equipment to a facility to enable FDA's remote interactive evaluation. Additionally, FDA is not able to accept equipment or devices from a facility for our use in conducting a remote interactive evaluation.

[12] Generally, for manufacturing facilities, such requests for records or other information prior to the remote interactive evaluation will be made under section 704(a)(4) of the FD&C Act.

V. Concluding a Remote Interactive Evaluation

Upon completion of a remote interactive evaluation, FDA will have a closeout meeting with the facility's management. During this meeting, FDA will usually present a written list of observations, if any, and describe and discuss any observations in sufficient detail to enable understanding and foster an appropriate response.[13] This written list of observations will not be a final Agency action or decision. FDA will not issue a Form FDA 483, Inspectional Observations. As with an inspection, FDA encourages facilities to respond during the discussion and/or provide responses in writing to the observations within 15 U.S. business days.

Depending on the purpose and outcome of the remote interactive evaluation, the information and documentation collected may be used to, among other regulatory purposes:

- Support FDA's assessment of pending applications, including whether to approve an application
- Preclude the need for an inspection in follow-up to a reported concern or defect
- Support a regulatory meeting, warning letter, import alert, recall activities, or enforcement action
- Rank or prioritize a facility for an inspection, particularly a surveillance CGMP inspection
- Justify a follow-up or compliance inspection or any other surveillance activity

After the remote interactive evaluation concludes, FDA will provide a copy of the final remote interactive evaluation report to the facility. A remote interactive evaluation report and any written list of observations may be subject to a disclosure request under the Freedom of Information Act.

If FDA determines that an inspection will be necessary based on the outcome of the remote interactive evaluation, we will use the information obtained from the remote interactive evaluation to prepare for and conduct the inspection.

VI. Impacts of Remote Interactive Evaluations on Established Commitments and Timeframes

In general, the use of remote interactive evaluations should help FDA operate within normal timeframes (i.e., in a similar manner as an inspection) as outlined below, especially for higher priority activities in spite of challenges related to the COVID-19 pandemic.

[13] If the remote interactive evaluation, including the review of any records before or during the evaluation, is intended to supplement a scheduled inspection, then FDA usually will combine any observations from the remote interactive evaluation(s) into a single written list of observations issued at the close of the inspection, which would be issued on a Form FDA 483, Inspectional Observations.

FDA intends to use information from a remote interactive evaluation to meet user fee commitments and to update FDA's relevant internal databases. FDA expects that a remote interactive evaluation will generally enable us to meet a user fee goal date. However, FDA will notify applicants if we expect to miss a user fee goal date.

A. Commitments for Pre-Approval and Pre-License Inspections

FDA will adhere to existing response timeframes applicable to inspections.

- Any responses or corrective actions submitted to the FDA in response to the observations identified during the remote interactive evaluation will be considered in the application assessment if provided within 15 U.S. business days of FDA's communication. FDA may defer consideration of responses or corrective actions in the current review cycle if received after 15 days.
- Responses received after 15 U.S. business days will be considered in the next application user fee cycle, should the application receive a complete response action and the facility requires re-evaluation.

B. Timeframes for All Inspection Types

FDA generally intends to use existing timelines established for reporting on and evaluating the outcome of an inspection for the remote interactive evaluation.

Any responses or corrective actions submitted to the FDA in response to the issues identified during the remote interactive evaluation will be considered with respect to further regulatory action if provided within 15 U.S. business days of FDA's communication of the observations.