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Conducting Remote Regulatory Assessments

Questions and Answers Guidance for Industry

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Inspections and Investigations
Office of Combination Products
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Center for Devices and Radiological Health
Center for Tobacco Products
Center for Veterinary Medicine
Human Foods Program**

June 2025

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Questions and Answers

Guidance for Industry¹

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

In response to the Coronavirus Disease 2019 (COVID-19) pandemic, FDA adapted its operations for field activities to provide oversight of regulated industry while mitigating the spread of COVID-19. One set of tools used during the COVID-19 public health emergency for oversight of FDA-regulated products was remote regulatory assessments (RRAs). The term “RRA” (as defined in the Question and Answers section) is used to describe a category of activities for which FDA may use different terminologies, but that are all considered to be *types* of RRAs, including “remote interactive evaluations”² and “remote record reviews.” Such activities, along with others identified in this guidance, are considered RRAs for purposes of this guidance. When faced with travel restrictions during the COVID-19 pandemic, FDA used RRAs to assess establishments and their compliance with applicable FDA requirements. Based on this

¹ This guidance has been prepared by the Office of Inspections and Investigations in cooperation with the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Tobacco Products, the Center for Devices and Radiological Health, the Center for Veterinary Medicine, the Human Foods Program, and the Office of Combination Products.

² See Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities, Draft Guidance for Industry, issued October 2023. See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manufacturing-and-bioresearch-monitoring-facilities>. We update guidance documents periodically. For the current version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

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experience,³ FDA has noted the value of RRAs and concluded that they are a beneficial oversight tool outside the COVID-19 pandemic and for a range of FDA-regulated products.⁴ FDA has developed this guidance to provide answers to frequently asked questions related to RRAs. This guidance is intended to help enhance industry's understanding of RRAs, thereby facilitating FDA's process for conducting RRAs. The guidance finalizes the revised draft guidance of the same title issued on January 26, 2024 (89 FR 5244).

Throughout this guidance, the terms, "FDA," "the Agency," "we," "us," and "our" refer to the Food and Drug Administration. In this guidance, the term "establishment" includes any facility, entity, person, importer, or site, whether foreign or domestic, subject to the laws administered by FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe our current thinking on a topic and 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

FDA uses a variety of tools⁵ for oversight of FDA-regulated products and establishments. During the COVID-19 pandemic, FDA used RRAs to help the Agency conduct oversight, mitigate risk, and meet critical public health needs with respect to certain FDA-regulated products. RRAs have included: (1) mandatory⁶ RRAs involving review of records or other information submitted by certain establishments upon request from FDA under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act); (2) mandatory reviews of records from food importers subject to section 805 of the FD&C Act⁷ (hereinafter referred to as "requests for Foreign Supplier Verification Program (FSVP) records under 21 CFR 1.510(b)(3) or 1.512(b)(5)(ii)(C)"); and (3) voluntary RRAs involving remote requests for records and/or interactive evaluations (such as remote livestreaming video of operations, teleconferences, and screen sharing).

³ See, e.g., FDA's November 2021 "An Update to the Resiliency Roadmap for FDA Inspectional Oversight," where we reported on the use of RRAs as a tool to fortify FDA oversight efforts throughout the pandemic. <https://www.fda.gov/media/154293/download>

⁴ See, e.g., Question 2, describing to whom voluntary and mandatory RRAs may apply.

⁵ See, e.g., the discussion of alternative tools used for oversight listed in FDA's May 2021 "Resiliency Roadmap for FDA Inspectional Oversight," and section 704 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374). <https://www.fda.gov/media/148197/download>

⁶ As used in this guidance, references to a "mandatory RRA" mean RRAs for which an establishment's participation is required by legal authorities.

⁷ Section 805 of the FD&C Act requires importers as defined for purposes of section 805 of the FD&C Act to perform certain risk-based Foreign Supplier Verification Programs (FSVP) activities. Further, section 805(d) of the FD&C Act provides for FSVP records to be made available promptly to the FDA upon request. The FSVP regulation states that, if requested in writing by FDA, records must be sent to FDA electronically, or through any other means that delivers the records promptly, rather than making them available for review at an importer's place of business. 21 CFR 1.510(b)(3), 1.512(b)(5)(ii)(C).

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FDA has identified significant benefits in using RRAs. For instance, RRAs have assisted FDA in verifying corrective actions taken in response to inspections of previously compliant manufacturers⁸ and in gaining compliance insight when it was not practicable to inspect. RRAs have also provided information about deficient practices, leading FDA to take regulatory actions and/or conduct inspections, as well as informing future inspection planning. RRAs were used to help support review and promote timely approval or authorization of marketing submissions for FDA-regulated products. In the food programs, RRAs have assisted in determining compliance with veterinary feed directive regulations, assessing foreign manufacturing process records, adding foreign establishments to import alerts, and issuing warning letters.

Based on these experiences, FDA has determined that RRAs are valuable oversight tools and, therefore, under certain circumstances, can assist FDA in its mission to protect public health, oversee regulated industry, and help ensure regulated products comply with FDA requirements.

With respect to section 704(a)(4) of the FD&C Act, this provision, as amended by the Food and Drug Omnibus Reform Act of 2022 (FDORA),⁹ gives FDA authority to request (and requires establishments to provide) any records or other information that FDA may inspect under section 704 of the FD&C Act, in advance of or in lieu of inspections of such establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or device,¹⁰ or a site or facility that is subject to inspection under section 704(a)(5)(C) of the FD&C Act (i.e., sites, entities, or facilities subject to bioresearch monitoring (BIMO) inspections).

The Agency believes that FDA's use of both mandatory and voluntary RRAs, as applicable, for FDA-regulated products is in the interest of the public health, and the Agency is issuing this guidance to provide further transparency to interested parties about the circumstances in which the Agency may opt to use mandatory and voluntary RRAs.

The Agency is also issuing this guidance to promote greater consistency in the manner RRAs are conducted, including by explaining processes for responding to an RRA request, and by outlining factors we use for evaluating whether an establishment has responded timely and appropriately to a mandatory request.

⁸ In instances where FDA has identified objectionable conditions regarding compliance with laws and regulations enforced by FDA (e.g., Current Good Manufacturing Practice requirements for FDA-regulated products), FDA may subsequently determine compliance based on a voluntary commitment of corrective actions, or, when warranted, FDA may pursue a regulatory action. If FDA pursues a regulatory action after conducting an RRA, we generally will conduct an inspection to confirm that corrective actions have been implemented; however, for certain regulatory actions and with respect to select instances involving certain programs, FDA could determine that a subsequent RRA is appropriate.

⁹ FDORA was enacted as part of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 (2022). FDORA sections 3611(b)(1)(A) and 3612(a), respectively, added device establishments, and sites, entities, or facilities subject to bioresearch monitoring inspections as establishments that are subject to mandatory requests for records or other information under section 704(a)(4) of the FD&C Act (21 U.S.C. 374(a)(4)).

¹⁰ The terms “drug” and “device” are defined at section 201(g)(1) and (h) of the FD&C Act, respectively. With respect to drugs, a “drug” includes human and animal drugs (including all compounded human and animal drugs), and biological drug products for humans. References to drug and device manufacturers in this guidance means establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or device, respectively. See, e.g., section 510 of the FD&C Act and 21 CFR 207.1 and 807.3.

III. Questions and Answers

This section is intended to provide FDA's current thinking regarding the requesting, conducting, and use of RRAs by FDA.

A. Remote Regulatory Assessment Fundamentals

1. What is an RRA?

An RRA is an examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. RRAs assist in protecting human and animal health, informing regulatory decisions, and verifying certain information submitted to the Agency.

RRAs are a tool FDA may use to support regulatory decisions and oversight activities. Mandatory RRAs are those conducted under legal authorities mandating the establishment's participation. Requests for records or other information from establishments subject to section 704(a)(4) of the FD&C Act, and requests for FSVP records under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C), are included among mandatory RRAs.¹¹ RRAs that are not conducted under statutory or regulatory authorities mandating an establishment's participation are voluntary in that an establishment can decline to participate or withdraw participation during the RRA, in which case the Agency may consider other tools for evaluating compliance with FDA requirements.

RRAs complement FDA's authority to conduct inspections under section 704(a)(1) of the FD&C Act and other applicable FDA authorities. RRAs do not limit the authority of FDA to conduct inspections under section 704(a)(1) of the FD&C Act and other applicable FDA authorities.

2. Who may be subject to an RRA?

- *Mandatory RRAs*

Mandatory RRAs include those conducted for: (1) establishments that are subject to section 704(a)(4) of the FD&C Act;¹² and (2) importers, as defined in 21 CFR 1.500, that are subject to FSVP under section 805 of the FD&C Act and to the records review requirements in 21 CFR 1.510(b)(3) or 1.512(b)(5)(ii)(C), as applicable.¹³

Upon initiating a mandatory RRA, FDA intends to make clear the authorities under which the RRA is being requested.

¹¹ We note that the fact that an establishment is subject to a mandatory RRA does not mean that all RRA requests made to the establishment are mandatory (e.g., a remote interactive evaluation is not conducted under mandatory RRA authorities and would thus be voluntary).

¹² As described in the Background section, mandatory records request authority under section 704(a)(4) of the FD&C Act applies to drug and device establishments and to sites, entities, or facilities subject to BIMO inspections.

¹³ Although discussed in this guidance in response to certain frequently asked questions, RRAs conducted under section 704(a)(4) of the FD&C Act or under FSVP are not necessarily the only types of mandatory RRAs for which FDA has authority.

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- *Voluntary RRAs*

If an RRA is not mandated by statute or regulation (or FDA opts against exercising its mandatory RRA authority in a certain instance), FDA may request that any establishment subject to FDA jurisdiction participate in a voluntary RRA.

3. Are RRAs replacing other established means of obtaining information outside of inspections?

No, RRAs are not intended to limit or replace other established means of obtaining information necessary for FDA to accomplish its public health mission outside of inspections, including, among other things, applicant information request letters, registration information and updates meetings, product submissions, application assessments, or follow-up communications during outbreaks or other emergencies. Similarly, if, for example, FDA contacts an applicant to inform it that an application or other submission is missing certain information, this is not an RRA. Although these activities may be conducted remotely, the Agency does not consider these activities to be RRAs.¹⁴

4. Is an RRA an inspection?

An RRA is not an inspection under sections 704(a)(1) or 704(a)(5) of the FD&C Act. Generally, an inspection, such as described in section 704(a)(1) of the FD&C Act, involves duly designated officers or employees of the FDA physically entering (at reasonable times and in a reasonable manner), establishments subject to regulation under the FD&C Act to determine compliance with applicable requirements.¹⁵

However, because remote requests for FSVP records are under the authority of section 805 of the FD&C Act and FDA's implementing regulations,¹⁶ these record requests function as inspections in that FDA uses these record requests to evaluate a food importer's compliance with FSVP.

5. When may FDA initiate or request to conduct an RRA?

FDA may initiate or, in the case of a voluntary RRA, request to conduct, an RRA whenever we determine an RRA is appropriate to help fulfill the Agency's regulatory responsibilities and to protect human and animal health. For example:

- When FDA cannot conduct an inspection due to travel limitations brought on by public health emergencies, natural disasters, or other situations making travel infeasible.
- When FDA determines that an RRA will assist us in conducting elements of establishment oversight or support regulatory decisions. Examples include preparing for an already planned

¹⁴ FDA will indicate when we consider an activity to be an RRA so establishments can differentiate RRA interactions from non-RRA interactions.

¹⁵ See section 704(a)(1) of the FD&C Act. Relatedly, for requests for records and other information under section 704(a)(4) of the FD&C Act, FDA will not issue a Form FDA 482, Notice of Inspection, or Form FDA 483, Inspectional Observations, during the RRA process.

¹⁶ 21 CFR 1.500 et. seq. Under 21 C.F.R. §1.510(b)(3) and 1.512(b)(5)(ii)(C), as applicable, if requested in writing by FDA, the importer must send records to the Agency electronically, or through another means that delivers records promptly. Also see FDA Fact Sheet "[What to Expect during a Foreign Supplier Verification Program Inspection](#)".

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inspection, following up on a consumer complaint, assisting in verifying that an establishment has completed certain corrective actions (e.g., in response to a previous inspection, or previous RRA), or supporting the review of a marketing submission.

FDA intends to use a risk-based approach to determine whether to initiate or request an RRA. Factors that may be considered include, but are not limited to, establishment location, inspection history, complexity of product and process, and travel restrictions. Programs and centers within FDA may assess risk in the context of a potential RRA differently based on those and other factors.

The above examples are illustrative, and the ultimate decision to initiate or request an RRA rests with FDA, as we retain discretion to use RRAs as appropriate. FDA does not accept requests to perform an RRA. When FDA determines an inspection (as opposed to an RRA) is necessary, FDA intends to perform an inspection.

6. Will FDA use RRAs during or as part of an FDA inspection of an establishment?

No, FDA does not plan to conduct RRAs and inspections¹⁷ of an establishment under sections 704(a)(1) or 704(a)(5) of the FD&C Act¹⁸ simultaneously. An RRA is conducted remotely by FDA staff, without FDA staff present at an establishment conducting an inspection. However, an RRA could precede, prompt, or be a follow-up to, an inspection. When an RRA precedes an inspection, FDA will generally conclude the RRA prior to initiating the inspection. FDA may combine any information gained from the RRA with any resulting observations from the subsequent inspection. In such circumstances, FDA would confirm any observations from the RRA during the subsequent inspection before including them on any Form FDA 483, Inspectional Observations, issued at the conclusion of the subsequent inspection.

Additionally, FDA may conduct an RRA following an inspection to conduct follow-up activities with the establishment or to assist in verifying corrective actions, if appropriate.

FDA may seek to conduct an RRA (e.g., livestreaming) during oversight activities independently conducted by state or foreign regulatory partners.¹⁹

7. What are the benefits of an RRA?

FDA, industry, and the public can all benefit from RRAs as RRAs help the Agency to meet critical public health needs. These potential benefits may include, but are not limited to:

- Allowing FDA to remotely evaluate compliance of FDA-regulated products, clinical studies, and establishments, as appropriate. This may identify issues that lead establishments to promptly make corrective actions, which in addition to addressing such issues, may enhance the establishment's preparedness for their next FDA inspection.

¹⁷ FDA considers inspections that are conducted by state officers or employees duly commissioned under section 702(a)(1)(A) of the FD&C Act to be FDA inspections for the purposes of this guidance.

¹⁸ With respect to FSVP RRAs, see Question 4.

¹⁹ Generally, FDA does not intend to conduct RRAs during Medical Device Single Audit Program (MDSAP) audits.

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- Reducing resource expenditure. For example, when an RRA precedes an inspection under section 704(a) of the FD&C Act, FDA may not need to review as many records during the inspection, reducing the time FDA is present at the establishment.
- Helping to support timely regulatory decisions (including the approval of an application or authorization for emergency use), without an inspection, when appropriate conditions are fulfilled, such as the ability to verify information in the marketing submission through use of an RRA. In such cases, the application approval, or the authorization, must still meet applicable standards.
- Providing FDA additional information to incorporate into a risk-based inspection schedule, thereby helping FDA use inspectional resources more efficiently and effectively.
- Assisting FDA in verifying corrective actions.²⁰

B. Remote Regulatory Assessment Expectations

8. How may FDA request an RRA?

FDA generally intends to use the following processes for requesting voluntary or initiating mandatory RRAs.²¹

FDA's request will state whether the RRA is mandatory or voluntary (and in the case of a mandatory RRA, the authorities under which it is being requested).

- *In general, for voluntary RRAs*
 - FDA expects to contact an establishment through the establishment's point of contact,²² by email or phone, once we determine a voluntary RRA is appropriate.
 - FDA may use the establishment's registration, establishment information provided in a marketing submission, or additional information available to FDA, to identify the point of contact, authorized official, or U.S. agent.
 - FDA will obtain the establishment's consent to the voluntary RRA before we begin the RRA. Where practicable, FDA generally intends to seek to obtain such consent in writing.
 - Obtaining the establishment's consent typically includes:
 - notifying the establishment's point of contact of the purpose and planned scope of the RRA and of the right to refuse consent; and

²⁰ See footnotes 2 and 8.

²¹ This guidance represents the Agency's current thinking on how RRAs apply generally to FDA-regulated products. Other Agency documents provide additional information about RRAs with respect to specific circumstances. See, e.g., [SMG 6001.1](#); [FDA Compliance Program Guidance Manual 7303.878, FSVP Inspections](#); [Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities, Draft Guidance for Industry, October 2023](#).

²² FDA will typically request to speak with an establishment's owner, operator, or agent in charge at the site (i.e., top management official at the site), or their designee.

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- requesting that such person confirm that the establishment voluntarily consents and has the ability to participate in the voluntary RRA requested.
 - As part of the request, FDA will typically offer the establishment the opportunity to have a discussion to inform the establishment's decision on whether to provide consent for the voluntary RRA. Such a discussion might cover considerations, as applicable and appropriate, including:
 - FDA's expectations for, and any establishment limitations in participating in, the RRA.
 - The scheduling of virtual interviews and meetings.
 - Technological capabilities.²³
 - The process and timeline for requesting records or other information for review.
 - How and when FDA will provide feedback to the establishment.
 - The general process and other aspects related to logistics and capabilities.
- *In general, for mandatory RRAs*
 - FDA will initiate the request in accordance with the relevant legal authority and intends to follow any established procedures.
 - The point of contact listed in the establishment's registration may be used as the point of contact for the RRA request.
 - FDA will use Form FDA 4003 to request records or other information under section 704(a)(4) of the FD&C Act.
 - For pre-approval and pre-licensing inspections, there may be situations when, in advance of the inspection, records are requested of an establishment under section 704(a)(4) of the FD&C Act related to products named in multiple applications. In these situations, FDA intends to issue one Form FDA 4003 to the establishment to cover requests for records or other information for the relevant products in the applications being assessed.
 - When making a request under section 704(a)(4) of the FD&C Act, FDA will provide a sufficient description of the records or other information requested, as well as our rationale for requesting such records or other information in advance of, or in lieu of, an inspection.²⁴
 - Upon receipt of the requested records, we will provide confirmation of receipt to the establishment.²⁵

²³ Any technical expectations, as applicable, will be discussed between FDA and the establishment prior to or during an opening meeting. In conducting the RRA, FDA will determine best logistical approaches and/or technology methods, as applicable, in coordination with the establishment.

²⁴ See section 704(a)(4)(A) of the FD&C Act.

²⁵ See section 704(a)(4)(B) of the FD&C Act.

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- Under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C) for imported foods, FDA uses Form FDA 482d to request FSVP records.

Regardless of whether an RRA is mandatory or voluntary, FDA does not intend to issue a Form FDA 482, Notice of Inspection, as part of the RRA process.²⁶

9. What might an establishment expect to happen during an RRA?

RRAs may entail, but are not limited to, any combination of the following, depending on the type of RRA involved:

- FDA requests and reviews records and other information (this may include records or information from electronic systems, and source records from non-clinical and clinical studies).
- Virtual meetings between FDA and responsible establishment personnel to review, where appropriate, the information provided to FDA, the establishment's electronic systems, the establishment's operations, and/or the establishment's standard operating procedures. Interactions beyond the virtual meetings between FDA and an establishment may continue throughout an RRA.
- Use of livestream and/or pre-recorded video, where appropriate, to examine facilities, operations, data, and other information.

FDA may review electronic systems and source records, including by screen sharing and livestream/video.²⁷ FDA may provide updates to the establishment on observations and outstanding issues, whenever feasible, throughout the RRA. FDA expects to make reasonable and appropriate efforts to discuss observations with the management of the establishment, to minimize surprises, errors, and misunderstandings.

While mandatory RRAs that are conducted under relevant legal authorities involve activities detailed by such authorities, an establishment required pursuant to such authorities to participate in a mandatory RRA could agree to participate in activities beyond what is required. For instance, FDA may request that an establishment subject to a records request under section 704(a)(4) of the FD&C Act instead voluntarily participate in an RRA that accommodates review through interactive technologies such as video streaming.

10. Are there any consequences for declining to participate in an RRA?

- *Voluntary RRAs*

Because of the voluntary nature of these assessments, FDA will not take enforcement action solely based on an establishment declining a voluntary RRA.²⁸ FDA may consider other activities necessary to

²⁶ See footnote 15.

²⁷ FDA generally does not intend to record RRAs conducted via livestream, video, or screen sharing; however, FDA may request records we review during those sessions. If FDA does record, it will first inform the establishment.

²⁸ This would not be considered a refusal to permit access or entry for purposes of section 301(e) or (f), or 807, of the FD&C Act.

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exercise our oversight responsibilities regarding that establishment, such as an inspection, based on considerations such as when the establishment was last inspected, our assessment of risks, and other relevant factors. An establishment may decline to participate in a voluntary RRA, but an establishment may not opt out of an FDA inspection.²⁹

However, if an establishment declines to participate in a voluntary RRA, FDA may not be able to assess the establishment's activities until we exercise other oversight tools. Indeed, a voluntary RRA may be the most expedient means for FDA to assess the establishment, especially when factors prevent FDA from conducting a timely inspection. For example, in circumstances which temporarily limit FDA's ability to conduct an inspection, such as travel restrictions, it may take FDA longer to assess an establishment or, for example, a marketing submission in which an establishment is referenced, absent an RRA, because we lack necessary information.

- *Mandatory RRAs*

FDA may consider the following actions, among others, as declining to participate in a mandatory RRA: failing to respond, withdrawing participation, or refusing to provide records, upon a request made in accordance with relevant legal authorities. There can be consequences for declining mandatory RRAs. For example, an establishment that refuses a request for records or other information under section 704(a)(4) of the FD&C Act may be in violation of the FD&C Act.³⁰

Similarly, if an importer refuses FDA's written request for FSVP records under 21 CFR 1.510(b)(3) or 1.512(b)(5)(ii)(C), the importer may be in violation of section 805 of the FD&C Act, and the food offered for import by the importer may be subject to refusal under section 801(a)(3) of the FD&C Act.³¹

FDA intends to take appropriate action against persons³² and products that are in violation of the FD&C Act.

11. Are there any technological expectations for an RRA?

The technological expectations will vary depending on the type of RRA and its scope. Certain RRAs involve records requests, and the records may be submitted electronically or through other means, as applicable. Other RRAs may require additional technological capability. For example, if FDA expects that the RRA could include the use of live streaming video, FDA may inquire about hardware or internet connectivity to assess IT operability, security, and privacy controls to protect the confidentiality of the data. The quality of the remote connection (e.g., connectivity, image quality, cameras used) should be adequate for FDA to review, observe, examine, and evaluate the requested records, documents, and other information (including electronic systems). To the extent practicable, technologies employed should also allow access for remotely viewing and evaluating operations at the establishment, as appropriate (e.g., aseptic practices, equipment cleaning and set up, material weighing and dispensing, instrument set up, sampling, and testing).

²⁹ See e.g., section 704(a)(1) of the FD&C Act.

³⁰ See e.g., section 301(e) of the FD&C Act (Prohibited Acts).

³¹ 21 CFR 1.514(a).

³² See section 201(e) of the FD&C Act (definition of "person").

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If an establishment is unable to support streaming video or other live virtual interactions, or if FDA determines that the streaming video or any other virtual interaction during the RRA does not permit a sufficient examination of the establishment or of a corrective action, FDA may use other available tools or may terminate the RRA and consider other actions necessary to exercise our oversight responsibilities regarding that establishment, such as an inspection.

Recommendations for sending records or other information are further explained in Question 15, below.

C. Requests for Records or Other Information as Part of Remote Regulatory Assessments

12. What records or other information may FDA request as part of an RRA?

For voluntary RRAs, FDA may request records or other information appropriate to determine whether an establishment or FDA-regulated product is in compliance with applicable requirements. The records and other information will typically be similar to what FDA would request during an inspection under section 704(a)(1) of the FD&C Act.

In the case of mandatory RRAs, the records or other information we request, and the circumstances under which we request them, will conform to the relevant legal authority. For example, under section 704(a)(4) of the FD&C Act, FDA may request any records or other information subject to inspection under section 704 of the FD&C Act. For mandatory RRAs under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C), FDA may request any and all records that are required to be maintained under 21 CFR Part 1, Subpart L.

Examples of records or other information the Agency may request during a voluntary or mandatory RRA may include, but are not limited to:

- Records of specific production lots or batches as well as product-specific information, such as periodic product reviews,³³ product quality reports, equipment records, process validation records and reports, test results, records of product postmarket defects, or other information related to compliance with Current Good Manufacturing Practice requirements.
- Certain summary records or lists of records, such as a summary of batches manufactured and their disposition, or a summary of discrepancies and investigations related to manufacturing and testing.
- Read-only access to electronic databases³⁴ or a request that an establishment walk us through information in their database or provide data queries or summary data generated by the establishment from their databases.
- Standard Operating Procedures and records generated by the establishment to document control of quality systems and/or to demonstrate compliance with FDA requirements.

³³ See 21 CFR 211.180(e).

³⁴ In the case of mandatory RRAs, see e.g. sections 704(a)(4)(A) and 704(a)(5)(D), and FDA Investigations Operations Manual 5.14 (“Read-Only Access to Electronic Databases During Bioresearch Monitoring Inspection Assignments”)

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- For FSVP importers, records related to hazard analysis, the importer's determination of appropriate supplier verification activities, performance of supplier verification activities, and/or corrective actions.
- For establishments subject to BIMO inspection, records or data related to the reporting or conduct of FDA-regulated research.

Where applicable, FDA intends to take appropriate efforts to minimize the quantity of records or other information requested and may request that establishments take reasonable efforts to facilitate and expedite FDA's collection and review of records. See Questions 14 and 15 for additional details.

13. For what purposes may FDA use the records and other information gathered during an RRA?

Depending on the scope of the RRA, the records and other information may be used by FDA for, among other things,³⁵ the following purposes:

- Support FDA's assessment of pending marketing submissions, including whether to approve an application or whether to issue a response, such as a complete response letter.³⁶
- Determine whether an establishment or product is or is not in compliance with certain FD&C Act or Public Health Service Act requirements, and other applicable requirements.
- Facilitate assessment of the need for an inspection in follow-up to a reported concern or defect.
- Support actions such as a regulatory meeting, warning letter, import action, recall activity, or other advisory action, or to support an administrative or judicial action.
- Determine the priority of establishments for inspection, particularly a surveillance inspection.

14. If the RRA requests records or other information, what is the timeframe for submitting the records and other information to FDA?

For mandatory RRAs, FDA will request that records and other information be submitted within a timeframe consistent with the relevant legal authority.³⁷ For voluntary RRAs, FDA may suggest

³⁵ See, e.g., section 704(a)(4)(C) of the FD&C Act.

³⁶ A complete response letter is either "a written communication to an applicant from FDA usually describing all of the deficiencies that the Agency has identified in a new drug application or abbreviated new drug application that must be satisfactorily addressed before it can be approved" (21 CFR 314.3); or "a written communication to an applicant from FDA usually describing all of the deficiencies that the [A]gency has identified in a biologics license application or supplement that must be satisfactorily addressed before it can be approved" (21 CFR 600.3(l)); see also 21 CFR 314.110 and 21 CFR 601.3.

³⁷ For example, for RRAs under section 704(a)(4) of the FD&C Act, persons subject to the request must provide the requested records or other information within a reasonable timeframe, within reasonable limits, and in a reasonable manner. See Section 704(a)(4)(A). FDA may request, for example, that the facility respond within 15 calendar days (or when language translation of records is requested, within 30 calendar days). In certain circumstances, as reasonable, FDA may request a facility to respond to the request in a timeframe of less than 15 days to accommodate the needs of the specific request (e.g., to meet an application goal date, deadline, or other time-sensitive reasons).

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timeframes to ensure the RRA is completed in a reasonable amount of time and expects establishments to work diligently to provide the requested records and other information. If necessary, establishments should communicate to the FDA point of contact as soon as possible if there is a need for an extension. The circumstances that relate to FDA's expectations for reasonable request timeframes may include:

- The size, available resources, and capabilities of the establishment, including those that might exist for small businesses.
- The type, complexity, and volume of the records and other information being requested.
- The reason for the request, such as an application action goal date, deadline, or other time-sensitive reasons.
- Need for translation of records.

15. How should records or other information in response to an RRA request be provided to FDA?

Except as provided below, requested records or other information generally should be submitted in an electronic format. FDA intends to identify and use a secure means to send requested records and information. For electronic documents, establishments should identify any limitations on external access and ensure that encrypted and password-protected files can be accessed by FDA. FDA will follow federal laws and regulations governing the confidentiality and retention of records and information submitted to the Agency (see, e.g., 5 U.S.C. 552(b)(4), and 18 U.S.C. 1905, 21 CFR Part 20).

FDA recognizes that some establishments maintain documents in paper format. Requested documents maintained in paper format should be scanned as searchable Portable Document Format (PDF) files, when possible, and sent by the secure means identified by FDA. If a paper format is the only option for sending copies of records, FDA will provide the name and contact information of the FDA staff member to whom the records should be sent.

FDA may request that records and other information submitted to FDA be in English or accompanied by an English translation.³⁸ If translated, there should be a verification that the translation is complete and accurate, and, when applicable, should include the name, address, and a brief statement of the qualifications of the translator. Copies of the original records and information should also be included in the response, where appropriate. For certain RRAs, if a verified³⁹ translation is not immediately available, FDA may request that the initial translation be followed up with a verified translation as soon as practicable.

See also [SMG 6001.1](#). For RRAs under section 805(d) of the FD&C Act, persons subject to the request must provide the records promptly. FDA generally expects FSVP records to be sent within 72 hours of the request. See FDA's Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, available here: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-foreign-supplier-verification-programs-importers-food-humans-and-animals>.

³⁸ For RRAs of FSVP importers, upon FDA request, the importers must provide within a reasonable time an English translation of records maintained in a language other than English. See 21 CFR 1.510(b)(1), 1.512(b)(5)(C)(ii)(A).

³⁹ See, e.g., 21 CFR 10.20(c)(2).

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If the records or other information are provided as part of a request under section 704(a)(4) of the FD&C Act, the records and information may be submitted in either electronic or physical form. FDA will provide confirmation upon receipt of the records.⁴⁰ In general, FDA intends to maintain open communications to discuss any records received over the course of the RRA.

For RRAs under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C), records must be sent electronically, or through any other means that delivers the records promptly upon written request from FDA.

D. Completion of a Remote Regulatory Assessment

16. What may occur upon completion of an RRA?

Upon completion of an RRA, FDA may have a closeout meeting⁴¹ with the establishment's management. At the closeout meeting, FDA may present a written list of RRA observations, if any, and describe and discuss such observations in sufficient detail to enable understanding and foster an appropriate response. For purposes of this guidance, RRA observations are defined as conditions and/or practices observed during the RRA that indicate, in the judgment of the FDA employee(s) conducting the RRA, a potential violation of the laws enforced by FDA. FDA does not intend to issue a Form FDA 483, Inspectional Observations, for an RRA.⁴² (See Question 6 for a discussion of how observations from an RRA may be confirmed during an inspection and included on a Form 483).

An establishment should be aware that a written list of RRA observations may be subject to a request under the Freedom of Information Act at the time the disclosure to the establishment is first made (see 21 CFR 20.101(a)) and may be made publicly available, with applicable redaction of information that is exempt from public disclosure (see, e.g., 5 U.S.C. 552(b), 18 U.S.C. 1905, 21 U.S.C. 331(j), 360j(c), 360nn(e), and 387f(c), and 21 CFR Part 20).

FDA encourages establishments to respond during a closeout meeting, and/or provide written responses to observations received at the closeout meeting within fifteen (15) U.S. business days. Responses or corrective actions submitted to FDA during that timeframe in response to the issues identified during the RRA generally will be considered before further Agency action or decision. Establishment responses are available for public disclosure as described in 21 CFR 20.103 with redaction of non-public information, as appropriate.

FDA's written list of RRA observations is not a final Agency action or decision. However, information collected during an RRA may be used in support of such actions or decisions. Following an RRA, FDA may conduct an inspection or may consider other actions, as appropriate, including an enforcement action.

As part of the RRA process, FDA intends to ordinarily prepare a report consisting of a narrative and supporting documents that summarizes information reviewed, conditions and practices found, and RRA

⁴⁰ See section 704(a)(4)(B) of the FD&C Act.

⁴¹ There may be some instances where a closeout meeting may not happen, such as for some requests under section 704(a)(4) of the FD&C Act. In such circumstances, FDA intends to notify the establishment that the RRA is concluded, along with any pertinent information.

⁴² FDA will use a Form FDA 483a, FSVP Observations, to issue observations to an importer based on RRAs that are FSVP record reviews under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C).

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observations identified. In general, FDA expects to provide a written copy of the narrative portion of the RRA report⁴³ to the establishment, following the determination that the RRA is closed (see 21 CFR 20.64(d)(3)). At that time, the RRA report and its supporting documents may also be subject to public disclosure, with applicable redactions, in response to a FOIA request.

Appendix 1

Guidance History[*]	Date	Description
Level 1 Revised Draft Guidance	January 2024	Conducting Remote Regulatory Assessments-Questions and Answers; Revised Draft Guidance for Industry, January 26, 2024 (89 FR 5244). See Notice of Availability for more information.**
Level 1 Final Guidance	June 2025	Conducting Remote Regulatory Assessments-Questions and Answers; Guidance for Industry See Notice of Availability for more information.**

*This table was implemented beginning June 2025 and previous guidance history may not be captured in totality.

** The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage.

⁴³ In some instances, a report may not be written or provided, such as when the requested records under section 704(a)(4) of the FD&C Act were used to prepare for an inspection or for some requests for FSVP records under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C).