SMG 6001.1

FDA Staff Manual Guides, Volume IV – Agency Program Directives

Inspection

FDA Remote Regulatory Assessment Standard Practices

Effective Date: 01/31/2025

1. Purpose

The purpose of this Staff Manual Guide (SMG) is to outline operational roles, responsibilities, and procedures, including approaches and tools to be used for foreign and domestic Remote Regulatory Assessment (RRA) activities within the Food and Drug Administration (FDA or the Agency). RRAs are examinations of an FDA-regulated establishment[1] 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. This SMG is derived from existing agency RRA procedures and is intended to be consistent with the RRA Guidance for Industry (GFI) "Conducting Remote Regulatory Assessments".[2]

[1] The term establishment in this document includes any facility, entity, person, importer, or site, whether foreign or domestic, subject to the laws administered by FDA.
[2] When final, the RRA Guidance for Industry: "Conducting Remote Regulatory Assessments" will represent FDA's current thinking on the topic. For the most recent version, see https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

With respect to RRA procedures specific to the use of section 704(a)(4) of the FD&C Act, this SMG replaces SMG 9004.1 (Aug. 2017).

2. Background

FDA utilizes RRAs to conduct oversight, mitigate risk, and meet critical public health needs with respect to certain FDA-regulated products. FDA has collaborated across program areas to enhance the use of RRAs and develop this RRA SMG to ensure a consistent operational approach. Coordinating standard RRA tools and best practices that support center, office, and program-specific needs will enable greater transparency and optimal alignment of business processes.

This RRA SMG addresses how the FDA conducts mandatory RRAs under section 704(a)(4) of the FD&C Act, which are requests for records or other information in advance of or in lieu of an inspection and under section 805(d) of the FD&C Act for records under the Foreign Supplier Verification Program (FSVP) regulation. The SMG also addresses voluntary RRAs, which are remote examinations not conducted under statutory or regulatory authorities mandating an establishment's participation (e.g., Remote Interactive Evaluations (RIE))[3], as applicable for all types of FDA regulated products (Attachment A). RRAs are not considered inspections under section 704(a)(1) or 704(a)(5) of the FD&C Act, which involve 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 FDA requirements. However, the Foreign Supplier Verification Program (FSVP) requires importers to respond to remote requests of FSVP records under the authority of section 805(d) of the FD&C Act and FDA's implementing regulation. (21 CFR Part 1 Subpart L). These record requests function as inspections in that FDA uses these records requests to evaluate a food importer's compliance with FSVP.

[3] RIE Guidance Document: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manhttps://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manufacturing-and-bioresearch-monitoring-facilitiesufacturing-and-bioresearch-monitoring-facilities

3. Scope

This SMG describes RRA operational procedures for all centers and programs. It also provides a framework for FDA employees when developing new or modifying existing standard operating procedures (SOPs) or work instructions related to RRAs. When organizational units do not have a process that matches the content referenced below, this SMG should be used as the overarching framework for developing internal processes, guidelines, or directives. This approach ensures that RRAs are aligned across the Agency while also providing flexibility for addressing needs unique to each center and program.

4. Policy

This SMG establishes the following policies, which are further described in Responsibilities and Procedures Sections below.

Centers and Office of Inspections and Investigations (OII) staff should refer to this SMG as a procedural guide to ensure that record requests are made in a reasonable manner.

Centers and OII staff should check the resources readily available to them for past or current record requests to the same establishment to avoid duplication, when possible.

5. Responsibilities

Below is a list of standard and cross-programmatic RRA responsibilities. The specific position titles may vary depending on procedures specific to centers or programs. Each listed responsibility and the corresponding role may be conducted by a single FDA employee or multiple FDA employees as appropriate. Ultimately, specific roles and responsibilities related to RRAs will be assigned by OII or the appropriate center or office.

A. General RRA Responsibilities (by position type):

1. Program or Center Leadership

    a. Approves and assures implementation of all procedures or work instructions related to RRAs. The center or program office will determine if an establishment should be selected for an RRA.

2. First Line Supervisor

    a. Assigns RRAs to FDA employees

b. Reviews and provides formal supervisory concurrence of (i.e., endorses) the RRA Report (RRAR)

c. Determines follow-up with establishment after appropriate agency review and input as required (when/if appropriate)

d. Approves (or delegates the approval of) the narrative portion of the RRAR. Approves any applicable redactions of first party non-public information (i.e., information the establishment does not have access to) prior to issuing the RRA Closure Letter for first party release

e. Consults with Freedom of Information Act (FOIA) Disclosure Points of Contact (POC) (as needed)

3. RRA Lead (or RRA POC)

a. Conducts RRA and creates the RRAR (or leads a team in performing those activities)

NOTE: RRA Lead may be an OII or center employee

4. RRA Team Members

a. Assist the RRA Lead and participate in the conduct of the RRA (e.g., center Subject Matter Experts (SME), etc.)

5. Program Support Staff

a. Support RRAs through administrative tasks, such as uploading documents into information management systems as defined per SOPs and coordinating other RRA functions as assigned (e.g., Consumer Safety Technicians, Management Analyst, Legal Instrument Examiners)

6. FOIA Disclosure POC

a. Reviews RRARs for third-party release pursuant to a FOIA request

b. Performs disclosure consultations for program/center RRA POC as needed for first-party releases

7. Process Improvement Staff/Quality Management Staff

a. Assist in the development of program and center-level RRA procedures (i.e., SOPs, Work Instructions, Job Aids, or other quality-control documentation)

b. Evaluate process improvement feedback related to RRAs

c. Review data related to RRAs for trends to improve the process

6. Procedures

RRAs and FDA establishment inspections will not be performed concurrently.

However, RRAs could precede, prompt, or, in limited situations, follow an inspection (see NOTE below).

RRAs will be conducted by trained FDA employees (generally, those who are responsible for inspections, audits, and other related inspectional activities).

NOTE: Post FDA Inspection/foreign regulatory authority Inspection:

- In certain appropriately limited circumstances, a voluntary RRA may be used following an inspection: if additional information or evidence is needed to support the inspectional observations (both written and verbal) to determine whether it is appropriate to pursue a specific regulatory pathway, with appropriate review and coordination between offices and/or center(s) involved in the originating inspection and post-inspection activities.

- Mandatory RRAs generally should not be used following an FDA inspection (e.g., to supplement a recently completed inspection). If a mandatory RRA is being considered following either an FDA inspection or a foreign regulatory inspection (including under a Mutual Recognition Agreement), concurrence from OCC and the appropriate office(s) and/or center(s) must be obtained and documented to ensure appropriate review and coordination at the agency-level.

A. Requests under FD&C Act Section 704(a)(4)

1. Uses

A request under section 704(a)(4) is limited to records or other information that FDA may inspect: (1) under section 704 from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device; or (2) under section 704(a)(5) at a Bioresearch Monitoring site or facility. Such records and information may relate to the following inspection types, among others:

- Surveillance
- For-Cause
- Inspections in support of a marketing application
- Post-Approval/Authorization

Records and other information not subject to request and production under section 704(a)(4), may be requested via a voluntary RRA[4].

2. **Form of Request**

Centers and OII staff should ensure that each records request made pursuant to section 704(a)(4) includes, at a minimum, the following statement, which provides a general description to the regulated establishment of consequences for refusal to provide requested records within the specified timeframe:

- Failure to submit the requested records or other information by the date requested may result in violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act), including, but not limited to, section 301(e) [21 U.S.C. 331(e)]. For establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device, failure to submit the requested records or other information by the date requested also may cause your products to be adulterated within the meaning of section 501(j) of the FD&C Act [21 U.S.C. 351(j)]."

The request must include a sufficient description of the records or other information requested and a rationale for requesting such records or other information in advance of or, or in lieu of, an inspection.

Form FDA 4003 (Attachment D) should be issued to the establishment and coupled with the RRA Introductory Letter (Attachment B)

3. Description of Records or Information Sought by FDA when Utilizing FD&C Act Section 704(a)(4)

As discussed above, section 704(a)(4) allows FDA to request that a person provide records or other information that FDA may inspect: (1) under section 704 at a drug or device establishment; or (2) under section 704(a)(5) at a BIMO site or facility.

FDA's inspection of an establishment's manufacturing, processing, packing, or holding of prescription drugs, nonprescription drugs intended for human use, or devices extends to all things in such establishments – including records, files, papers, processes, controls, and facilities – unless specifically

[4] Voluntary RRAs should clearly indicate both the voluntary nature of the request and include a statement that the request is *not* being made pursuant to section 703 of the FD&C Act.

exempted.[5] For example, FDA may request that an establishment manufacturing prescription drugs provide records of particular batches as well as product-specific information, such as annual product reviews or product quality reports. FDA may also reasonably request that drug and device establishments provide certain records to facilitate and expedite FDA's review, such as summaries of other records.[6] In such cases, FDA should include a brief statement explaining that such summary information is meant to expedite FDA review and is typically reviewed during on-site inspections. It is appropriate to ask for such summaries or translations, in the same way that such a request might be made during an inspection. In cases where an establishment states that it cannot provide records because they do not currently exist, it is appropriate to ask the responsible person to attest to that fact. In some cases, the lack of such records may violate applicable legal requirements.

For BIMO sites and facilities that FDA may inspect under section 704(a)(5), the inspection extends to all records and other information related to the studies and submissions described in section 704(a)(5)(E), including records and information related to the conduct, results, and analyses of, and the protection of human and animal trial participants participating in, such studies.

Along with the particular documents sought for review, Center and OII staff may also choose to request that the establishment provide an accompanying statement, certified and signed by the establishment's most responsible person, stating that the information provided is accurate and reliable.

4. <u>Action If Records Not Provided Under FD&C Act Section 704(a)(4)</u>

FDA may deem the following actions, among others, as declining to participate in a mandatory RRA: failing to respond, withdrawing participation, and refusing to provide records upon a lawful request. There are 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, e.g., section 301(e) of the FD&C Act (Prohibited Acts).

Additionally, where a section 704(a)(4) records request concerning a drug or device is issued in advance of an inspection, to obtain records and other information that FDA needs to prepare for the inspection (as reflected in the "rationale" for the request), FDA may consider asserting a section 501(j) violation if the records request is unreasonably refused or delayed, and such

[5] Q&A on CGMP Requirements: https://www.fda.gov/drugs/pharmaceutical-quality-resources/qa-cgmp-requirements

[6] In requesting such information from databases, FDA investigators follow the procedures described in the Investigations Operations Manual (IOM) 5.3.8.3.2

noncompliance has the effect of delaying or limiting our ability to conduct the inspection[7].

5. **Confirmation of Receipt of Records or Other Information under FD&C Act Section 704 (a)(4)**

   The confirmation of receipt should include, at a minimum:

   a. Language indicating that the confirmation "constitutes a confirmation of receipt of records or other information requested under FD&C Act section 704(a)(4)."

   b. Language indicating that the confirmation affirms only that the FDA has received the records or other information but not that they are complete, accurate, responsive, or otherwise satisfy the request.

   c. The address, firm name, and POC at the firm who responded to the request. This information may or may not be the same as the individual or establishment that submitted the records.

   d. Identification of the FDA center or office sending the confirmation.

   e. Method by which the establishment transmitted the information to the FDA.

   f. Date the FDA received the information.

   g. When records or other information that have been the subject of a single request arrive at FDA in a staggered manner, such as on different days, the requester may opt to confirm receipt after the final record has been received or confirm the receipt of the records and other information as they arrive (see Form 4003a, Records Receipt (Attachment E)).

B. RRA Selection Criteria

1. Program leadership, working across centers and offices, will identify establishments that are appropriate candidates for an RRA, and depending on the program, will also coordinate with state offices.

2. RRAs may be used when FDA determines an RRA is appropriate to help fulfill the Agency's regulatory responsibilities and to protect human and animal health, such as when FDA's ability to inspect is limited, when the agency

[7] Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection | FDA

needs assistance in determining the need for (or extent of) an inspection, or when an RRA can enhance the utility of a planned inspection.

3. A risk-based approach will be used to determine whether to request an RRA. OII program offices and centers will collaboratively consider factors such as resource availability, an establishment's regulatory compliance history, the amount of time since the last inspection, and, as needed, other program-specific selection criteria. OII program offices and centers may utilize (or modify) established procedures to assess risk based on, for example, the product, current priorities, and other information available.

C. Planning RRAs

1. Program leadership, working across centers, offices, and state programs, will make determinations about the appropriate use of RRAs.

2. To the extent possible, proactive cross-programmatic communications will be utilized for conducting RRAs to avoid redundancy at the agency-level. Centers and appropriate OII program offices will work together to develop SOPs so that RRA workflows, associated data, and documents are entered in the same system and are retrievable by those that need access.

D. Conducting RRAs

1. Each RRA will be led by an FDA employee who is trained to conduct inspections or review information related to the appropriate programs/industry/products for the assignment.

2. For RRAs other than FSVP RRAs[8], FDA will send an RRA introductory letter (Attachment B) by email to the establishment's top management official at the site providing notification of the agency's intent to conduct an RRA.

NOTE: For voluntary RRAs (or any voluntary components of RRAs), the introductory letter will include a request for a written response agreeing to participate.

3. The RRA introductory letter should contain the standard minimum content listed in Attachment B and should include additional content as needed per program specific operations.

NOTE: For section 704(a)(4) RRAs, the Introductory Letter must also include the commodity-specific rationale for conducting the RRA referenced in Form FDA 4003 (see Section 6.A.2 above).

[8] For FSVP RRAs, Form FDA 482d is used instead of Attachment B.

4. The introductory letter states that establishments may authenticate the identity of FDA employees using options such as HHS Employee Directory (HHS Employee Directory (psc.gov).

NOTE: If the establishment requests identity verification other than that which is referenced above as proof of employment, the FDA employee should discuss the most appropriate method of identification with their supervisor (in consultation with OCC).

5. For mandatory RRAs, FDA will request that records and other information be submitted within a timeframe[9] consistent with the relevant legal authority. For voluntary RRAs, FDA employees should provide the establishment a reasonable[10] timeframe to submit requested records and other information.

6. Requests for records to foreign establishments will clearly state that the establishment is responsible for ensuring it complies with all applicable non-U.S. privacy laws before submitting information to the FDA.

7. It is important to note that some establishments may not use terms familiar to FDA staff when naming or referencing records in response to an FDA request. FDA staff should strive to use clear, generally understood terminology when requesting documents, and to communicate clearly with establishments that seek further clarification.

8. A reasonable request for records should delineate the timespan covered by the request. It is important for all centers and OII staff to consider requesting information generated by the establishment more recently than the last inspection as well as other reasonable timespans within the applicable record retention requirement for the establishment.

9. Centers and OII staff may request that establishments provide, within a reasonable timeframe, records in English. Original records that are not in English should be included in the response.

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[9] 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 considers a reasonable timeframe for section 704(a)(4) requests to be 15 calendar days, or 30 calendar days when language translation of records is required. However, there may be circumstances in which a section 704(a)(4) records request necessitates a shorter or longer response timeframe. In the event of a public health incident, it is reasonable that the response timeframe requested may be shorter.

[10] See Question #14 of RRA Guidance for Industry: “Conducting Remote Regulatory Assessments". When final, the RRA Guidance for Industry: “Conducting Remote Regulatory Assessments” will represent FDA’s current thinking on the topic. For most recent version, see https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

FDA should request that the English translation be verified to be complete and accurate, and include the name, address, and a brief statement of the qualifications of the translator.

NOTE: 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.

10. By requesting that records be provided in English, FDA intends to minimize the time needed for review. If a verified translation is not provided, FDA may request that the initial translation be followed up with a verified translation as soon as practicable.

    a. The method for submitting a response with the requested records.

       Centers and OII staff should request that records be sent by electronic means (e.g., via a secure file sharing program), when practicable. If the establishment has concerns about the security of sending documents electronically, FDA staff may advise the establishment to consider contacting SecureEmail@fda.hhs.gov to obtain a trusted certificate to send encrypted messages to FDA. FDA's policy is to encourage establishments to provide electronic responses. However, if electronic responses are not feasible, responses consisting of paper records are acceptable.

       Individual offices may choose to use a shared email account to request and receive records and send the confirmation of receipt; procedures associated with the use of such an account should be described in office-level procedures.

       Other approved and secure tools may also be employed to transmit information to FDA based on Program needs[11].

    b. The name and contact information of the FDA staff member responsible for the records request.

       By providing an FDA contact, the establishment may efficiently seek a response to any questions or concerns about the records request.

[11] Foreign Suppliers Verification Programs (FSVP) - Importer Portal for Records Submission | FDA

11. During an RRA with a live or interactive component (i.e., RIE), FDA employees should discuss all observations (both written and verbal) with establishment management as soon as practicable unless there are extenuating circumstances (e.g., data integrity concerns, possible fraud, or misrepresentation of information) that would require additional internal evaluation before discussing with the establishment. This will help maintain communications and to minimize any misunderstandings at the close-out meeting.

12. During an RRA, if the FDA employee conducting the RRA discovers information related to a cross-programmatic commodity (or a commodity that is under the coverage of a different center) that may require programmatic follow-up, the employee will share that information with the relevant center/OII program office.

NOTE: When a party other than FDA conducts oversight activities (e.g., state and foreign regulatory partners), FDA may, as appropriate, conduct RRAs (e.g., livestreaming or records request) during the other party's oversight activities.

E. Providing RRA Observations

1. At the conclusion of an RRA, the FDA employee conducting the RRA will hold a close-out meeting (if appropriate, and as described for section 704(a)(4) requests below) with the top management official at the site or designee. When appropriate, the employee may provide the establishment with a written list of Remote Regulatory Assessment Observations (RRAOs), which may be discussed at this meeting.

NOTE: For RRAs performed under:

- Section 704(a)(4) of the FD&C Act: a written notification that the section 704(a)(4) RRA has concluded will be provided. Close out meetings may also take place based on program-based procedures, concurrently, with the issuance of written notification.

- Section 805(d) of the FD&C Act: observations will be notated on FDA Form 483a.

F. Concluding an RRA

After the RRA is concluded, typically a written RRAR will be generated. Exceptions include section 704(a)(4) assessments as determined by program office or center procedures (e.g., when used "in advance of" assessments) and FSVP (which utilizes the EIR format). The RRAR will be tailored specifically to

each program office, but will comprise the standard headings listed in Attachment C.

NOTE: For section 704(a)(4) assessments which generally do not require an RRAR (per program office or center procedures), Forms FDA 4003/4003a will be utilized and uploaded along with collected records into the appropriate system to ensure intra-agency retrievability by those that need access. If a section 704(a)(4) assessment supports a regulatory action, an RRAR or appropriate internal documentation will be created as referenced above.

G. Post-RRA Communications

1. The process for releasing an RRAR outside of the FDA should follow the process established for releasing Establishment Inspection Reports (EIRs).

2. After an RRA is concluded, any establishment response to a written list of RRAO(s) that FDA receives within 15 U.S. business days generally should be reviewed before FDA considers any additional follow-up action. All responses received will be uploaded to a system as defined per SOPs.

NOTE: For any communications the RRA POC receives from the establishment following the conclusion of the RRA that may require further discussion or follow-up, the RRA POC should relay these communications to the POC's supervisor (and others as appropriate).

The RRAR and subsequent correspondence may be reviewed by other offices, as appropriate, prior to initiating any regulatory action.

H. RRA Classification [12]

The following RRA classifications should be utilized across all programs and commodities, except as noted below:

- rNAI – Remote-No Action Indicated

No RRA observations identified

- rVAI – Remote-Voluntary Action Indicated

RRA observations were identified and documented but based on the nature of the observations and/or the agency's determination the facility can voluntarily

[12] The classifications above do not pertain to onsite or remote (RRA) FSVP inspections under section 805(d). FSVP will continue to use OAI, VAI, and NAI per standard practice.

correct its deficiencies, the agency is not recommending at this time: (1) an administrative or judicial action; or (2) an advisory action [13].

- rOAI – Remote-Official Action Indicated

RRA observations were identified and documented that warrant consideration for advisory, administrative, or judicial action; and/or failure to respond to a request for records or other information under section 704(a)(4).

- rU –Remote-Unclassified

RRA is not classified due to one or more reasons (e.g., in "advance of" inspection, establishment terminates voluntary assessment, or inability to determine regulatory compliance)

I. RRA Closure for non-FSVP RRAs

1. RRARs eligible for release to the establishment (and under FOIA) will follow agency standard requirements with a dedicated process established for release outside of the agency.

2. Generally, the office (OII program office or center) that classifies the RRA is responsible for the RRAR and RRA Closure Letter. Due to programmatic variations and assignments, refer to current agency procedures and MOUs (which address reorganization responsibility changes) to determine the lead office for releasing the RRA Closure letter and the narrative portion of the RRAR.

3. The RRA Closure Letter will be sent to the establishment's top management official at the site or designee at the establishment within 45 calendar days following the determination that the RRA is closed (see 21 CFR 20.64(d)(3)). If an inspection is initiated following the conclusion of an RRA but prior to the RRA being deemed "closed", then both the RRA findings and inspectional findings will be evaluated together. In these cases, the RRA closure letter and narrative portion of the RRA will generally be transmitted 45 calendar days after both the inspection and RRA are deemed "closed" (see 21 CFR 20.64(d)(3)). Copies may be sent to other company officials at the discretion of the operational unit that conducted the RRA.

NOTE:

- Due to required statutory FOIA timeframes, in rare instances, after the RRA is closed, third party release may occur before the establishment has received a copy of the RRAR.

[13] In certain cases, an untitled letter or regulatory meeting may be applicable to either an rOAI or rVAI for certain program areas with justification documented.

- Only a copy of the narrative portion of the RRA report will be included with the RRA Closure letter.

J. <u>Release of RRA Report</u>

1. For First-party Release:

   The narrative portion of the RRAR, if prepared, is provided to the establishment by the OII program office or center responsible for release (see Attachment D). Non-public information to which the establishment does not have access may need to be redacted (see 21 CFR 20.101(b)).

2. For Third party Release:

   Generally, following release of the narrative portion of the RRAR to the first party (i.e., establishment) the narrative portion of the RRAR may be publicly disclosed to any member of the public through the FOIA process (see 21 CFR 20.101(a)) or through authorized proactive public release to a FOIA Reading Room. All non-public information is redacted, as appropriate prior to public release.

7. Glossary/Definitions

To gain a common understanding of terminology used to describe the FDA RRA process, the following terms are used throughout this SMG:

A. **Remote Regulatory Assessment (RRA**): 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 (Attachment A).

B. **704(a)(4) Assessment:** A mandatory RRA that is authorized under section 704(a)(4) of the FD&C Act. This mandatory RRA consists of requesting (and assessing) records and other information in lieu of or in advance of inspections of establishments engaged in the manufacture, preparation, propagation, compounding, or processing of human or animal drugs[14], medical devices, or BIMO establishments. Section 704(a)(4) assessments enable the FDA to evaluate a facility's conformance with facility information included in applications and other submissions and their compliance with applicable FD&C Act requirements, through a review of records and other information provided to FDA by a responsible agent of the facility.

C. **Remote FSVP Inspection:** Foreign Supplier Verification Programs (FSVP) RRAs are authorized by law in accordance with section 805(d) of the FD&C Act

[14] Including human biological products regulated as drugs under the FD&C Act

and 21 CFR part 1 subpart L, and function as inspections in that they enable the FDA to evaluate an importer's compliance through a remote review of records and correspondence with an importer. Remote FSVP Inspections are mandatory RRAs. For FSVP RRAs, FDA issues a Form FDA 482d, Request for FSVP Records, and a Form FDA 483a, FSVP Observations, if observations are found.

D. **Remote Interactive Evaluation (RIE)**: Voluntary RRAs that include interactive assessments and may also include virtual tools such as teleconferences, screen-sharing, or live streamed video. See, e.g., Guidance for Industry: "Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities".[15]

E. **Remote Regulatory Assessment Observations (RRAO**): Conditions or practices observed that, in the judgment of the FDA employee(s) conducting the RRA, indicate a potential violation of applicable FDA requirements.

F. **Remote Regulatory Assessment Report (RRAR):** A report consisting of a narrative and supporting documents that communicates the summary of information reviewed, conditions and practices found, and the observations identified (Attachment C).

G. **RRA Conclusion:** The point at which the RRA POC has completed interactions with the establishment, holds a close-out meeting with establishment management, or designee, and, when appropriate, issues written RRAOs to the establishment's top management official onsite.

NOTE: For RRAs performed under:

- Section 704(a)(4) of the FD&C Act: a formal notification may be provided instead of a meeting
- Section 805(d) of the FD&C Act: Observations will be notated on Form FDA 483a

J. **RRA Closure:** The point at which the RRA has concluded, the RRAR has been reviewed and finalized, and any regulatory decision or action has been completed or a decision has been made not to take an action (see 21 CFR 20.64 (d)(3)).

K. **RRA Closure Letter:** A correspondence sent to the establishment subject to the RRA (similar to a Field Management Directive (FMD) 145 cover letter), which states that the Agency has determined the RRA is closed and the Agency is

[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manufacturing-and-bioresearch-monitoring-facilities

providing the narrative portion of the RRAR to the assessed establishment (if applicable).

8. Records

The RRA Lead Center or Office will be responsible for maintaining the requests for records made, the firm's responses, and the record receipt. All records associated with the record request (including memos, forms, exhibits, reports, and correspondence between FDA and the establishment[16]) should be uploaded into the appropriate FDA repository information system. Centers and appropriate OII program offices will work together to develop SOPs so that RRA workflows, associated data and documents are entered in the same system and are retrievable by those that need access. Each program is responsible for defining how the records are stored and accessed.

9. Effective Date

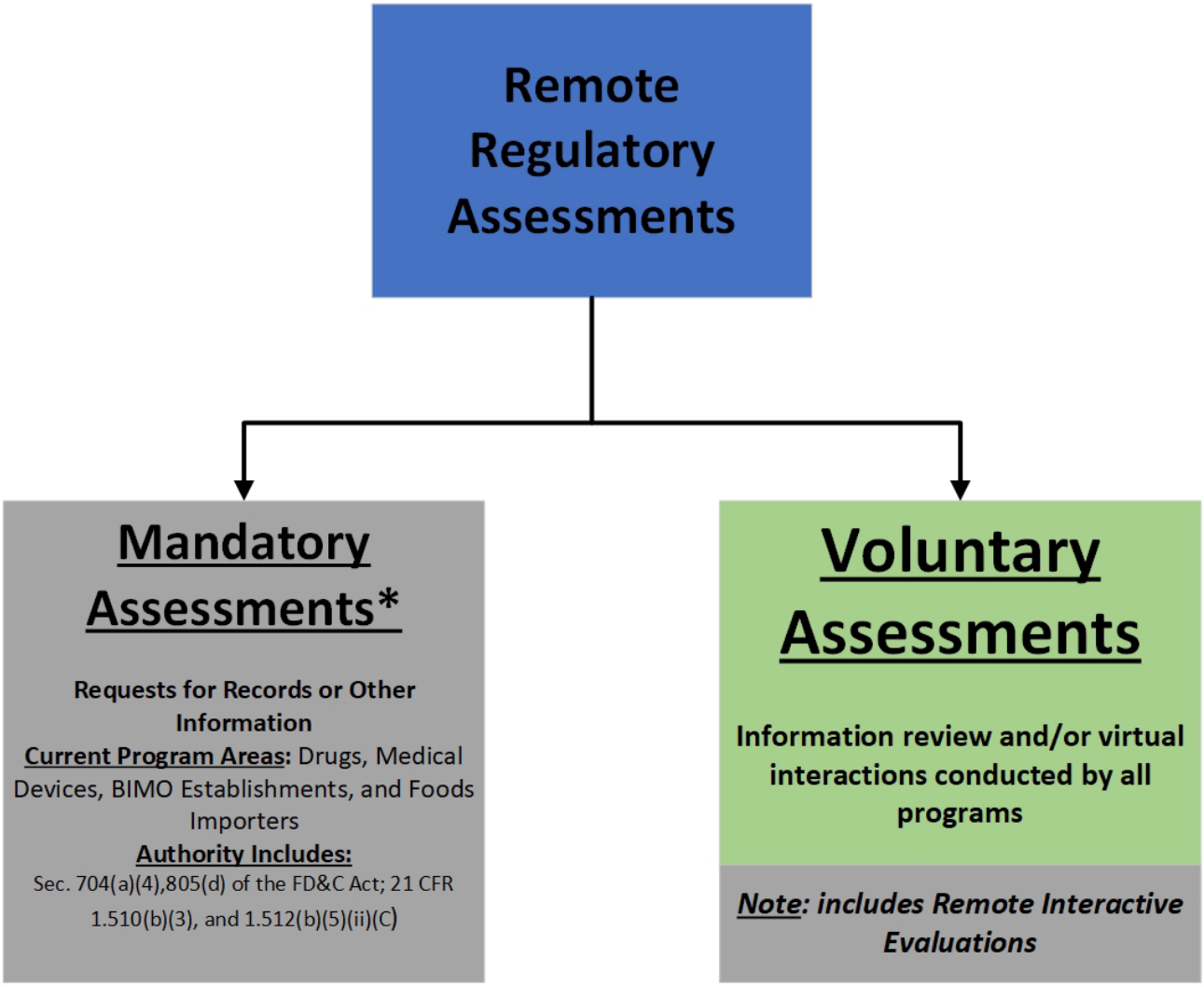
The effective date of this guide is 01/31/2025. With respect to RRA procedures specific to the use of section 704(a)(4)of the FD&C Act, this SMG replaces SMG 9004.1 (Aug. 2017).

10. Document History - SMG 6001.1, "FDA Remote Regulatory Assessment Standard Practices"

Status (I, R, C)	Approval Date	Location of Change History	Contact	Approving Official
Initial	10/18/2022	N/A	ACRA, ORA (FIAC Chair)	Judy McMeekin, ACRA, ORA (FIAC Chair)
Revision	1/17/2024	N/A	ACRA, ORA	Michael Rogers, ACRA, ORA

[16] See IOM Sections 5.1.1.5 and 5.1.1.6

Attachment A - Remote Regulatory Assessments Visual



*While mandatory RRAs that are conducted under certain authorities involve activities detailed by such authority, an establishment could agree to participate in activities beyond what is required.

Attachment B- RRA Introductory Letter Template

1) Date:

(proposed date-optional for programs)

2) Legal Name and Address of the Establishment

3) Name and Contact Information (phone, email address, etc.) of Corresponding FDA POC

NOTE: if additional authentication is necessary (HHS Employee Directory (psc.gov))

4) Purpose of the RRA

(Note: include the purpose of the RRA and clearly identify the product and process being reviewed and identify why the RRA is being conducted (e.g., verify information to support application review, conducting as a follow-up, etc.))

5) For section 704(a)(4) RRAs:

> Include the following statement:
> Under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)(4)], FDA requests that you provide the records described in the attached Form FDA 4003. If the records requested do not exist, please state that fact in your response.
>
> Per section 704(a)(4), you are required to provide these records in response to FDA's request. These records may be requested and used in advance of or in lieu of inspection. For additional questions, please see "RRA Guidance for Industry: "Conducting Remote Regulatory Assessments".[17]

6) General Description of RRA Process with Identification of Specific Statutory or Regulatory Authority or Voluntary Nature, as Applicable[17]

[17] When final, the RRA Guidance for Industry: "Conducting Remote Regulatory Assessments" will represent FDA's current thinking on the topic. For most recent version, see https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

Attachment C- RRA Report Template

- Dates of RRA:
- FEI:
- Establishment Information:
  - Name
  - Address
  - Phone
  - Email Address
- FDA Employees:
- Summary of Assessment
- Persons Interviewed and Individual Responsibility
- Information Reviewed during RRA
  - Listing of records or other information. Include name of record or description of information and specific type of record or information if needed for clarification so that anyone who follows-up can see what specifically was reviewed.
- Products and Processes Assessed
- RRAOs and Management Response/General Discussion with Management
- Attachments
  - Copy of signed introductory RRA letter and establishment's written response (s) to such letter
  - RRAOs (if applicable)
  - Any additional information as requested by assignment
- Documents Reviewed