

1 **Conducting Remote Regulatory** 2 **Assessments**

3 **Questions and Answers**

4 **Draft Guidance for Industry**

5 **This draft guidance document is for comment purposes only.**

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9 comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630
10 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the
11 docket number FDA-2022-D-0810.

12 For questions or information regarding this guidance, contact the Office of Regulatory Affairs
13 (ORA), Office of Policy, Compliance, and Enforcement (OPCE), Food and Drug
14 Administration at ORAPolicyStaffs@fda.hhs.gov.

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16 **Food and Drug Administration**
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26 **January 2024**

27 **Conducting Remote Regulatory**
28 **Assessments**

29 **Questions and Answers**

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34 *Administration 12420 Parklawn Drive, Element Building, Rockville, MD 20857*

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Conducting Remote Regulatory Assessments

Questions and Answers Guidance for Industry¹

This draft guidance, when finalized, represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 Such activities, along with others identified in this draft guidance, are considered RRAs for purposes of this guidance. In the presence of travel restrictions during the COVID-19 pandemic, FDA utilized RRAs to assess establishments and their compliance with applicable FDA requirements. Based on

¹ This draft guidance has been prepared by the Office of Regulatory Affairs in cooperation with the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Food Safety and Applied Nutrition, the Center for Tobacco Products, the Center for Devices and Radiological Health, the Center for Veterinary Medicine, the Office of Food Policy and Response, 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 most recent 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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87 this experience,³ FDA has noted the value of RRAs and concluded that they should be used for certain
88 scenarios outside the COVID-19 pandemic and for all types of FDA-regulated products.⁴ FDA has
89 developed this guidance to provide answers to frequently asked questions related to RRAs. When
90 finalized, this guidance is intended to help enhance industry’s understanding of RRAs, thereby facilitating
91 FDA’s process for conducting RRAs.

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

95 FDA’s guidance documents, including this draft guidance, do not establish legally enforceable
96 responsibilities. Instead, guidance documents describe our current thinking on a topic and should be
97 viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use
98 of the word *should* in Agency guidance means that something is suggested or recommended, but not
99 required.

100 **II. Background**

101 FDA uses a variety of tools⁵ for oversight of FDA-regulated products and establishments. During the
102 COVID-19 pandemic, FDA used RRAs to help the Agency conduct oversight, mitigate risk, and meet
103 critical public health needs with respect to certain FDA-regulated products. RRAs have included: (1)
104 mandatory RRAs involving review of records or other information submitted by certain establishments
105 upon request from FDA under section 704(a)(4) of the FD&C Act and review of records from food
106 establishments subject to FD&C Act section 805⁶ (the latter hereinafter referred to as “requests for
107 Foreign Supplier Verification Program (FSVP) records under 21 CFR 1.510(b)(3) or 1.512(b)(5)(ii)(C)”);
108 and (2) voluntary RRAs involving remote requests for records and/or interactive evaluations (such as
109 remote livestreaming video of operations, teleconferences, and screen sharing).

110 FDA’s experiences have identified significant benefits in using RRAs. For instance, RRAs have assisted
111 FDA in verifying corrective actions taken in response to inspections of previously compliant

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.

⁴ See, e.g., question A.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).

⁶ 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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112 manufacturers⁷ and in gaining compliance insight when it was not practicable to inspect. RRAs have also
113 provided information about deficient practices, leading FDA to take regulatory actions and/or conduct
114 inspections, as well as informing future inspection planning. RRAs were used to help support review and
115 promote timely approval or authorization of marketing submissions for FDA-regulated products. In the
116 food program, RRAs have assisted in determining compliance with veterinary feed directive regulations,
117 assessing foreign manufacturing process records, adding foreign establishments to import alerts, and
118 issuance of warning letters.

119 Based on these experiences, FDA has determined that RRAs are valuable and, therefore, under certain
120 circumstances, should be continued to assist FDA in its mission to protect public health, oversee regulated
121 industry, and ensure all types of regulated products comply with FDA requirements.

122 With respect to section 704(a)(4), this provision of the FD&C Act, including as recently amended by the
123 Food and Drug Omnibus Reform Act of 2022 (FDORA),⁸ gives FDA authority to request (and requires
124 establishments to provide) any records or other information that FDA may inspect under section 704 of
125 the FD&C Act, in advance of or in lieu of inspections of such establishments that engage in the
126 manufacture, preparation, propagation, compounding, or processing of a drug or device,⁹ or a site or
127 facility that is subject to inspection under section 704(a)(5)(C) (i.e., sites, entities, or facilities subject to
128 bioresearch monitoring (BIMO) inspections).

129 The Agency believes that FDA’s use of both mandatory and voluntary RRAs, as applicable, for all types
130 of FDA-regulated products is in the interest of the public health, and the Agency is issuing this guidance
131 to provide further transparency to stakeholders about the circumstances in which mandatory and
132 voluntary RRAs may be used.

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

⁷ 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 an RRA is appropriate.

⁸ 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) added device and bioresearch monitoring establishments 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)).

⁹ The terms “drug” and “device” are defined at FD&C Act sections 201(g)(1) and (h), 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.

136 **III. Questions and Answers**

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

139 **A. Remote Regulatory Assessment Fundamentals**

140 *1. What is an RRA?*

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

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

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

156 *2. Who may be subject to an RRA?*

157 • *Mandatory RRAs*

158 Mandatory RRAs include those conducted for: (1) establishments that are subject to section 704(a)(4) of
159 the FD&C Act¹⁰; and (2) importers, as defined in 21 CFR 1.500, that are subject to FSVP under section
160 805(d) of the FD&C Act and implementing regulations in 21 CFR 1.510(b)(3) or 1.512(b)(5)(ii)(C), as
161 applicable.¹¹

¹⁰ As described above, section 704(a)(4)’s mandatory records request authority applies to drug and device establishments and to sites, entities, or facilities subject to BIMO inspections. See footnote 8 for information on recent amendments that made device establishments and BIMO sites, entities, and facilities subject to mandatory records request authority under section 704(a)(4) of the FD&C Act.

¹¹ As discussed above, RRAs have included these mandatory remote requests for records or other information. Although they are discussed in this draft guidance in response to certain frequently asked questions, RRAs conducted under section 704(a)(4) or under FSVP are not necessarily the only types of mandatory RRAs for which FDA has authority.

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

164 • *Voluntary RRAs*

165 If an RRA is not mandated by statute or regulation (or FDA opts against exercising its mandatory RRA
166 authority in a certain instance), FDA may request that any establishment (e.g., food producers, tobacco
167 product manufacturers, drug or medical device manufacturers^{12,13}, clinical investigators, or others)
168 participate in a voluntary RRA.

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

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

178 4. *Is an RRA an inspection?*

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

184 However, because remote requests for FSVP records are under the authority of section 805(d) of the
185 FD&C Act and FDA’s implementing regulation, these record requests function as inspections in that FDA
186 uses these records requests to evaluate a food importer’s compliance with FSVP.

¹² In this draft guidance, references to drug and device manufacturers 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.

¹³ By virtue of applying to both drug and device establishments, section 704(a)(4) of the FD&C Act also applies to establishments that manufacture, prepare, propagate, compound, or process combination products (see section 503(g)(1)(C) of the FD&C Act) and the drug and device constituent part(s) (defined under 21 CFR Part 4) of such combination products. Establishments that engage in the manufacture, preparation, propagation, compounding, or processing of combination products that are not subject to the authorities under section 704(a)(4) of the FD&C Act may voluntarily participate in an RRA.

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

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

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

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

- 191 • When FDA cannot conduct an inspection due to travel limitations brought on by public health
192 emergencies, natural disasters, or other situations making travel infeasible.
- 193 • When FDA determines that an RRA will assist us in conducting elements of establishment
194 oversight or support regulatory decisions. Examples include preparing for an already planned
195 inspection, following up on a consumer complaint, assisting in verifying that an
196 establishment has completed certain corrective actions (e.g., in response to a previous
197 inspection, or previous RRA), or supporting the review of a marketing submission.

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

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

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

207 No, FDA does not plan to conduct RRAs and inspections¹⁶ of an establishment under sections 704(a)(1)
208 or 704(a)(5) of the FD&C Act simultaneously. An RRA is conducted remotely by FDA staff without
209 FDA staff present at an establishment conducting an inspection. However, an RRA could precede,
210 prompt, or be a follow-up to, an inspection. When an RRA precedes an inspection, FDA will generally
211 conclude the RRA prior to initiating the inspection. FDA may combine any information gained from the
212 RRA with any resulting observations from the subsequent inspection. In such circumstance, FDA would
213 confirm any observations from the RRA during the subsequent inspection before including them on any
214 Form FDA 483 Inspectional Observations issued at the conclusion of the subsequent inspection.

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

217 FDA may decide to conduct an RRA (e.g., livestreaming) during oversight activities independently
218 conducted by state or foreign regulatory partners.¹⁷

¹⁶ FDA considers inspections that are done with state officers or employees duly commissioned under 702(a)(1)(A) of the FD&C Act to be FDA inspections for the purposes of this draft guidance.

¹⁷ Generally, FDA does not intend to conduct RRAs during Medical Device Single Audit Program (MDSAP) audits.

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219 7. *What are the benefits of an RRA?*

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

- 222 • Allowing FDA to remotely evaluate compliance of FDA-regulated products, clinical studies,
223 and establishments, as appropriate. This may identify issues that lead establishments to
224 promptly make corrective actions, which may enhance the establishment’s preparedness for
225 their next FDA inspection.
- 226 • Having an RRA precede an inspection under section 704(a) of the FD&C Act could reduce
227 resource expenditure. For example, FDA may not need to review as many records during the
228 inspection, reducing the time FDA is present at the establishment.
- 229 • Helping to support timely regulatory decisions (including the approval of an application or
230 authorization for emergency use), without an inspection, when appropriate conditions are
231 fulfilled, such as the ability to verify information in the marketing submission. In such cases,
232 the application approval, or the authorization, must still meet applicable standards.
- 233 • Providing FDA additional information to incorporate into a risk-based inspection schedule,
234 thereby helping FDA use inspectional resources more efficiently and effectively.
- 235 • Assisting FDA in verifying corrective actions.¹⁸

236 **B. Remote Regulatory Assessment Expectations**

237 8. *How may FDA request an RRA?*

238 FDA may use multiple processes for requesting voluntary or initiating mandatory RRAs.¹⁹

- 239 • *In general, for Voluntary RRAs*
 - 240 ○ FDA expects to contact an establishment through the establishment’s point of
241 contact,²⁰ by email or phone, once we determine an RRA is appropriate based on
242 FDA mission needs.

¹⁸ See footnotes 2 and 7.

¹⁹ When finalized, this draft guidance will represent the Agency’s current thinking on how RRAs apply generally to all FDA-regulated products. Other Agency documents may exist that provide additional information about RRAs with respect to specific circumstances. See, e.g., FDA Staff Manual Guide 9004.1, Policy and Procedures for Requesting Records in Advance of or in Lieu of a Drug Inspection; 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.

²⁰ 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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- 243 ○ FDA may use the establishment’s registration, establishment information provided in
244 a marketing submission, or additional information available to FDA, to identify the
245 point of contact, authorized official, or U.S. agent.
- 246 ○ FDA will obtain the establishment’s consent to the RRA before we begin the RRA.
247 Where practicable, FDA generally intends to seek to obtain such consent in writing.
248 This typically includes:
- 249 ▪ notifying the establishment’s point of contact of the purpose and planned
250 scope of the RRA and of the right to refuse consent; and
- 251 ▪ requesting that such person confirm the establishment voluntarily consents
252 and has the ability to participate in the voluntary RRA requested.
- 253 ○ If the establishment consents to the voluntary RRA, FDA will typically provide an
254 opportunity to discuss, as applicable and appropriate:
- 255 ▪ FDA’s expectations for, and any establishment limitations in participating in,
256 the RRA.
- 257 ▪ The scheduling of virtual interviews and meetings.
- 258 ▪ Technological capabilities.²¹
- 259 ▪ The process and timeline for requesting records or other information for
260 review.
- 261 ▪ How and when FDA will provide feedback to the establishment.
- 262 ▪ Any questions relating to the process or other aspects of the RRA.
- 263 • *In general, for Mandatory RRAs*
- 264 ○ FDA will initiate the request in accordance with the relevant legal authority and
265 intends to follow any established procedures.
- 266 ▪ For example, for purposes of section 704(a)(4) of the FD&C Act, FDA will
267 use Form FDA 4003 (for drug establishments) or a similar method for other
268 establishments subject to section 704(a)(4) to request records or other
269 information.²² When making a section 704(a)(4) request, FDA will, under
270 this statutory authority, provide a sufficient description of the records or
271 other information requested, as well as our rationale for requesting such
272 records or other information in advance of, or in lieu of, an inspection.²³

²¹ Any technical requirements, 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.

²² The point of contact listed in the registration may be used as the point of contact. For pre-approval and pre-licensing inspections, there may be situations when 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 all of the products in the applications being assessed.

²³ See section 704(a)(4)(A) of the FD&C Act, as amended by FDORA.

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

301 • *Voluntary RRAs*

302 Because of the voluntary nature of these assessments, declining to participate in a voluntary RRA will not
303 result in any enforcement action by the Agency based on the declination.²⁷ FDA may consider other
304 activities necessary to exercise our oversight responsibilities regarding that establishment, such as an
305 inspection, based on considerations such as when the establishment was last inspected, our assessment of
306 risks, and other relevant factors. An establishment may decline to participate in a voluntary RRA, but an
307 establishment may not opt out of an FDA inspection.

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

315 • *Mandatory RRAs*

316 FDA may deem the following actions, among others, as declining to participate in a mandatory RRA:
317 failing to respond, withdrawing participation, and refusing to provide records upon a lawful request.
318 There are consequences for declining mandatory RRAs. For example, an establishment that refuses a
319 request for records or other information under section 704(a)(4) of the FD&C Act may be in violation of
320 the FD&C Act.²⁸

321 Similarly, if an importer refuses FDA’s written request for FSVP records under 21 CFR 1.510(b)(3) or
322 1.512(b)(5)(ii)(C), the importer may be in violation of section 805 of the FD&C Act, and the food offered
323 for import by the importer may be subject to refusal under section 801(a)(3) of the FD&C Act.²⁹

324 FDA intends to take appropriate action against persons³⁰ and products that are in violation of the FD&C
325 Act.

326 11. *Are there any technological expectations for an RRA?*

327 The technological expectations will vary depending on the type of RRA and its scope. Certain RRAs
328 involve records requests, and the records may be submitted electronically or through other means. Other
329 RRAs may require additional technological capability. For example, if FDA expects that the RRA could
330 include the use of live streaming video, FDA may inquire about hardware or internet connectivity to
331 assess IT operability, security, and privacy controls to protect the confidentiality of the data. The quality

²⁷ This would not be considered a refusal for purposes of section 301(e) or (f), or 807, of the FD&C Act.

²⁸ See e.g., section 301(e) of the FD&C Act (Prohibited Acts).

²⁹ 21 CFR 1.514(a).

³⁰ See section 201(e) of the FD&C Act (Definitions).

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332 of the remote connection (e.g., connectivity, image quality, cameras used) should be adequate for FDA to
333 review, observe, examine, and evaluate the requested records, documents, and other information
334 (including electronic systems). To the extent practicable, technologies employed should also allow access
335 for remotely viewing and evaluating operations at the establishment, as appropriate (e.g., aseptic
336 practices, equipment cleaning and set up, material weighing and dispensing, instrument set up, sampling,
337 and testing).

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

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

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

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

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

350 In the case of mandatory RRAs, the records or other information we request, and the circumstances under
351 which we request them, will conform to the relevant legal authority. For example, under section
352 704(a)(4) of the FD&C Act, FDA may request any records or other information subject to inspection
353 under section 704. For mandatory RRAs under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C), FDA may
354 request any and all records that are required to be maintained under 21 CFR 1, Subpart L.

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

- 357 • Records of specific production lots or batches as well as product-specific information, such as
358 periodic product reviews,³¹ product quality reports, equipment records, process validation
359 records and reports, test results, records of product postmarket defects or other information
360 related to compliance with Current Good Manufacturing Practice requirements.
- 361 • Certain summaries or lists of records, such as a summary of batches manufactured and their
362 disposition, or a summary of discrepancies and investigations related to manufacturing and
363 testing.

³¹ See 21 CFR 211.180(e).

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- 364 • Read-only access to electronic databases³² or a request that an establishment walk us through
365 information in their database or provide data queries or summary data generated by the
366 establishment from their databases.
- 367 • Standard Operating Procedures and records generated by the establishment to document
368 control of quality systems and/or to demonstrate compliance with the applicable FDA
369 requirements.
- 370 • For FSVP importers, records related to hazard analysis, the importer’s determination of
371 appropriate supplier verification activities, performance of supplier verification activities,
372 and/or corrective actions.
- 373 • For establishments subject to BIMO inspection, records or data related to the reporting or
374 conduct of FDA-regulated research.

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

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

380 Depending on the scope of the RRA, the information and documentation may be used by FDA for, among
381 other things,³³ the following regulatory purposes:

- 382 • Support FDA’s assessment of pending marketing submissions, including whether to approve
383 an application or whether to issue a response, such as a complete response letter.³⁴
- 384 • Determine whether an establishment or product is or is not in compliance with certain FD&C
385 Act or PHS Act requirements, and other applicable requirements.
- 386 • Facilitate assessment of the need for an inspection in follow-up to a reported concern or
387 defect.
- 388 • Support actions such as a regulatory meeting, warning letter, import action, recall activity, or
389 other advisory action, or to support an administrative or judicial action.
- 390 • Determine the priority of establishments for inspection, particularly a surveillance inspection.

³² See FDA Investigations Operations Manual (IOM) 5.10.2.1.

³³ See, e.g., section 704(a)(4)(C) of the FD&C Act, as added by FDORA.

³⁴ 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 agency 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.

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

393 For mandatory RRAs, FDA will request that records and other information be submitted within a
394 timeframe consistent with the relevant legal authority.³⁵ For voluntary RRAs, FDA may suggest
395 timeframes to ensure the RRA is completed in a reasonable amount of time and expects establishments to
396 work diligently to provide the requested records and other information.

397 The circumstances that relate to FDA’s expectations for reasonable request timeframes may include:

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

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

406 Except as provided below, requested records or other information generally should be submitted in an
407 electronic format. FDA intends to provide a secure means to send requested records and information. For
408 electronic documents, establishments should identify any limitations on external access and ensure that
409 encrypted and password-protected files can be accessed by FDA. FDA will follow applicable federal law
410 governing the confidentiality of records and information submitted to the Agency (see, e.g., 5 U.S.C.
411 552(b)(4), 18 U.S.C. 1905, 21 C.F.R. Part 20).

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

³⁵ 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). See also FDA’s Staff Manual Guide, 9004.1, Policy and Procedures for Requesting Records in Advance of or in lieu of a Drug Inspection for more information on timeframes. 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>.

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417 FDA may request that records and other information be in English or accompanied by an English
418 translation.³⁶ If translated, the translation should be complete and accurate, and, when applicable, should
419 include the name, address, and a brief statement of the qualifications of the translator. Copies of the
420 original records and information should also be included in the response, where appropriate. For certain
421 RRAs, if a verified translation is not immediately available, FDA may request that the initial translation
422 be followed up with a verified translation as soon as practicable.

423 If the records or other information are provided as part of a section 704(a)(4) request, the records and
424 information may be submitted in either electronic or physical form. FDA will provide confirmation upon
425 receipt of the records.³⁷ In general, FDA intends to maintain open communications to discuss any records
426 received over the course of the RRA.

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

429 **D. Completion of a Remote Regulatory Assessment**

430 *16. What may occur upon completion of an RRA?*

431 Upon completion of an RRA, FDA may have a closeout meeting³⁸ with the establishment's management.
432 At the closeout meeting, FDA may present a written list of RRA observations, if any, and describe and
433 discuss such observations in sufficient detail to enable understanding and foster an appropriate response.
434 For purposes of this guidance, RRA observations are defined as conditions and/or practices observed
435 during the RRA that indicate, in the judgment of the FDA employee(s) conducting the RRA, a potential
436 violation of the laws enforced by FDA. FDA does not intend to issue a Form FDA 483, Inspectional
437 Observations, for an RRA.³⁹ (See question 6 for a discussion of how observations from an RRA may be
438 confirmed during an inspection and included on a Form 483).

439 An establishment should be aware that a written list of observations may be subject to a request under the
440 Freedom of Information Act at the time the disclosure to the establishment is first made (see 21 CFR
441 20.101(a)) and may be made publicly available, with applicable redaction of information that is exempt
442 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),
443 and 387f(c), and 21 C.F.R. Part 20).

444 FDA encourages establishments to respond during the meeting, and/or provide written responses to the
445 observations within fifteen (15) U.S. business days. Responses or corrective actions submitted to FDA
446 during that timeframe in response to the issues identified during the RRA generally will be considered

³⁶ 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).

³⁷ Section 704(a)(4)(B) of the FD&C Act.

³⁸ 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.

³⁹ 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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447 before further Agency action or decision. Establishment responses are available for public disclosure as
448 described in 21 CFR 20.103 with redaction of non-public information, as appropriate.

449 FDA’s written list of RRA observations is not a final Agency action or decision. However, evidence
450 collected in the course of an RRA may be used in support of such actions or decisions.

451 Following an RRA, FDA may conduct an inspection. FDA may consider other actions, as appropriate,
452 including an enforcement action.

453 As part of the RRA process, FDA intends to ordinarily prepare a report consisting of a narrative and
454 supporting documents that communicates the summary of information reviewed, conditions and practices
455 found, and the observations identified. FDA generally expects to provide a written copy of the narrative
456 portion of the RRA report⁴⁰ to the establishment, following the determination that the RRA is closed (see
457 21 CFR 20.64(d)(3)). At that time, the report and supporting documents, with any applicable redactions,
458 also become available for public disclosure upon request.

⁴⁰ There may be some instances where 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).