

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

## 3 **Questions and Answers**

### 4 **Draft Guidance for Industry**

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6 **This draft guidance document is for comment purposes only.**

7  
8 Comments and suggestions regarding this draft document should be submitted within 60 days of  
9 publication in the Federal Register of the notice announcing the availability of the draft  
10 guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written  
11 comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630  
12 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the  
13 docket number FDA-2022-D-0810.

14 For questions or information regarding this guidance, contact the Office of Regulatory Affairs  
15 (ORA), Office of Strategic Planning and Operational Policy (OSPOP), Food and Drug  
16 Administration at [ORAPolicyStaffs@fda.hhs.gov](mailto:ORAPolicyStaffs@fda.hhs.gov).

17  
18 **U.S. Department of Health and Human Services**  
19 **Food and Drug Administration**  
20 **Office of Regulatory Affairs**  
21 **Office of Food Policy and Response**  
22 **Office of Combination Products**  
23 **Center for Biologics Evaluation and Research**  
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25 **Center for Devices and Radiological Health**  
26 **Center for Food Safety and Applied Nutrition**  
27 **Center for Tobacco Products**  
28 **Center for Veterinary Medicine**

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30 **July 2022**

31 **Conducting Remote Regulatory**  
32 **Assessments**

33 **Questions and Answers**

34 **Draft Guidance for Industry**

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36 **This draft guidance document is for comment purposes only.**

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41  
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55		<b>Table of Contents</b>	
56	<b>I. Introduction</b>	.....	3
57	<b>II. Background</b>	.....	4
58	<b>III. Questions and Answers</b>	.....	5
59	<b>A. Remote Regulatory Assessment Fundamentals</b>	.....	6
60	1. <i>What is an RRA?</i>	.....	6
61	2. <i>Who may be subject to an RRA?</i>	.....	6
62	3. <i>Are RRAs replacing other established means of obtaining information outside of inspections?</i>	.....	7
63	4. <i>Is an RRA an inspection?</i>	.....	7
64	5. <i>When may FDA initiate or request to conduct an RRA?</i>	.....	7
65	6. <i>Will FDA use RRAs during or as part of an FDA inspection of an establishment?</i>	.....	8
66	7. <i>What are the benefits of an RRA?</i>	.....	8
67	<b>B. Remote Regulatory Assessment Expectations</b>	.....	9
68	8. <i>How may FDA request an RRA?</i>	.....	9
69	9. <i>What might an establishment expect to happen during an RRA?</i>	.....	10
70	10. <i>Are there any consequences for declining to participate in an RRA?</i>	.....	11
71	<b>C. Requests for Records or Other Information as Part of Remote Regulatory Assessments</b>	.....	12
72	12. <i>What records or other information may FDA request as part of an RRA?</i>	.....	12
73	13. <i>For what purposes may FDA use the records and other information gathered during an RRA?</i>	..	13
74	14. <i>If the RRA requests records, what is the timeframe for submitting the records to FDA?</i>	.....	14
75	15. <i>How should records or other information in response to an RRA request be provided to FDA?</i>	..	14
76	<b>D. Completion of a Remote Regulatory Assessment</b>	.....	15
77	16. <i>What may occur upon completion of an RRA?</i>	.....	15
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80 **Conducting Remote**  
81 **Regulatory Assessments**  
82 **Questions and Answers**

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83  
84 **Guidance for Industry<sup>1</sup>**

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 listed on the title page.

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86  
87 **I. Introduction**

88  
89 In response to the Coronavirus Disease 2019 (COVID-19) pandemic, FDA adapted its operations for field  
90 activities to provide oversight of regulated industry while mitigating the spread of COVID-19. One set of  
91 tools used during the pandemic for oversight of FDA-regulated products has been remote regulatory  
92 assessments (RRAs), as further described in this guidance. The term “RRA” (as defined in the Question  
93 and Answers section) is used to describe a category of activities for which FDA may use different  
94 terminologies, but that are all considered to be *types* of RRAs, including “remote interactive evaluations,”<sup>2</sup>

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<sup>1</sup> This 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, and the Center for Veterinary Medicine at the Food and Drug Administration.

<sup>2</sup> See Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency, Guidance for Industry, April 2021. 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>. See also ORA’s RRA Fact Sheet: ORA’s Office of Medical Products and Tobacco Operations RRA Activities During Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

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95 and “remote record reviews.” Such activities, along with others identified in this guidance, are considered  
96 RRAs for purposes of this guidance. In the presence of travel restrictions during the COVID-19 pandemic,  
97 FDA utilized certain types of RRAs to assess establishments and their compliance with applicable FDA  
98 requirements. Based on this experience<sup>3</sup>, FDA has noted the value of RRAs and concluded that they  
99 should be used for certain scenarios outside the current pandemic and for all types of FDA-regulated  
100 products.<sup>4</sup> FDA has developed this guidance to provide answers to frequently asked questions related to  
101 RRAs. This guidance is intended to help enhance industry’s understanding of RRAs, thereby facilitating  
102 FDA’s process for conducting remote assessments.

103

104 Throughout this guidance, the terms, “FDA,” “the Agency,” “we,” and “us” refer to the Food and Drug  
105 Administration and the terms “your” and “yours” refer to regulated industry.

106

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

113

## 114 **II. Background**

115

116 FDA uses a variety of tools<sup>5</sup> for oversight of FDA-regulated products and establishments. In this  
117 guidance, the term “establishment” includes any facility, entity, person, importer, or site, whether foreign  
118 or domestic, subject to the laws administered by FDA. During the COVID-19 pandemic, FDA has used  
119 RRAs to help the Agency conduct oversight, mitigate risk, and meet critical public health needs with  
120 respect to certain FDA-regulated products. To date, RRAs have included review of records or other  
121 information submitted upon request from FDA under sections 704(a)(4)<sup>6</sup> and 805<sup>7</sup> (the latter hereinafter  
122 referred to as “requests for Foreign Supplier Verification Program (FSVP) records under 21 CFR

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<sup>3</sup> 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.

<sup>4</sup> See, for example, question A.2. describing to whom voluntary and mandatory RRAs may apply.

<sup>5</sup> See, for example, 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 USC 374].

<sup>6</sup> Section 704(a)(4) of the FD&C Act gives FDA authority to request (and requires establishments to provide) any records or other information that FDA may inspect under section 704(a) of the FD&C Act, in advance of or in lieu of inspections of establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug.

<sup>7</sup> 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 Program (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. FSVP regulations state 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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123 1.510(b)(3) or 1.512(b)(5)(ii)(C)” or similar) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)  
124 (mandatory RRAs); and records assessments and/or interactive evaluations (such as remote livestreaming  
125 video of operations, teleconferences, and screen sharing) conducted pursuant to voluntary participation by  
126 industry (voluntary RRAs).

127  
128 FDA’s experiences so far have identified significant benefits in using RRAs. For instance, RRAs have  
129 assisted FDA in verifying corrective actions taken in response to inspections of previously compliant  
130 manufacturers<sup>8</sup> and in gaining compliance insight when it was not practicable to inspect. RRAs have also  
131 provided information about deficient practices, which led FDA to take regulatory actions, conduct  
132 inspections, and have informed future inspection planning. RRAs have been used to help support, and  
133 reduce delays of, approval or authorization of marketing submissions for FDA-regulated products during  
134 the COVID-19 pandemic. In the food program, they have assisted in determining compliance with  
135 veterinary feed directive regulations, assessing foreign manufacturing process records, adding foreign  
136 firms to import alerts, and with issuance of warning letters.

137  
138 Based on these experiences, FDA has determined that RRAs are valuable and, under certain  
139 circumstances, will continue to assist FDA during and beyond the COVID-19 pandemic, in its mission to  
140 protect public health, oversee regulated industry, and ensure all types of regulated products comply with  
141 FDA requirements.

142  
143 FDA had previously issued guidance<sup>9</sup> regarding the use of voluntary remote interactive evaluations of  
144 certain establishments during the COVID-19 public health emergency; a remote interactive evaluation is a  
145 type of RRA. The Agency believes that FDA’s use of both voluntary and mandatory RRAs, as applicable,  
146 for all types of FDA-regulated products is in the interest of the public health, and the Agency is issuing this  
147 guidance to provide further transparency to stakeholders about the circumstances in which RRAs may be  
148 used both during and beyond the COVID-19 pandemic and promote greater consistency in the way RRAs  
149 are conducted.

150

### 151 **III. Questions and Answers**

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

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<sup>8</sup> In instances where FDA has identified objectionable conditions regarding compliance with Current Good Manufacturing Practice (CGMP) requirements, FDA may determine that a manufacturer is compliant with CGMP based on a voluntary commitment of corrective actions, or, when warranted, FDA may pursue an advisory action (e.g., warning letter or regulatory meeting) or an enforcement action (e.g., seizure or injunction). After an advisory or enforcement action, FDA may conduct an inspection to confirm that corrective actions have been implemented.

<sup>9</sup> Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency, Guidance for Industry, April 2021. This guidance covers remote interactive evaluations for certain drug products under CDER, CBER, and CVM jurisdiction. 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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156 **A. Remote Regulatory Assessment Fundamentals**

157

158 *1. What is an RRA?*

159

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

163

164 RRAs are a tool FDA may use to support regulatory decisions and oversight activities. Currently, requests  
165 for records or other information from drug establishments under section 704(a)(4) of the FD&C Act, and  
166 requests for FSVP records under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C), are RRAs that FDA conducts  
167 for which participation is mandatory (i.e., are not voluntary). RRAs that are not conducted under statutory  
168 or regulatory authority are voluntary in that an establishment can decline to participate or withdraw  
169 participation during the RRA, in which case the Agency would consider other tools for evaluating  
170 compliance with FDA requirements.

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

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

175

176 *• Voluntary RRAs*

177 If an RRA is not mandatory (or FDA opts against exercising its mandatory RRA authority in a certain  
178 instance), FDA may request that any establishment (e.g., food producers, tobacco product manufacturers,  
179 drug<sup>10</sup> or medical device manufacturers, clinical investigators, or others) participate in a voluntary RRA.

180 *• Mandatory RRAs*

181 Mandatory RRAs include the following: Establishments that engage in the manufacture, preparation,  
182 propagation, compounding, or processing of a drug<sup>11,12</sup> are subject to section 704(a)(4) of the FD&C Act.  
183 Under FSVP, importers, as defined at 21 CFR 1.500, are subject to section 805(d) of the FD&C Act and  
184 implementing regulations in 21 CFR 1.510(b)(3) or 1.512(b)(5)(ii)(C), as applicable.

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<sup>10</sup> Drug manufacturers include establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug.

<sup>11</sup> A drug includes human and animal drugs (including drug products produced by facilities registered as human drug compounding outsourcing facilities under section 503B of the FD&C Act), and biological drug products for humans.

<sup>12</sup> Regarding application of this guidance to combination products (defined under 21 CFR Part 3), the opportunity to participate voluntarily in an RRA applies to all combination products that are not subject to the authorities under section 704(a)(4) of the FD&C Act. Elements of the guidance specific to drugs (i.e. a 704(a)(4) request) also apply to drug-led combination products (see section 503(g)(1)(C) of the FD&C Act), including the drug constituent part(s) (defined under 21 CFR Part 4) of such combination products.

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

187  
188 No, RRAs are not intended to limit or replace other established means of obtaining information necessary  
189 for FDA to accomplish its public health mission outside of inspections, including, among other things,  
190 applicant information request letters, registration confirmations, meetings, product submission or  
191 application assessments, or follow-up communications during outbreaks or other emergencies. Similarly,  
192 if, for example, FDA calls an establishment to inform them that a submission or application is missing  
193 certain information, this is not an RRA. Although these activities may be conducted remotely, the Agency  
194 does not consider these RRAs.

195  
196                   4. *Is an RRA an inspection?*

197  
198 Generally, an inspection, such as described in section 704(a)(1) of the FD&C Act, involves duly  
199 designated officers or employees of the FDA physically entering (at reasonable times and in a reasonable  
200 manner), establishments subject to regulation under the FD&C Act to determine compliance with  
201 applicable FDA requirements.<sup>13</sup> For this reason, we do not consider an RRA to satisfy statutory  
202 requirements that specify inspection under section 704 of the FD&C Act (e.g., section 510(h) or 503B(b)  
203 of the FD&C Act).<sup>14</sup>

204  
205 However, remote requests for FSVP records are under the authority of section 805(d) of the FD&C Act  
206 and FDA’s implementing regulation.<sup>15</sup> These record requests function as inspections in that FDA uses  
207 these records requests to evaluate a food importer’s compliance with FSVP.  
208

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

210  
211 FDA may initiate or, in the case of a voluntary RRA, request to conduct an RRA, whenever we determine  
212 an RRA is appropriate to help fulfill the Agency’s regulatory responsibilities and protect human and  
213 animal health. For example:

- 214
- 215           • When FDA cannot conduct an inspection due to travel limitations brought on by pandemics,  
216           natural disasters, or other unstable situations making travel infeasible.
  - 217
  - 218           • When FDA determines that an RRA will assist FDA in conducting elements of establishment  
219           oversight or support regulatory decisions. Examples include preparing for an already planned  
220           inspection, following up on a consumer complaint, assisting in verifying that an establishment has

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<sup>13</sup> See FDA’s, [Investigations Operations Manual](#), Section 2.2.1.1, Authority to Enter and Inspect (2021).

<sup>14</sup> FDA will not issue a Form FDA 482 Notice of Inspection or Form FDA 483, Inspectional Observations during the RRA process.

<sup>15</sup> FSVP records requests that FDA makes at an importer’s place of business are also made under these same legal authorities.

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221 completed certain corrective actions (e.g., in response to a previous inspection, or previous RRA),  
222 or supporting the review of a marketing submission.

223  
224 FDA will use a risk-based approach to determine whether to initiate or request an RRA. Factors that may  
225 be considered include, but are not limited to, firm location, inspection history, complexity of product and  
226 process, and travel restrictions. Programs and centers within FDA may assess risk differently based on the  
227 product.

228  
229 The above examples are illustrative, and the ultimate decision to initiate or request an RRA rests with FDA  
230 as FDA retains discretion to deploy RRAs as appropriate. At this time, we do not accept requests for FDA  
231 to perform an RRA.

232

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

235

236 No, at this time, FDA does not plan to conduct RRAs and inspections<sup>16</sup> of an establishment  
237 simultaneously. An RRA is conducted remotely by FDA staff without FDA staff present at an  
238 establishment conducting an inspection. However, an RRA could precede, prompt, or be a follow-up to, an  
239 inspection. When an RRA precedes an inspection, FDA will generally conclude the RRA prior to initiating  
240 the inspection. FDA may combine any information gained from the RRA with any resulting observations  
241 from the subsequent inspection. In such circumstance, FDA would confirm any observations from the  
242 RRA during the inspection before including them on the Form FDA 483 Inspectional Observations.

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

245 When oversight activities are conducted by a party other than FDA (e.g., state and foreign regulatory  
246 partners), FDA may conduct RRAs (e.g., livestreaming) during these oversight activities.

247

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

249

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

252

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

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<sup>16</sup> 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 guidance.

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- Having an RRA precede an inspection under section 704(a)(1) of the FD&C Act could reduce resource expenditure by (1) potentially reducing the time FDA is present at the establishment, and (2) helping optimize FDA's time on-site, by reducing the extent of records to be reviewed during the inspection.
  - FDA can make 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. 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 taken in response to inspections of previously compliant manufacturers.
  - Helping to support, and reduce delays of, approval or authorization of marketing submissions for FDA-regulated products.

271

272 **B. Remote Regulatory Assessment Expectations**

273

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

275

276 Multiple processes for requesting voluntary or initiating mandatory RRAs may be used by FDA's Centers  
277 or Office of Regulatory Affairs.<sup>17</sup>

278

- 279
- *In general, for Voluntary RRAs*

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- 290
- FDA will contact an establishment through the establishment's point of contact<sup>18</sup>, by email or phone, once we determine an RRA is appropriate based on FDA mission needs.
  - 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 correspondence or phone contact will include a request that the establishment's top management official at the site, or their senior designee, provide written confirmation of the establishment's willingness and ability to participate in the type of RRA requested.

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<sup>17</sup> 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 During the COVID-19 Public Health Emergency, Guidance for Industry, April 2021.

<sup>18</sup> FDA will typically request to speak with an establishment's top management official at the site or their senior designee.

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- 291                   ○ Following the establishment’s written agreement to participate, subsequent to or  
292                   during our initial contact, we will work with the establishment to schedule virtual  
293                   interviews and meetings, confirm technological capabilities, and request records or  
294                   other information for review, as appropriate.  
295
- 296           • *In general, for Mandatory RRAs*  
297
- 298                   ○ Under section 704(a)(4) of the FD&C Act for drug establishments, FDA uses Form  
299                   FDA 4003 to request records or other information.<sup>19</sup> This request includes a sufficient  
300                   description of the records requested.  
301
- 302                   ○ Under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C) for imported foods, FDA uses Form  
303                   FDA 482d to request FSVP records.

304   Regardless of whether an RRA is voluntary or mandatory, FDA will not issue a Form FDA 482, Notice of  
305   Inspection.

306

307                   9. *What might an establishment expect to happen during an RRA?*  
308

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

- 311
- 312           • FDA requests and reviews records, documents, and other information (such as electronic  
313           systems, and source records from non-clinical and clinical studies).
  - 314           • Virtual meetings between FDA and responsible establishment personnel to review, where  
315           appropriate, the information provided, the electronic systems, the establishment’s operations,  
316           and/or the establishment’s standard operating procedures (SOPs). Interactions between FDA  
317           and an establishment may continue during the course of an RRA.
  - 318           • Use of livestream and/or pre-recorded video, where appropriate, to examine facilities,  
319           operations, data, and information.

320   FDA may provide updates to the establishment on observations and outstanding issues, whenever feasible,  
321   throughout the RRA.

322

323   While mandatory RRAs that are conducted under certain authorities involve activities detailed by such  
324   authority, an establishment could agree to participate in activities beyond what is required. For instance, a  
325   drug establishment subject to a 704(a)(4) records request could voluntarily participate in a separate RRA  
326   that entails video streaming.  
327

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<sup>19</sup> 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 to support products named in multiple applications. In these situations, one Form FDA 4003 will be issued to the establishment to cover requests for records or other information for all of the products in the applications being assessed.

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

329  
330  
331

*Voluntary RRAs*

332 Declining a voluntary RRA request will not result in any enforcement action by the Agency based on  
333 declining the RRA. However, when an establishment declines FDA’s request to conduct a voluntary  
334 RRA<sup>20</sup>, FDA may not be able to conduct timely assessment of the establishment’s activities due to  
335 insufficient information. For example, FDA may not be able to provide an applicant with a timely decision  
336 on an application or product’s approval, clearance, or authorization if we lack information about an  
337 establishment referenced in the marketing submission.

338

339 Similarly, if an establishment declines to participate in a voluntary RRA, FDA, based on considerations  
340 such as when the establishment was last inspected, information available to us, and our assessment of  
341 risks, may consider other actions necessary to verify information submitted to FDA or obtain further  
342 information and to exercise our oversight responsibilities of that establishment, such as an inspection.

343

344 *Mandatory RRAs*

345 There are consequences for declining mandatory RRAs. For example, if a drug establishment refuses a  
346 request for records or other information under section 704(a)(4) of the FD&C Act (“704(a)(4) request”),  
347 that establishment may be in violation of the FD&C Act<sup>21</sup> and imported drugs from the establishment may  
348 be subject to refusal.

349 If an importer refuses FDA’s written request for FSVP records under 21 CFR 1.510(b)(3) or  
350 1.512(b)(5)(ii)(C), the importer may be in violation of section 805 of the FD&C Act, and the food offered  
351 for import by the importer may be subject to refusal under Section 801(a)(3) of the FD&C Act. 21 CFR  
352 1.514(a).

353

354 FDA may take appropriate action against products or establishments that are in violation of the FD&C Act.

355 FDA may deem the following actions, among others, as declining to participate in a mandatory RRA:  
356 withdrawing participation and refusing to provide records upon a lawful request.

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

358

359 The technological expectations will vary depending on the type of RRA and its scope. Certain RRAs  
360 involve records requests, and the records may be submitted electronically or through other means. Other  
361 RRAs may require additional technological capability. For example, if FDA expects that the RRA could  
362 include the use of live streaming video, FDA may inquire about hardware or internet connectivity to assess

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<sup>20</sup> This would not be considered a refusal for purposes of section 301(e) or (f), or 807, of the FD&C Act.

<sup>21</sup> See, e.g., section 301(e) of the FD&C Act (Prohibited Acts).

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363 IT operability, security, and privacy controls to protect the confidentiality of the data. The quality of the  
364 remote connection (e.g., connectivity, image quality, cameras used) should be adequate for FDA to review,  
365 observe, examine, and evaluate the requested records, documents, and other information (including  
366 electronic systems). To the extent practicable, technologies employed also should allow access for  
367 remotely viewing and evaluating operations at the establishment, as appropriate (e.g., aseptic practices,  
368 equipment cleaning and set up, material weighing and dispensing, instrument set up, sampling, and  
369 testing).

370  
371 If an establishment is unable to support streaming video or other live virtual interactions, or if FDA  
372 determines that the streaming video or any other virtual interaction during the RRA does not permit a  
373 sufficient examination of the establishment or of a corrective action, FDA may use other available tools or  
374 may terminate the RRA and consider other actions necessary to exercise our oversight responsibilities of  
375 that establishment, such as an inspection.

376  
377 Recommendations for sending records or other information are further explained in question 15, below.  
378

379 **C. Requests for Records or Other Information as Part of Remote Regulatory Assessments**  
380

381 *12. What records or other information may FDA request as part of an RRA?*  
382

383 For voluntary RRAs, FDA may request records or other information appropriate to determine whether an  
384 establishment, FDA-regulated product, or clinical study is in compliance with applicable FDA  
385 requirements. The records and other information will typically be similar to what FDA would request  
386 during an inspection under section 704(a)(1) of the FD&C Act. There are records and information  
387 requirements in the FD&C Act, the Public Health Service (PHS) Act, and implementing regulations.  
388

389 In the case of RRAs authorized under section 704(a)(4) of the FD&C Act, FDA may request any records  
390 subject to inspection under section 704(a). For RRAs under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C),  
391 FDA may request any and all records that are required to be maintained under 21 CFR 1, Subpart L.  
392

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

- 395
- 396 • Records of specific production lots or batches as well as product-specific information, such as  
397 periodic product reviews<sup>22</sup>, product quality reports, equipment records, process validation records  
398 and reports, test results, product complaints or other information related to compliance with  
399 Current Good Manufacturing Practice requirements.
- 400

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<sup>22</sup> See 21 CFR 211.180(e)

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- 401       • Certain summaries or lists of records, such as a summary of batches manufactured and their  
402       disposition, or a summary of discrepancies and investigations related to manufacturing and testing.  
403
- 404       • Read-only access to electronic databases<sup>23</sup> or a request that an establishment walk us through  
405       information in their database or provide data queries or summary data generated by the  
406       establishment from their databases.  
407
- 408       • SOPs and records generated by the establishment to document control of quality systems and/or to  
409       demonstrate compliance with the applicable FDA requirements.  
410
- 411       • For FSVP importers, records related to hazard analysis, the importer’s determination of  
412       appropriate supplier verification activities, performance of supplier verification activities, and/or  
413       corrective actions.  
414
- 415       • Records or data related to the reporting or conduct of FDA-regulated research.

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

419

420                   *13. For what purposes may FDA use the records and other information gathered*  
421                   *during an RRA?*  
422

423       Depending on the scope of the RRA, the information and documentation may be used for, among others,  
424       the following regulatory purposes by FDA:

- 425
- 426       • Support FDA’s assessment of pending marketing submissions, including whether to approve an  
427       application or whether to issue a response, such as a complete response letter.<sup>24</sup>  
428       • Determine whether an establishment or product is or is not in compliance with certain FD&C Act  
429       or PHS Act requirements, and other applicable FDA requirements.  
430       • As appropriate, to facilitate assessment of the need for an inspection in follow-up to a reported  
431       concern or defect.  
432       • As appropriate, support actions such as a regulatory meeting, warning letter, import action, recall  
433       activity, or enforcement action.

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<sup>23</sup> See FDA Investigations Operations Manual (IOM) 5.10.2.1.

<sup>24</sup> 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(II)); see also 21 CFR 314.110 and 21 CFR 601.3.

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*Draft — Not for Implementation*

- 434       • Determine the priority of establishments for inspection, particularly a surveillance inspection.

435  
436               *14. If the RRA requests records, what is the timeframe for submitting the records*  
437               *to FDA?*

438  
439 For mandatory RRAs, FDA will request that records be submitted within a specified timeframe<sup>25</sup> that  
440 provides an establishment with a reasonable time to respond, based on the individual circumstances of the  
441 request. For voluntary RRAs, FDA may suggest timeframes to ensure the RRA is completed in a  
442 reasonable amount of time and expects establishments to work diligently to provide the requested records.

443  
444 The circumstances that relate to FDA’s expectations for reasonable request timeframes may include:

- 445       • The size, available resources, and capabilities of the establishment.  
446       • The type, complexity, and volume of the records being requested.  
447       • The reason for the request, such as an application action goal date, deadline, or other time-  
448       sensitive reasons.  
449       • Need for translation of the document.

450  
451               *15. How should records or other information in response to an RRA request be*  
452               *provided to FDA?*

453  
454 Requested records or other information should be submitted in an electronic format. FDA will provide a  
455 secure means to send requested records and information. For electronic documents, establishments should  
456 identify any limitations on access and ensure that encrypted and password-protected files can be accessed  
457 by FDA. FDA will follow applicable federal law governing the confidentiality of records and information  
458 submitted to the Agency (see, e.g., 5 U.S.C. § 552(b)(4), 18 U.S.C. § 1905).

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

464 FDA may request that records be in English or accompanied by an English translation.<sup>26</sup> If translated, the  
465 records translation should be complete and accurate, and, when applicable, should include the name,  
466 address, and a brief statement of the qualifications of the translator. Copies of the original records should

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<sup>25</sup> For RRAs under section 704(a)(4) of the FD&C Act, persons subject to the request must provide the requested records within a reasonable timeframe. 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 RRA’s under 805(d), persons subject to the request must provide the records promptly.

<sup>26</sup> 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).

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467 also be included in the response, where appropriate. For certain RRAs, if a verified translation is not  
468 immediately available, FDA may request that the initial translation be followed up with a verified  
469 translation as soon as practicable.

470 If the records are provided as part of a section 704(a)(4) request, the records may be submitted in either  
471 electronic or physical form. FDA will provide confirmation upon receipt of the records.<sup>27</sup>

472 For RRAs under 21 CFR 1.510(b)(3) and 1.512(b)(5)(ii)(C), records must be sent electronically, or  
473 through any other means that delivers the records promptly upon written request from FDA. 21 CFR  
474 1.510(b)(3); 21 CFR 1.512(b)(5)(ii)(C).

475

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

477

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

479

480 Upon completion of an RRA, FDA may have a meeting<sup>28</sup> with the establishment's management. FDA may  
481 present a written list of RRA observations, if any, and describe and discuss any observations in sufficient  
482 detail to enable understanding and foster an appropriate response. For purposes of this guidance, RRA  
483 observations are defined as conditions and/or practices observed, in the judgment of the FDA employee(s)  
484 conducting the RRA, that indicate a potential violation of the laws enforced by FDA. FDA will not issue a  
485 Form FDA 483, Inspectional Observations, for an RRA.<sup>29</sup> (See question 6 for a discussion of how  
486 observations from an RRA may be confirmed during an inspection and included on a Form 483.)

487 An establishment should be aware that any written list of observations may be subject to a request under  
488 the Freedom of Information Act at the time the disclosure to the establishment is first made (see 21 CFR  
489 20.101(a)) and may be made publicly available with any applicable redaction of information that is  
490 otherwise exempt from public disclosure (see, e.g., 5 U.S.C. § 552(b), 18 U.S.C. § 1905, 21 U.S.C. 331(j),  
491 21 U.S.C. 360j(c), 21 U.S.C. § 360nn(e), 21 U.S.C. 387f(c), and 21 CFR part 20).

492 FDA encourages establishments to respond during the meeting, and/or provide responses in writing to the  
493 observations within 15 U.S. business days. Any responses or corrective actions submitted to FDA during  
494 that timeframe in response to the issues identified during the RRA generally will be considered before  
495 further Agency action or decision. Establishment responses are available for public disclosure as described  
496 in 21 CFR 20.103 with redaction of non-public information, as appropriate.

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<sup>27</sup> Section 704(a)(4)(B) of the FD&C Act.

<sup>28</sup> There may be some instances where a meeting may not happen, such as for some section 704(a)(4) records requests.

<sup>29</sup> 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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*Draft — Not for Implementation*

497 FDA’s written list of RRA observations will not be considered a final Agency action or decision.  
498 However, evidence collected in the course of an RRA may be used in support of any such action or  
499 decision.

500 Following an RRA, FDA may conduct an inspection. FDA may also take any other appropriate actions,  
501 including an enforcement action, when significant issues are discovered.

502 As part of the RRA process, FDA will ordinarily prepare a report consisting of a narrative and supporting  
503 documents that communicates the summary of information reviewed, conditions and practices found, and  
504 the observations identified. FDA will provide a written copy of the narrative portion of the RRA report<sup>30</sup>  
505 to the establishment, following the determination that the RRA is closed as described in 21 CFR  
506 20.64(d)(3). At that time, the report and supporting documents, with any applicable redactions, also  
507 become available for public disclosure upon request.

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<sup>30</sup> There may be some instances where a report will not be written or provided, such as when the requested records under 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).