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19 September 2022

Dockets Management Staff (HFA-305),
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Reference: Docket No. FDA-2022-D-0810 for "FDA conducting Remote Regulatory Assessments-Questions and Answers, Draft Guidance for Industry," Request for Comments."

Dear Madam or Sir,

PDA appreciates the opportunity to provide feedback to FDA as the agency further refines the use of Remote Regulatory Assessments (RRAs). In general, the draft guidance provides useful information that will be of help to the industry. In our attached comments, PDA offers specific comments and suggestions that we believe will be helpful in the further development of this important guidance.

One specific comment that PDA would like to highlight is our recommendation that executed RRAs should be visible to the public and other health authorities in FDA's Inspections database (or Firm/Supplier Evaluation Resources database) to provide evidence of FDA's ongoing oversight, even if an on-site inspection did not occur. This is particularly important for the purposes of mutual recognition. We believe these could be clearly identified in the inspection database as a Remote Regulatory Assessment just as other categories are already present.

PDA is a non-profit international professional association of more than 10,000 individual members scientists having an interest in fields of pharmaceutical, biological, device manufacturing, and quality. Our comments have been prepared by a committee of PDA members with expertise in the areas covered in the Public Docket on behalf of PDA's Regulatory Affairs and Quality Advisory Board and Board of Directors.

If you have any questions, please do not hesitate to contact me via email at johnson@pda.org.

Sincerely,

Richard Johnson
President and CEO

cc. Glenn Wright, PDA; Carrie Horton, PDA

PDA response to the draft guidance for "Conducting Remote Regulatory Assessments - Questions and Answers; Draft Guidance for Industry, Request for Comments."
Docket No. FDA-2022-D-0810

Line	Current Language	Proposed Language	Comments
176-184	• *Voluntary RRAs* "If an RRA is not mandatory (or FDA opts against exercising its mandatory RRA authority in a certain instance), FDA may request that any establishment (e.g., food producers, tobacco product manufacturers, drug[10] or medical device manufacturers, clinical investigators, or others) participate in a voluntary RRA." • *Mandatory RRAs* "Mandatory RRAs include the following: Establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug[11,12] are subject to section 704(a)(4) of the FD&C Act. Under FSVP, importers, as defined at 21 CFR 1.500, are subject to section 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 applicable."		As the term "drug" appears in the text under both Voluntary and Mandatory RRAs, PDA recommends additional clarity or specific examples be added to clarify when an RRA is Voluntary or Mandatory in regard to the activities of a drug manufacturer.
196-203	"Generally, an inspection, such as described in section 704(a)(1) of the FD&C Act, involves duly designated officers or employees of the FDA physically entering (at reasonable times and in a reasonable manner), establishments subject to regulation under the FD&C Act to determine compliance with applicable FDA requirements.[13] For this reason, we do not consider an RRA to satisfy statutory requirements that specify inspection under section 704 of the FD&C Act (e.g., section 510(h) or 503B(b) of the FD&C Act).[14]"	FDA should clarify how this assessment will be entered into the system and identified as part of their continued surveillance activities.	PDA recommends that the FDA updates their statutory requirement to align the Remote Interactive Evaluations (RIEs) and the current inspectional process.

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Docket No. FDA-2022-D-0810

Line	Current Language	Proposed Language	Comments
318 - 319	"• Use of livestream and/or pre-recorded video, where appropriate, to examine facilities, operations, data, and information."	"• Use of livestream and/or pre-recorded video, where appropriate, to examine facilities, operations, data, and information. **Where recording activities are to be part of the RRA the FDA will request from the site and comply with any country or region-specific regulations where requirements exist regarding the video recording of personnel.** **Where pre-recorded videos will be requested to be made as part of the RRA, the FDA will, in consultation with the company, provide specifics for the video recording such as, duration, room, area conditions at the time the recording, etc.** **Where livestream is being performed FDA will provide notification if and when recording of the livestream is occurring."**	PDA recommends: The addition of text to recognize country and region-specific regulations regarding video recording of personnel, for example the EU General Data Protection Regulations (GDPR). The addition of text to provide additional detail on the specific parameters of pre-recordings to be made as part of the RRA to ensure understanding between the FDA and company. Where livestream is being performed the FDA should provide notification when recordings are being captured as in the case currently when the FDA captures images in-person.

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Line	Current Language	Proposed Language	Comments
366-369	"To the extent practicable, technologies employed also should allow access for remotely viewing and evaluating operations at the establishment, as appropriate (e.g., aseptic practices, equipment cleaning and set up, material weighing and dispensing, instrument set up, sampling, and testing)."	"To the extent practicable, technologies employed also should allow access for remotely viewing and evaluating operations at the establishment, as appropriate (e.g., aseptic practices, equipment cleaning and set up, material weighing and dispensing, instrument set up, sampling, and testing) **consistent with local regulation. FDA will provide notice if the activities associated with the RRA are recorded."**	As noted in the above comment some jurisdictions in which FDA-registered facilities are located limit the extent to which personnel may be filmed/recorded in the workplace. PDA believes that it would be beneficial for FDA to acknowledge that this type of constraint sometimes exists in the text.
378-418			In regard to Section C. "Request for Records or Other Information as Part of the Remote Regulatory Assessments" PDA would recommend including additional detail on what form of communication will be used for the request (e.g., official letter, email, etc.) and what standard information will be included (e.g., how records are to be submitted, to whom the site is to contact in regard to the request, etc.).

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Line	Current Language	Proposed Language	Comments
480-481	"Upon completion of an RRA, FDA may have a meeting with the establishment's management. FDA **may** present a written list of RRA observations, if any, and describe and discuss any observations in sufficient Detail to enable understanding and foster an appropriate response."	"Upon completion of an RRA, FDA may have a meeting[28] with the establishment's management. FDA **will** present a written list of RRA observations, if any, and describe and discuss any observations in sufficient detail to enable understanding and foster an appropriate response."	PDA believes that communicating in writing (rather than verbal communication) will help avoid any potential ambiguity and foster a more appropriate and holistic response given the 15-day timeline requested for the establishment.
502-507	"As part of the RRA process, FDA will ordinarily prepare a report consisting of a narrative and supporting documents that communicates the summary of information reviewed, conditions and practices found, and the observations identified. FDA will provide a written copy of the narrative portion of the RRA report[30] to the establishment, following the determination that the RRA is closed as described in 21 CFR 20.64(d)(3). At that time, the report and supporting documents, with any applicable redactions, also become available for public disclosure upon request."	"As part of the RRA process, FDA will ordinarily prepare a report consisting of a narrative and supporting documents that communicates the summary of information reviewed, conditions and practices found, and the observations identified. FDA will provide a written copy of the narrative portion of the RRA report[30] to the establishment, following the determination that the RRA is closed as described in 21 CFR 20.64(d)(3). At that time, the report and supporting documents, with any applicable redactions, also become available for public disclosure upon request. **FDA's Inspection Database will be updated to reflect execution of the RRA."**	PDA believes that it would be beneficial for executed RRAs to be visible to provide evidence of FDA's ongoing oversight, even if an on-site inspection did not occur (e.g., for purposes of mutual recognition). These could be clearly identified in the FDA's Inspections database (or Firm/Supplier Evaluation Resources database) as an RRA just as other categories already present.