September 23, 2022

Submitted electronically via regulations.gov

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

Re: Conducting Remote Regulatory Assessments, Questions and Answers, Draft Guidance for Industry (Docket No. FDA-2022-D-0810)

Dear Sir or Madam,

The Food Industry Association (FMI) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA's) Draft Guidance, "Conducting Remote Regulatory Assessments, Questions and Answers" ("Draft Guidance").[1] As the Food Industry Association, FMI works with, and on behalf of, the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain—from retailers that sell to consumers, to producers that supply food and other products, as well as a wide variety of companies providing critical services—to amplify the collective work of the industry. Read more about us at www.FMI.org.

FMI appreciates the issuance of the Draft Guidance and FDA's transparency in sharing additional details on the circumstances in which it plans to conduct remote regulatory assessments (RRAs). We also appreciate FDA's dialogue with industry on the potential structure of RRAs during the initial design phase, as well as the agency's willingness to conduct a pilot project to further refine the concept and test workability. Our members believe voluntary RRAs for foods, if structured appropriately, can enhance FDA field operations and play a role in improving food safety and regulatory compliance during and beyond the COVID-19 pandemic. FMI agrees that using a risk-based approach to determine when to request an RRA and incorporating the information obtained from an RRA into a risk-based inspection schedule will help the agency best allocate its inspectional resources.

FMI also appreciates FDA's commitment to modernizing its inspectional operations to incorporate new technologies. As FDA has recognized, new technology like teleconference and screen sharing software presents opportunities for industry and FDA to more effectively communicate about records provided as part of RRAs and FDA inspections. That said, we have identified certain areas where the use of technology, as anticipated by the Draft Guidance, raises concerns for our members. Likewise, we believe there are a few areas in which the Draft Guidance as it relates to voluntary RRAs for foods can be modified or enhanced to provide

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[1] 87 Fed. Reg. 44129 (July 25, 2022).

greater clarity and address several key issues of importance to industry. We explain these in more detail below.

Livestream video technology is not appropriate for use in RRAs.

FMI encourages the use of video communication and screen sharing software to facilitate records review but strongly opposes the use of livestream video in a food manufacturing facility, whether as part of an RRA or in conjunction with state or foreign oversight activities (see page 8 of the Draft Guidance). Video streaming in a facility could infringe on facility employee privacy interests, especially if visible employees did not expect or consent to being filmed and video of the streaming is later shared. Additionally, the use of video streaming would pose a risk to the confidentiality of proprietary, commercially sensitive processes, equipment, and design in the facility. To the extent the technology captures and retains the video, that risk would be heightened substantially. Moreover, livestream video is not an effective, desirable, or appropriate substitute for in-person inspection. Assessing compliance of a facility with Good Manufacturing Practices (GMPs) cannot be achieved via the limited scope of a video camera. An effective inspection requires an investigator to use all their senses to evaluate a facility. Finally, many food facilities do not have a reliable internet connection in the manufacturing portions of their facility to facilitate video communication.

Document requests should be narrowly tailored to achieve the specific objective of the RRA. Overly broad, burdensome document requests will discourage participation.

We appreciate FDA's statement in the guidance that it "will take appropriate efforts to minimize the quantity of records or other information requested" during an RRA. FMI urges FDA to narrowly tailor the scope of the documents it requests in connection with a voluntary RRA to those that relate directly to the purpose of the RRA, as identified in FDA's initial request for the RRA as discussed further below. This is particularly important in the context of food facilities because many of the documents these facilities maintain incorporate scores of other documents by reference. Thus, a request for a single document may extend to far more documents than FDA anticipates or intends, putting stress on already busy facility personnel. By avoiding broad, unfocused document requests FDA will help encourage industry participation in voluntary RRAs.

In addition to narrowly tailoring its document requests, FDA should operate under the presumption that any requested documents will be shared with FDA over screen share during the RRA, not uploaded to a document sharing service or otherwise provided to FDA in advance. Real-time review of requested documents reduces the burden on the establishment of preparing for the RRA and protects the security of records to be reviewed. Only in the rare circumstance in which screen share technology is not available, or when a facility specifically requests it, should facilities have to provide requested documents to FDA in advance. Of course, in those circumstances it is critical that the records be securely transferred and held. FMI urges FDA to provide more detail in the final guidance about how the agency will facilitate secure document transfer and ensure the records remain securely protected once shared, as well as the agency's plans and policies with regard to retention of the records. In addition, the agency should provide information in the guidance regarding how company IT departments can verify the security of information and data provided.

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Additional structure and clarity around the procedures for conducting RRAs would encourage participation from industry.

FMI urges FDA to include more detail about the procedure for requesting, holding, and concluding voluntary RRAs in the final guidance. Specifically, we suggest the following timeline and procedure:

- FDA requests the RRA: FMI supports FDA's contacting a facility using the information provided in the facility's registration as stated on page 9 of the Draft Guidance. However, as part of the request for an RRA, FMI urges FDA to provide 1) the reason or purpose for the RRA and 2) a list of records the agency will expect to review if the facility decides to participate in the RRA. The purpose of the RRA and the potential burden it would place on the facility are two key factors a facility should be permitted to consider in deciding whether to participate in an RRA.

- FDA holds the RRA:

    - As part of the RRA, the facility and FDA should conduct an opening meeting. The opening meeting should review the purpose and scope of the RRA, as well as provide the facility the opportunity to share the context and other background information relevant to records it intends to share.

    - FDA should review requested records with the facility in real-time via screen sharing technology. As discussed above, the agency should not require the facility to email or otherwise upload records unless the facility specifically requests it or screen sharing is not possible. Reviewing documents through Zoom, Teams or other similar technologies ensures facilities have the opportunity to explain the documents and to do so in real time, minimizing the potential for confusion or misunderstanding. Further, for the reasons discussed above, a voluntary RRA for foods should not include livestream video walkthroughs of the manufacturing portions of facilities.

    - Although the Draft Guidance states at page 15 that FDA "may" hold a meeting with the facility's manager, FMI strongly urges FDA to commit to hosting a close out meeting for every RRA. At this meeting, FDA would share any written comments (referred to in the Draft Guidance as "observations") it may have and give the facility an opportunity to ask questions. Again, to encourage participation and minimize the potential for misunderstanding, FMI suggests the final guidance clarify that any and all FDA written comments arising from the RRA will be communicated at the close out meeting and that the agency's narrative report closing out the RRA (see below) will be limited to the topics addressed at the meeting. Ensuring there is clarity regarding the agency's comments on the RRA is especially important considering that the comments may prompt an inspection and, if confirmed during the inspection, be included on a Form 483, or may otherwise prompt enforcement action.

- Narrative Report: FMI urges FDA to commit to formally concluding the RRA within a set period of time. Specifically, we suggest the final guidance state that FDA will provide the narrative report referred to on page 16 of the Draft Guidance no later than 15 business days following the close out meeting. FMI believes timely conclusion of RRAs will further support and encourage participation.

Additional comments

In addition to the concerns raised above, we also have the following additional suggestions for improving the Draft Guidance:

- To afford company's flexibility and ensure RRAs are not disruptive to daily operations, FDA should allow a facility to choose the screen sharing technology it prefers during an RRA (e.g., Zoom, Microsoft Teams, WebEx, etc.). This will ensure facilities use software they are already familiar with and have evaluated for security purposes.

- To differentiate RRAs from FDA inspections and avoid any potential for confusion, FMI recommends the agency use the term "comments" rather than "observations" for any written communications offered by FDA during the close out meeting.

- For mandatory RRAs conducted for compliance with Foreign Supplier Verification Program (FSVP) requirements, FMI encourages FDA to underscore that FSVP responses are not required to be provided electronically. Providing paper copies is acceptable. While the Draft Guidance alludes to this on pages 14 and 15, FMI believes the text would benefit from additional clarity.

- "FDA staff" responsible for conducting RRAs should be qualified to carry out RRA activities. Furthermore, FDA should continue to ensure appropriate staffing of inspection personnel to effectively carry out statutory and regulatory responsibilities.

FMI supports FDA's development of a framework for conducting RRAs, and we encourage FDA to continue efforts to engage with industry as it moves forward with these efforts.

Should you have questions about these comments, please feel free to contact me at sbharris@fmi.org.

Sincerely,

Stephanie Harris

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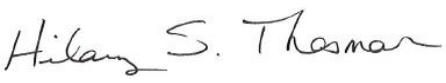

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