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Re: Conducting Remote Regulatory Assessments, Questions and Answers, Draft Guidance for Industry (Docket No. FDA-2022-D-0810)

To Whom It May Concern:

SNAC International thanks the Food and Drug Administration ("FDA") for the opportunity to comment on the draft guidance for stakeholders entitled, "*Conducting Remote Regulatory Assessments, Questions and Answers*" ("Draft Guidance").[1]

SNAC International is the international trade association of the snack food industry representing snack manufacturers and suppliers. SNAC International represents over 400 companies worldwide, including but not limited to manufacturers of potato chips, tortilla chips, cereal snacks, pretzels, popcorn, kettle corn, cheese snacks, snack crackers, meat snacks, pork rinds, snack nuts, party mix, corn snacks, pellet snacks, fruit snacks, snack bars, granola, snack cakes, cookies, and various other snacks.

SNAC supports the use of new technologies and approaches to advance food safety, and we appreciate FDA's effort in developing this draft guidance, so industry understands fully how FDA intends to incorporate remote regulatory assessments (RRAs) into its inspectional toolkit. SNAC believes the collaborative dialogue, industry meetings, and RRA pilot program that FDA undertook as it refined its thinking about RRAs helped drive a common understanding. SNAC also appreciates FDA's commitment to take a risk-based approach to RRAs, both in prioritizing RRA requests and in considering the severity of RRA findings in scheduling inspections.

SNAC is mindful, however, that FDA will best promote voluntary participation in RRAs if the process is clear, any shared information is stored securely, and records review requests are tightly limited to the stated purpose of the RRA. To that end, we urge FDA to modify several areas of the Draft Guidance:

- Video Streaming: SNAC appreciates FDA proposes to incorporate updated technologies into the RRA program to promote efficient use of agency time and resources. However,

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

we urge FDA to reconsider any intention to use videos and/or photos of employees and live (360°) video streaming in a facility's production areas or request that a facility record and submit video footage of those areas. Many plants lack the technological infrastructure to support remote video inspections. Moreover, the limited scope of a video camera is not an appropriate substitute for a physical examination. Production areas should be examined in person so an inspector can use all senses in evaluating conditions and the plant personnel can interact with the inspector directly to address any questions.

- RRA Process: SNAC urges FDA to provide more details on the processes it will follow in requesting, holding, and concluding RRAs. We offer the following suggestions:

    - Record review: As discussed further below, FDA's commitment to minimize the quantity of records and information requested during an RRA is important. Broad, unfocused record requests will discourage participation. Equally important, record reviews should only be conducted over screen share. FDA should not request that a facility upload records for FDA's review in advance of an RRA. Reviewing documents over screen share using a screen share platform chosen by the facility would reduce the burden on the facility and ensure it has an opportunity to explain and answer questions regarding the reviewed documents in real time with FDA.

    - Record security: The Draft Guidance does not explain how FDA will securely facilitate file transfer and retain or use records once they have been shared. In the event screen sharing is not possible and a facility must provide requested documents in advance of an RRA, FDA should provide more information on how it will protect the confidentiality and security of the shared records and commit to a one-year retention period for any shared records.

    - Clarity of process: The RRA should always include both an opening meeting and a closing meeting. The opening meeting will give the facility an opportunity to provide context for any records requested and reviewed by the agency, and the closing meeting will ensure the facility can address immediately any observations from the RRA and allow for dialogue regarding the facility's performance. FDA should also commit to issuing a narrative report within a specified number of days following the closing meeting to ensure the RRA is promptly and clearly concluded.

- RRA Purpose and Scope: SNAC appreciates FDA's statement that the agency will work to minimize the quantity of records requested. To this point, SNAC recommends FDA state the purpose of the RRA in its initial request and outline clearly the documents it plans to review, taking care to limit the scope of requested records to that purpose. A facility can best decide whether participating in a voluntary RRA is in its interest if it understands in advance what records FDA will expect to review during the RRA and the burden gathering and sharing those records will impose on the facility.

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SNAC encourages FDA to consider all feedback from stakeholders as it moves ahead with the use of RRAs and finalizes the Draft Guidance. SNAC looks forward to partnering with FDA to advance additional science-based policies and frameworks that provide clarity and certainty to manufacturers and consumers. If you have any questions about our comments or if SNAC can provide any additional information, please contact Colleen Farley, SNAC International's Director of Advocacy, at cfarley@snacintl.org.

Regards,

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