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September 23, 2022

By Electronic Submission

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Re: Conducting Remote Regulatory Assessments, Questions and Answers, Draft Guidance for Industry (Docket No. FDA-2022-D-0810)

The Council for Responsible Nutrition (CRN) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) Draft Guidance, "Conducting Remote Regulatory Assessments, Questions and Answers" ("Draft Guidance").[1] CRN is the leading trade association for the dietary supplement industry, representing manufacturers of dietary ingredients and of national brand name and private label dietary supplements.[2]

CRN appreciates FDA's intention to expand use of modern technology to enable FDA regulated industries, including dietary supplement companies, to voluntarily participate in remote regulatory assessments (RRAs). In addition to voluntary participation, dietary supplement companies may be subject to requests for Foreign Supplier Verification Program (FSVP) records under 21 CFR 1.510(b)(3) or 1.512(b)(5)(ii)(C) (mandatory RRAs). We believe RRAs are a useful tool in FDA's risk-based approach to evaluating inspectional priorities and firms' regulatory compliance. Prior to the COVID-19 pandemic, FDA

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

[2] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 200 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

conducted 500-600 dietary supplement facility inspections per year, about 5% of supplement facilities.[3] While RRAs alone would not resolve FDA's inspections backlog, the tool could help direct inspections of dietary supplement facilities with the highest risk, thereby protecting public health.

RRAs are still new to the dietary supplement industry and some firms may not have the required technical capabilities to participate. At this time, most CRN members have not experienced an RRA. CRN encourages FDA to provide additional avenues to share questions or concerns as industry considers voluntary participation. At this time, we offer the following recommendations to enhance industry's understanding of how FDA intends to carry out RRAs and how the agency intends to ensure appropriate protection of business information exchanged as part of RRAs. Additional clarity may encourage voluntary participation in RRAs, as would an ongoing dialogue around these assessments as FDA expands use and contemplates their utility for supplements and other products.[4]

Remote Regulatory Assessment Expectations

CRN agrees it is necessary for FDA to meet with the establishment prior to conducting an RRA to confirm scope of the RAA, documents to be reviewed, and technological capabilities. We appreciate that the Draft Guidance states, "Following the establishment's written agreement to participate, subsequent to or during our initial contact, we will work with the establishment to schedule virtual interviews and meetings, confirm technological capabilities, and request records or other information for review, as appropriate."

In addition, the Draft Guidance states RRAs may entail "use of livestream, where appropriate, to examine facilities, operations, data, and information." CRN is concerned that use of livestream would pose a risk to confidentiality of processes and privacy of personnel in a facility. CRN encourages FDA to limit RRA requests for video streaming to records review only.

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

CRN recommends that FDA provide more detail about how the agency will facilitate secure document transfer and storage, as well as the agency's policies for records retention. For example, FDA should clarify if it will permit companies to use document transfer and video platforms of their choosing and, if not, FDA should identify any services or other technologies it is using to allow companies to assess security and other concerns before participating in an RRA. CRN also recommends that FDA clearly identify the purpose of the RRA in its initial request and limit requested documents to only those directly related to the purpose of the RRA. A list of the documents FDA expects to review in the agency's initial RRA request would help firms determine ability to participate in an RRA. We appreciate that the Draft Guidance states, "Where applicable, FDA will take appropriate efforts to minimize the quantity of records or other information requested and may request that establishments take reasonable efforts to

[3] Daniells S. FDA's Cara Welch on RRAs & third-party audits: 'We're staring at a backlog of inspections.' nutraingredients-usa.com. June 27, 2022. https://www.nutraingredients-usa.com/Article/2022/06/27/FDA-s-Cara-Welch-on-RRAs-third-party-audits-We-re-staring-at-a-backlog-of-inspections#. Accessed September 21, 2022.

[4] FDA. FDA Evaluation of Infant Formula Response. September 2022. https://www.fda.gov/media/161689/download. Accessed September 22, 2022.

facilitate and expedite FDA's collection and review of other records." We expect that RRAs will increase efficiency of FDA's regulatory oversight activities without overly burdening regulated industry.

The Draft Guidance indicates information and documentation from RRAs may be used by FDA to support advisory actions, such as a warning letter, or enforcement actions such as a seizure. CRN emphasizes that information obtained through RRAs should be used to support FDA regulatory actions, but not be the sole evidence for such actions. Other corroborating evidence, including an inspection, may be needed to justify regulatory actions.

Completion of a Remote Regulatory Assessment

CRN agrees a meeting with the establishment's management is necessary upon completion of an RRA to discuss RRA-related details so that the establishment could determine follow-up activities. CRN appreciates that the Draft Guidance explains, "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." The Draft Guidance also indicates that FDA will provide a written copy of the narrative portion of the RRA report to the establishment. The timely issuance of the narrative report would be useful for firms in support of compliance efforts.

Mandatory RRAs Conducted under the Foreign Supplier Verification Program (FSVP)

The draft guidance indicates FDA uses Form 303 FDA 482d to request FSVP records. CRN recommends that FDA clarify in guidance the agency will contact the FSVP importer to request for FSVP records.

As stated above, CRN believes use of livestream and video recording creates confidentiality and privacy concerns for facilities. If a firm is subject to mandatory RRAs, CRN recommends that FDA address whether it plans to record livestream or other use of video services and how any refusal to participate would be treated by FDA.

Thank you for considering our comments. We look forward to additional opportunities to dialogue with the agency as the dietary supplement industry gains more experience with RRAs in the future.

Sincerely,

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