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February 22, 2021

By Electronic Submission

Division of Dockets Management (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Requirements for Additional Traceability Records for Certain Foods; Proposed Rule, Docket No. FDA-2014-N-0053

Dear Sir or Madam:

The Council for Responsible Nutrition ("CRN") is pleased to submit these comments on the U.S. Food and Drug Administration's ("FDA's") Proposed Rule for Requirements for Additional Traceability Records for Certain Foods.[1]

Founded in 1973 and based in Washington, D.C., CRN is the leading trade association representing more than 180 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are firmly committed to ensuring the safety of their products, and are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control, and safety. Our supplier and manufacturer member companies adhere to additional voluntary guidelines as well as CRN's Code of Ethics.[2]

CRN understands, based on the preamble to the proposed rule and FDA's subsequently-released Frequently Asked Questions document[3] ("FAQs"), that FDA's proposed traceability recordkeeping requirements for the "high risk" foods on FDA's Food Traceability List ("FTL") will not apply to dietary supplements or dietary ingredients. The FAQs clarified that the risk-ranking model FDA used to develop the FTL assessed the risks of dried spices and dried vegetables in the commodity categories "Spices" and "Vegetables (Dried)," which were not included in the proposed FTL. Therefore, dried spices and dried vegetables will not be covered by the

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[1] *See* 85 Fed. Reg. 59984 (Sept. 23, 2020).

[2] To learn more about CRN, visit www.crnusa.org.

[3] FDA, Frequently Asked Questions about the Food Traceability Proposed Rule (Jan. 2021), https://www.fda.gov/media/145046/download.

proposed rule. Similarly, CRN assumes all dietary supplements and dietary ingredients, including dried herbs, dried vegetables, and fish or krill oil, were included in the commodity category "Dietary supplements," which is not on the FTL, and therefore will be exempt from the proposed rule.

CRN believes that is the right approach, for the reasons set forth in these comments. Briefly, and as detailed below, dietary supplements have only very rarely been associated with foodborne illness outbreaks, and, subject to the modification to section 1.1035(d)(1) we recommend below, dietary supplements and dietary ingredients should be exempt from the rule's requirements. To avoid confusion and prevent unnecessary costs, CRN requests that FDA adopt this recommended modification and confirm in its final rulemaking that dietary supplements and dietary ingredients will not be subject to this rule.

I. CRN understands that FDA does not intend for this rule to apply to dietary supplements or dietary ingredients.

Dietary supplements are not included on FDA's FTL. However, according to FDA's report on the methodology used to create the FTL, "Dietary Supplements" were one of the commodities included in the risk-ranking model FDA used to develop the FTL.[4] The fact that FDA considered including dietary supplements on the FTL but ultimately chose not to do so indicates that the agency does not intend for this rule to apply to dietary supplements or dietary ingredients. This conclusion aligns with FDA's statement in the FAQs that commodities included in FDA's risk-ranking model but not included on the FTL are not covered under the proposed rule.[5]

We note further that neither the text nor the preamble of FDA's proposed rule address the rule's applicability to dietary supplements or dietary ingredients. Similarly, during the three daylong public meetings FDA held to discuss the proposed rule, the agency never indicated that it intended for the rule to apply to dietary supplements or dietary ingredients.[6] And, while FDA

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[4] *See* FDA, Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223) at 53 (Aug. 2020), https://www.fda.gov/media/142247/download. Specifically, "Dietary Supplements" are listed in Table A-2 in Appendix A of FDA's report, which lists the commodities included in FDA's risk-ranking model.

[5] FAQs at 2.

[6] *See* FDA, Transcript of Public Meeting on Requirements for Additional Traceability Records for Certain Foods: Proposed Rule (Nov. 6, 2020), https://www.fda.gov/media/144265/download; FDA, Transcript of Public Meeting on Requirements for Additional Traceability Records for Certain Foods: Proposed Rule (Nov. 18, 2020), https://www.fda.gov/media/144266/download; FDA, Transcript of Public Meeting on Requirements for Additional

has published educational materials outlining how the proposed rule would apply to over a dozen different conventional food product supply chains, none of the supply chain examples provided by FDA concern dietary supplements.[7]

While dietary supplements are deemed to be food for most purposes under the Federal Food, Drug, and Cosmetic Act,[8] FDA has often made clear in its rulemakings when requirements that apply to food generally will also apply to dietary supplements, particularly when such application would not seem intuitive, as is the case here. CRN assumes that if FDA intended to apply the proposed rule to the dietary supplement industry—a large, rapidly growing industry with an annual economic impact of more than $122 billion[9]—it would be explicit in doing so. We thus interpret the proposed rule's silence with regard to dietary supplements and dietary ingredients as further evidence that FDA does not intend for this rule to apply to these products.

II. CRN agrees that this rule should not apply to dietary supplements or dietary ingredients.

CRN strongly supports FDA's decision not to subject persons who manufacture, process, pack, or hold dietary supplements or dietary ingredients to this rule. At least two findings support this decision.

Traceability Records for Certain Foods: Proposed Rule (Dec. 2, 2020), https://www.fda.gov/media/144612/download.

[7] *See, e.g.*, FDA, Critical Tracking Events (CTEs) and Key Data Elements (KDEs), https://www.fda.gov/media/142291/download (providing examples of soft cheese, seafood, and fresh-cut romaine supply chains); FDA, First Receiver Examples, https://www.fda.gov/media/142284/download (fresh-cut romaine, cantaloupe, finfish, shell egg, sprout, and mango supply chains); FDA, Creation and Transformation, https://www.fda.gov/media/142285/download (soft cheese, soft cheese with fresh herbs, potato deli salad, peanut butter, peanut butter cracker, peanut butter cookie, cucumber, salsa, and fresh-cut romaine supply chains).

[8] 21 U.S.C. § 321(ff).

[9] *See* CRN, Economic Impact of the Dietary Supplement Industry, https://www.crnusa.org/resources/economic-impact-dietary-supplement-industry. CRN also notes that, in 2019, 77 percent of Americans reported that they consume dietary supplements, *see* CRN, Dietary Supplement Use Reaches All Time High (Sept. 30, 2019), https://www.crnusa.org/newsroom/dietary-supplement-use-reaches-all-time-high, and that the value of the global dietary supplement market is estimated to reach more than $210 billion by 2026, *see* Reports and Data, Dietary Supplements Market To Reach USD 210.3 Billion By 2026 (Mar. 25, 2019), https://www.globenewswire.com/news-release/2019/03/25/1760423/0/en/Dietary-Supplements-Market-To-Reach-USD-210-3-Billion-By-2026-Reports-And-Data.html.

First, an analysis of data from recent years indicates that dietary supplements are very rarely associated with foodborne illness outbreaks in the United States. For example, of the 103 public health public health advisories from investigations of foodborne illness outbreaks since 2011 listed on FDA's website, only one outbreak was associated with a dietary supplement or dietary ingredient.[10] This means that the overwhelming majority of foodborne illness outbreaks in the United States in the past decade have been caused by conventional foods, not dietary supplements. This suggests that subjecting dietary supplements and dietary ingredients to this rule would offer minimal public health benefits. Doing so would also be inconsistent with FDA's statutory mandate to impose additional recordkeeping requirements for "high risk foods" with the explicit purpose of "prevent[ing] or mitigat[ing] foodborne illness outbreak[s]."[11] Given the infrequency with which dietary supplements and dietary ingredients are implicated in such outbreaks, it would be unreasonable to conclude that they pose a "high risk" of causing outbreaks.

Second, dietary ingredient manufacturing involves steps to "reduce the presence of microorganisms of public health significance." Section 1.1305(d)(1) of the proposed rule would exempt all persons who manufacture, process, pack, or hold produce that receives to this type of processing from the rule, based on FDA's finding that these items pose a "lesser public health risk."[12] CRN agrees with this exemption, which, as written, would exempt many dietary ingredients from the proposed rule. CRN notes, however, that non-produce foods that are subject to this type of processing would similarly pose a "lesser public health risk." We thus urge FDA to modify section 1.1305(d)(1) to exempt not only produce, but also any other food on the FTL subject to processing that adequately reduces the presence of microorganisms of public health significance. This modification would remove unnecessarily burdensome recordkeeping requirements for persons handling food that receives such processing, while still upholding the proposed rule's public health objectives.

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[10] *See* FDA, Public Health Advisories from Investigations of Foodborne Illness Outbreaks, https://www.fda.gov/food/outbreaks-foodborne-illness/public-health-advisories-investigations-foodborne-illness-outbreaks (current as of Dec. 22, 2020).

[11] *See* FSMA, Pub. L. No. 111-353, tit. II, § 204(d)(1), 124 Stat. 3885, 3931 (2011) (codified at 21 U.S.C. § 2223). In the preamble to the proposed rule, FDA reiterates that the rule's purpose is to prevent or mitigate the risk of foodborne illness outbreaks associated with the foods on FDA's FTL. *See* 85 Fed. Reg. 59984, 59985.

[12] *See* 85 Fed. Reg. 59984, 59996.

III. Conclusion

For the reasons outlined above, CRN strongly supports FDA's decision not to apply this rule to persons who manufacture, process, pack or hold dietary supplements. To avoid confusion and to prevent unnecessary costs, CRN requests that, upon issuing in its final rule, FDA confirm that the rule will not apply to such persons. We also urge FDA to modify proposed section 1.1035(d)(1) to exempt all foods—including dietary ingredients—that receive processing to adequately reduce the presence of microorganisms of public health significance from the rule's requirements.

Sincerely,

Haiuyen Nguyen
Senior Director, Scientific & Regulatory Affairs