Council for Responsible Nutrition
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May 14, 2025

Dayle Cristinzio
Director, Public Engagement Staff
Office of External Affairs, Office of the Commissioner,
U.S. Food and Drug Administration
Via email: Dayle.Cristinzio@fda.hhs.gov

Dear Ms. Cristinzio:

I write to you on behalf of the Council for Responsible Nutrition (CRN),[1] the leading trade association representing the dietary supplement community. We had great hopes at the beginning of this Administration that the FDA's communications with respect to dietary supplements would change. As the new leadership team at the Department of Health and Human Services embarks on making America healthy, CRN anticipated that dietary supplements would be given fairer treatment for their role promoting better health and an acknowledgement that these products are regulated by the agency. CRN has previously documented a sustained and persistent bias within FDA with respect to messaging related to dietary supplements.[2]

This week, FDA released a new consumer alert, "FDA 101:Product Recalls," and, regrettably, the agency continues to omit accurate information for consumers about dietary supplements. It is noteworthy that among the list of "FDA-Regulated Products" that are subject to recall, dietary supplements are omitted.[3] Now one might interpret that because dietary supplements are regulated as a category of food, the inclusion of "Human

[1] The Council for Responsible Nutrition (CRN), founded in 1973, is the leading trade association representing more than 160 dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control, and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Follow us on X @CRN_Supplements and LinkedIn.

[2] In September 2022, CRN conducted a content analysis of FDA's newly released *Supplement Your Knowledge* content for consumers, healthcare professionals, and teachers on dietary supplements. Our examination illustrated that FDA's public messages on dietary supplements overstated the potential risks of taking supplements while downplaying benefits and failed to communicate the robust regulatory framework that gives the agency authority over dietary supplements, leaving a misimpression that the regulation is Inadequate and missed easy opportunities to address public health issues by encouraging responsible supplement usage. CRN's analysis also raised concerns about FDA's messaging for healthcare providers as likely to discourage open dialogues between providers and their patients, excessively alarm patients of potential risks, and reduce the likelihood of candor about supplement usage.

[3] It's worth noting that almost every other category of products regulated by FDA is listed: Human food products, Animal food and feed, Cosmetics, Human drugs, Animal drugs, Medical devices, Radiation-emitting products, Vaccines, Blood and blood products, Transplantable human tissue, and even Tobacco products—but not dietary supplements.

food products" covers dietary supplements, but this could be misleading. Most consumers who view the site would not know that dietary supplements are subsumed as a category of human food products and would instead be left with the impression that dietary supplements are NOT subject to recall or even other forms of FDA regulation and oversight. Why were dietary supplements omitted from the list of "FDA-Regulated Products"?

Notably, dietary supplements are subject to more recall authority than some of the other listed products because all products regulated as food, including dietary supplements, are even subject to mandatory (not just voluntary) recall by FDA. If FDA believes a product poses a risk to human health and safety, it can demand a recall or conduct the recall itself and charge the cost of that action to the manufacturer. And FDA has used that authority with respect to supplements. That is not the case for drugs where FDA must depend on the cooperation of the manufacturer to implement the recall.

Accordingly, CRN respectfully requests that the FDA webpage "FDA 101:Product Recalls" be revised to include an explicit mention that dietary supplements are subject to recall and that any future communications (like the mass email distributed on May 13) reflect the status of dietary supplements as well.

I would be happy to discuss this matter with you or other ways that FDA's communications efforts could more accurately and fairly convey to consumers the regulatory status of dietary supplements and their positive contributions to better health.

Thank you for your consideration of our request,

Sincerely yours,

Steve Mister
President & CEO

cc: Cara Welch, Director, Office of Dietary Supplement Programs
Mark Hartman, Office of Food Chemical Safety, Dietary Supplements & Innovation
Kyle Diamantas, Acting Deputy Commissioner for Human Foods