



Council for Responsible Nutrition

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July 10, 2023

Dr. Robert McKinnon Califf, FACC, MD
Commissioner
U.S. Food and Drug Administration
United States Department of Health and Human Services
10903 New Hampshire Avenue, White Oak Building One, Room 2217
Silver Spring, MD 20993
Via email: commissioner@fda.hhs.gov

Re: FDA Reorganization of the Human Foods Program - Office of Dietary Supplement Programs

Dear Commissioner Califf,

On behalf of the Council for Responsible Nutrition (CRN)¹, the leading trade association representing the dietary supplement and functional food industry, we are writing to express our grave concerns about the FDA proposed reorganization of its Human Foods Program which downgrades the agency's regulation of dietary supplements under the proposed new framework. We respectfully request a meeting with the appropriate officials at FDA to discuss our concerns and to help us learn the rationale behind these changes.

The description of the reorganization of the Human Foods Program, along with the organization flowchart released by the agency last week would eliminate the Office of Dietary Supplement Programs (ODSP) under the current Center for Food Safety and Applied Nutrition (CFSAN). FDA proposes instead to insert the regulation of dietary supplements into a new combined office that will be called the Office of Food Chemical Safety, Dietary Supplements and Innovation. For our industry, this means that the attention and priorities given to dietary supplements, even as little as it was before, will be even less in this new structure.

As you reported to us on a call in January, when FDA asked the Reagan-Udall Foundation to conduct an evaluation of FDA's Foods program last Fall, the agency, unfortunately, intentionally left out a review of the dietary supplement piece of CFSAN, despite the fact that supplements are regulated as food. So, when the Reagan-Udall recommendations came back, there was no

¹ 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.

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mention of dietary supplements. It appears now FDA has just inserted supplement oversight into another Office.

CRN questions why the agency is pulling back on its responsibility to effectively regulate dietary supplements, when these products have grown into a nearly \$60 billion industry, and at a time when supplement use is higher than ever before. Seventy-five percent of Americans use a dietary supplement²; they deserve to have an agency overseeing this market that acknowledges their health benefits and devotes adequate resources to effectively regulate the market.

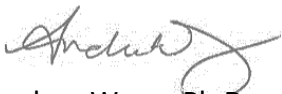
Despite widespread confidence in dietary supplements by consumers,³ issues related to labeling, misleading claims, manufacturing quality and counterfeit products still persist that demand FDA oversight and enforcement. In 2016, CRN strongly supported the elevation of the former Division of Dietary Supplements into an Office, a designation that brought more priority to FDA's oversight. Since then, the industry has successfully lobbied Congress to more than double annual funding to the Office to assure increasing attention and enforcement. The proposed reorganization jeopardizes those advances that reinforce consumer trust in these products.

Accordingly, CRN asks that FDA meet with CRN and discuss the future of dietary supplement regulation under this new framework. We look forward to an opportunity to explore this matter in more detail.

Sincerely,



Steve Mister
President & CEO



Andrea Wong, Ph.D.
Senior Vice President
Scientific & Regulatory Affairs

cc: Janet Woodcock, M.D., Principal Deputy Commissioner, Office of the Commissioner (janet.woodcock@fda.hhs.gov)
Julia Tierney, J.D., Chief of Staff, Office of the Commissioner (julia.tierney@fda.hhs.gov)
Douglas Stearn, J.D., Deputy Director, Office of Regulatory Affairs (douglas.stearn@fda.hhs.gov)
Cara Welch, Ph.D., Director, Office of Dietary Supplement Programs (cara.welch@fda.hhs.gov)

²CRN/Ipsos 2022 Consumer Survey on Dietary Supplements, <https://www.crnusa.org/newsroom/crn-reveals-survey-data-2022-consumer-survey-dietary-supplements>.

³ *Id.* According to the 2022 CRN/Ipsos Consumer Survey on Dietary Supplements, trust in the dietary supplement industry also high. More than three-quarters of Americans (77%) find the industry trustworthy. That number is even higher among supplement users, at 84%.