



Council for Responsible Nutrition

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September 25, 2023

By Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry. Docket No. FDA-2023-D-1027.

The Council for Responsible Nutrition (CRN)¹ appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) "Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry" (Draft Guidance)². CRN applauds FDA's commitment to improving eating patterns and reducing the burden of nutrition-related chronic diseases in the United States. Part of this work includes updating regulation and policy for the use of voluntary labeling claims that help consumers understand how individual foods contribute to a healthy or nutritious dietary pattern, such as the "Healthy Nutrient Content Claim" proposed rule released in September 2022 and this Draft Guidance on Dietary Guidance Statements. These label statements are intended to help consumers easily identify products that can help them achieve healthful diets that provide the recommended levels of beneficial nutrients. Overall, FDA's intended goal for the "healthy" regulation and guidance on Dietary Guidance Statements is to encourage food product manufacturers to innovate healthy options for American consumers.

The Role of Dietary Supplements in Helping Americans Meet Nutrient Needs

Nutritious dietary patterns provide health-promoting nutrients, including vitamins, minerals, and dietary fiber. Some nutrients are difficult to obtain in sufficient quantities in conventional foods and beverages while staying within calorie limits, e.g., vitamin D. Americans consistently under consume a range of

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.

² 88 Fed. Reg. 39256 (Jun. 15, 2023)

essential vitamins, minerals, and dietary components relative to the Estimated Average Requirement (EAR) or Adequate Intake (AI), including vitamins A, C, D, E, K, calcium, magnesium, dietary fiber, choline, and potassium.³ Vitamin D, calcium, dietary fiber, and potassium have been identified as nutrients and dietary components of public health concern because low intake is linked to negative health impacts. In fact, the most recent data being reviewed by the 2025 Dietary Guidelines Advisory Committee show as much as 96 percent and 44 percent of Americans aged 1 and older fail to meet the recommendation for vitamin D and calcium, respectively, and only 6 percent and 29 percent of the population meets the recommendation for dietary fiber and potassium.⁴

Certainly, nutrients should be obtained from foods first. However, dietary supplements containing vitamins, minerals, and beneficial food components can help close nutrition gaps for Americans, without adding significantly to intakes of saturated fat, sodium, and added sugar. Indeed, the current Dietary Guidelines for Americans (DGA) recognize that in some cases dietary supplements may be useful in providing one or more nutrients that otherwise may be consumed in less than recommended amounts.⁵ According to the DGA, taking a vitamin D supplement may be appropriate, for example, when it is difficult to consume enough vitamin D from foods or sunlight exposure is limited due to climate or use of sunscreen. The DGA acknowledges that most healthcare providers recommend prenatal vitamin and mineral supplements in addition to consuming a healthy diet, as well as special considerations that may require supplementation, such as vitamin B12 supplements for some older adults.

Dietary supplement use is prevalent among U.S. adults and contributes to overall nutrient intakes. Nearly 58 percent of adults report use of dietary supplements with the highest usage among older adults; and the top three dietary supplements are multivitamin-minerals, vitamin D, and omega-3 fatty acids.⁶ Multivitamin-mineral supplement use has been associated with a reduction in the percentage of the population below the EAR for several underconsumed nutrients.⁷ Thus, in addition to conventional foods, dietary supplements help individuals meet their nutrient requirements, including typically underconsumed nutrients and nutrients of public health concern for the general U.S. population.

Considerations for Use of Dietary Guidance Statements on Dietary Supplement Labels

The Draft Guidance states that Dietary Guidance Statements can be used on food labels “to suggest that an individual food or food group may contribute to or help maintain a nutritious dietary pattern” and

³ Dietary Guidelines Advisory Committee. 2020. Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. U.S. Department of Agriculture, Agricultural Research Service, Washington, DC. Available at: <https://doi.org/10.52570/DGAC2020>.

⁴ Eicher-Miller H; for the Food Pattern Modeling and Data Analysis Subcommittee. Data Analysis. Presented at: 2025 Dietary Guidelines Advisory Committee Meeting 3; September 13, 2023. <https://videocast.nih.gov/watch=51108>.

⁵ U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at [DietaryGuidelines.gov](https://www.dietaryguidelines.gov).

⁶ Mishra S, Stierman B, Gahche JJ, Potischman N. Dietary supplement use among adults: United States, 2017–2018. NCHS Data Brief, no 399. Hyattsville, MD: National Center for Health Statistics. 2021. DOI: <https://doi.org/10.15620/cdc:101131>

⁷ Blumberg JB, Frei BB, Fulgoni VL, Weaver CL, Zeisel CH. Impact of frequency of multi-vitamin/multi-mineral supplement intake on nutritional adequacy and nutrient deficiencies in U.S. adults. *Nutrients*. 2017;9(8):849.

provides recommendations for the amounts of food or food group that a food product bearing a Dietary Guidance Statement should contain as well as recommendations for limits on sodium, saturated fat, and added sugar. FDA states its recommendations are based upon current nutrition science and dietary recommendations, such as the DGA.

Surprisingly, however, the Draft Guidance also recommends that Dietary Guidance Statements should not be made on dietary supplements, stating:

“Current consensus reports recommendations, including the Dietary Guidelines, encourage Americans to meet nutrient requirements through the consumption of whole foods (e.g., whole fruits and vegetables). Therefore, manufacturers should not use Dietary Guidance Statements on products labeled as or purporting to be dietary supplements.”

This is a misrepresentation by omission. The DGA recommends in its “Key Dietary Principles” that nutrient needs be met primarily by foods, but also acknowledges this is not always possible and that dietary supplements are useful. The DGA goes on to provide recommendations for dietary supplement use when needs are not otherwise met in the general population, as well as in certain life stages. Therefore, a correct representation of recommendations coming from this consensus report includes the use of dietary supplements in some cases. FDA should acknowledge that current and future consensus reports, including the DGA, as well as certain authoritative medical organizations, may recommend the use of certain dietary supplements.

FDA's treatment of dietary supplements in the Draft Guidance on Dietary Guidance Statements is similar to its approach in the proposed rule redefining the “Healthy” nutrient content claim. Although the proposed rule does not expressly preclude dietary supplements from making the “healthy” claim, it makes it nearly impossible for any dietary supplement to claim “healthy” by requiring products to contain meaningful amounts of one or more food groups recommended in the DGA. This food groups-based approach limits opportunities for innovation of nutrient dense products that could be healthful in a diet, including dietary supplements. CRN previously submitted comments suggesting an additional approach based on nutrients to encourage and nutrients to limit to allow for dietary supplements that meet the criteria to bear the “healthy” nutrient content claim.⁸ We recommend FDA apply a similar approach based on nutrients to encourage and nutrients to limit for Dietary Guidance Statements.

Further, FDA should confirm that dietary supplements, as well as other products, including conventional foods, can continue to be associated with otherwise truthful and non-misleading statements without triggering the requirements for Dietary Guidance Statements when not relying on recommendations from consensus reports. Such claims may include representations of healthy or nutritious attributes if otherwise appropriate and adequately substantiated, such as by data or qualified experts.

In summary, dietary supplements that provide beneficial vitamins, minerals, and food components should be allowed to bear the “healthy” nutrient content claim as well as Dietary Guidance Statements, and the parameters for such claims must be appropriate to the product category. CRN suggests FDA first

⁸ Comment from Council for Responsible Nutrition to FDA on “Proposed Rule: Food Labeling: Nutrient Content Claims; Definition of Term “Healthy.” Docket No. FDA-2016-D-2335. Comment ID: FDA-2016-D-2335-1564. Posted Feb.16, 2023. <https://www.regulations.gov/comment/FDA-2016-D-2335-1564>.

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issue a final rule on the definition of the “healthy” nutrient content claim before finalizing the guidance on Dietary Guidance Statements to ensure consistency in how FDA views attributes of healthy or nutritious food products.

Thank you for considering our comments.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Haiuyen Nguyen', written in black ink.

Haiuyen Nguyen

Vice President, Regulatory & Nutrition Policy