



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Submitted via *Regulations.gov*

September 22, 2023

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

RE: Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry; Availability; Extension of the Comment Period (FDA-2023-D-1027)

Dear Division of Dockets Management,

The Healthcare Nutrition Council (HNC) is commenting on the U.S. Food and Drug Administration's (FDA or agency) request for information and comments on the "Questions and Answers About Dietary Guidance Statements in Food Labeling: Draft Guidance for Industry; Extension of the Comment Period" (FDA-2023-D-1027), which was published in the *Federal Register* on March 27, 2023. HNC is an association representing manufacturers¹ of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medical foods, and parenteral nutrition (PN). Our mission is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access of essential nutrition support therapies across the continuum of care.

Important considerations should be made for specialized nutrition products like oral nutrition supplements (ONS) when considering the labeling recommendations in the draft guidance for Dietary Guidance Statements in Food Labeling. ONS are high quality, scientifically based and nutrient dense foods for special dietary use (FSDU) which are intended to provide supplemental or sole source nutrition for individuals who are at risk of malnutrition or cannot achieve baseline nutritional intake from a normal diet. ONS are often ready-to-drink liquids, powders, and puddings. Under the current guidelines, ONS are not included in the food group equivalency criteria. We are writing to confirm our understanding that the agency intended to exclude this product category.

Up to one in two older adults are at risk for malnutrition^{2,3} and ONS often provide a complete and balanced profile of macro- and micronutrients to help them meet their nutrition goals and move toward a healthy dietary pattern. The WHO recognizes malnutrition as a major problem affecting older adults, and has published a strong recommendation that ONS with dietary advice should be recommended to older people affected by undernutrition.⁴ The populations who use ONS products often have nutritional goals which are vastly different from the general, healthy population and the specialized nutrition product category should be evaluated differently than conventional foods.

¹ HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.

² The Malnutrition Quality Collaborative. National Blueprint: Achieving Quality Malnutrition Care for Older Adults. Washington, DC: Avalere and Defeat Malnutrition Today. March 2017.

³ Kaiser, MJ; Bauer, JM; Ramsch, C; Ulter, W; Guigoz, Y; Cederholm, T; Thomas, DR; Anthony, PS; Charlton, KE; Maggio, M; Tsai, AC; Vellas, B; and Sieber, CC. Frequency of malnutrition in older adults: a multinational perspective using the mini nutritional assessment. *Journal of the American Geriatrics Society*. 2010; 58(9): 1734-1738.

⁴ World Health Organization. Integrated care for older people: guidelines on community-level interventions to manage declines in intrinsic capacity. Geneva: World Health Organization; 2017. License: CC BY-NC-SA 3.0 IGO. Retrieved from <https://www.who.int/ageing/publications/guidelines-icope/en/>.

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We applaud FDA's efforts to improve public health by revising the guidelines for Dietary Guidance Statements to more closely align with the latest scientific evidence, existing nutrition labeling regulations, and consumer eating habits. We ask the agency to consider aligning the nutrient and food group criteria with the proposed "healthy" definition for consistency and to publish the final "healthy" definition prior to publishing the Dietary Guidance Statements final guidance document. We ask the above requests be taken into consideration as this guidance is finalized and that ONS have the option to include an accurate Dietary Guidance Statement.

In summary, we ask FDA to clearly state in the preamble of the final guidance that there is flexibility for certain products that would otherwise not meet the definition's criteria and that the Dietary Guidance Statement criteria was intended for conventional foods but could be applied to specialized nutrition products. We ask FDA to confirm these specialized nutrition products, such as ONS along with other FSDU products and medical foods, were meant to be excluded from the Dietary Guidance Statement guidance and to affirm the option to use of these statements in the label of these products are subject to the guidance and should not be false or misleading.

We appreciate the opportunity to provide comments on this guidance. Please let me know if there are any questions.

Sincerely,

A handwritten signature in black ink that reads "Robert Rankin". The signature is written in a cursive, flowing style.

Robert Rankin
Executive Director