



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Submitted via *Regulations.gov*

February 16, 2023

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

RE: Healthcare Nutrition Council Comments re Food Labeling: Nutrient Content Claims; Definition of Term “Healthy” (FDA-2016-D-2335)

Dear Division of Dockets Management,

The Healthcare Nutrition Council (HNC) is commenting on the U.S. Food and Drug Administration’s (FDA or agency) proposed rule on the “Food Labeling: Nutrient Content Claims; Definition of Term “Healthy” (FDA-2016-D-2335), which was published in the *Federal Register* on September 29, 2022. 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.

HNC supports the FDA’s efforts to update the definition of “healthy” to reflect the latest scientific evidence and better assist consumers in making healthy dietary choices. Our previously submitted comments for your consideration are found on the HNC website [2018 here](#) and [2017 here](#). Following are specific comments on this proposed rule.

HNC believes unique considerations should be made for specialized nutrition products like oral nutrition supplements (ONS). 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 adequate nutritional intake from a normal diet.

We understand FDA’s intention to establish criteria which aligns with the Dietary Guidelines for Americans. However, we believe additional consideration for ONS is warranted. Under the proposed criteria ONS products will not be eligible to bear the “healthy” claim or the potential symbol currently being assessed by FDA. The implication that such products are unhealthy is contrary to the role they play in improving the nutritional status of individuals who are undernourished and may lead to confusion for those who rely on them. ONS have a well-established clinical purpose. 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 improve their nutritional status. The WHO recognizes malnutrition as a major problem in older adults and has published a strong recommendation that ONS with dietary advice should be recommended to older

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.



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people affected by undernutrition.⁴ The populations who use ONS products often have nutritional goals which are vastly different from the general, healthy population. However, the criteria for “healthy” is based on dietary guidelines which are intended for the general, healthy population. For these reasons HNC recommends FDA exclude ONS from the criteria for the use of “healthy.”

If ONS products are not expressly excluded from the criteria for the use of “healthy” HNC recommends FDA maintain nutrient criteria as an option in addition to the new food group criteria currently outlined in the proposed rule. We believe this approach would provide the flexibility necessary to promote healthy dietary choices across different groups of consumers and is aligned with consumer needs and preferences. ONS offer several nutrients, some of which are identified as nutrients of public health concern in the Dietary Guidelines for Americans (DGA), including but not limited to protein, vitamin A, vitamin C, vitamin D, vitamin E, choline, calcium, magnesium, dietary fiber, iron, and potassium. HNC proposes that products which contain at least 10% of the RDI or DV per reference amount customarily consumed (RACC) of at least one nutrient of public health concern fulfill the nutrient criteria option.

HNC also requests FDA to clarify in the final rule that the “healthy” definition is limited to the implied nutrient content claim and words which are currently defined as synonyms (i.e., “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”). We also request that FDA clarify the criteria does not apply to structure function claims, health claims, or other labeling statements. Using the word in a phrase such as “supports a healthy diet” or “use as part of a healthy diet” should not prompt a product for non-compliance to the claim.

In summary, we ask FDA to clearly state in the preamble of the final rule that there is flexibility for certain products that would otherwise not meet the definition’s criteria. Specifically, we ask that ONS be excluded from the criteria. If ONS are not expressly excluded from the criteria we request nutrient criteria be maintained as an option. Lastly, we request FDA clarify the scope of the implied nutrient content claim “healthy” by stating the criteria is limited to implied nutrient content claims and existing synonyms and should not apply to structure function claims, health claims, or other labeling statements.

We applaud FDA’s efforts to improve public health by revising the definition of “healthy” to more closely align with the latest scientific evidence, existing nutrition labeling regulations, and consumer eating habits. To help enhance these efforts, we request that the above requests be taken into consideration as this definition is finalized and that ONS have the option to be considered “healthy”. In future labeling for front-of-pack, we ask FDA to exclude medical foods, FSDU, and ONS since they are specialized nutrition products.

We appreciate the opportunity to provide comments on this impactful regulation. 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

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/>.