



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Submitted via [regulations.gov](https://www.regulations.gov)

July 11, 2025

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

RE: HNC Comments on Docket No. FDA-2024-N-2910 for “Food Labeling: Front-of-Package Nutrition Information”

Dear Division of Dockets Management,

The Healthcare Nutrition Council (HNC) is commenting on the U.S. Food and Drug Administration’s (FDA) proposed rule titled “Food Labeling: Front-of-Package Nutrition Information” that was published in the *Federal Register* on January 16, 2025. HNC represents 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 for people that require or benefit from advanced and specialized nutrition.

HNC acknowledges the agency’s effort in developing the front-of-package labeling proposed rule and appreciates the opportunity to provide comments. Consistent with current nutrition labeling exemptions for specialized nutrition products classified as medical foods,² HNC believes medical foods should be exempt from front-of-package labeling and appreciates that the proposed rule would provide for this exemption.³ Additionally, HNC also believes ONS, often categorized as foods for special dietary use (FSDU), and oral rehydration solutions (ORS), should be exempt from front-of-package labeling requirements.

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

² [21 CFR 101.9\(j\)\(8\)](#) and 21 USC 360ee(b)(3).

³ § 101.9(j), appears that medical foods (as defined by the Orphan Drug Act) are listed as exempt from nutrition labeling:

(j) *The following foods are exempt from this section or are subject to special labeling requirements:*

(8) *Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if:*

(i) *It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;*

(ii) *It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;*

(iii) *It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;*

(iv) *It is intended to be used under medical supervision; and*

(v) *It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.*

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Our request to add to the current list of exemptions is included here as number 5 (in bold). We ask FDA to include these exemptions in the final regulation.

Exemptions.

The following foods are exempt from the requirements in this section:

- (1) Any food exempt from § 101.9 under § 101.9(j), unless otherwise stated in this section;
- (2) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches;
- (3) Packages marketed as gifts that contain a variety or assortment of foods;
- (4) The unit containers in a multiunit retail food package where:
 - (i) The unit containers are exempt from Nutrition Facts labeling in accordance with § 101.9(j)(15); and
 - (ii) The multiunit retail food package label bears the Nutrition Info box in accordance with this section; and
- (5) Foods that are required or recommended by a healthcare professional and are formulated for use by an individual with a disease or condition who has special dietary needs.**

As explained in more detail below, ONS and ORS are formulated to supply a particular dietary need and are not intended to be consumed as a conventional food. Individuals purchasing and consuming ONS and ORS are doing so for specific dietary and nutritional needs due to a disease or condition. The proposed front-of-package labeling requirements would confuse consumers seeking to purchase ONS and ORS for specific dietary needs which could lead to poor compliance or cause them to purchase a product that would not fulfill their dietary needs.

ONS and ORS are included in clinical guidelines for patient care, often prescribed or recommended by healthcare professionals (HCPs), proven effective for the target population, HSA/FSA eligible (when prescribed), and may be covered by Medicaid and certain health insurance plans. ONS are high-quality, scientifically based and nutrient-dense foods for special dietary needs, such as for the prevention or treatment of malnutrition, and are typically available as ready-to-drink liquids (milk-style or juice-style) and powders. Other forms, such as puddings, may also be available. Separately, ORS are intended for individuals who are experiencing dehydration or are at risk of dehydration due to diarrhea or vomiting, such as children with norovirus or influenza. These ORS products are primarily comprised of glucose (sugar) and electrolytes (sodium). The glucose-to-electrolyte ratio in ORS is crucial for their effectiveness. ONS and ORS products are often recommended by HCPs and provided in healthcare settings and are also available at retail without a prescription. Importantly, ONS and ORS products are not intended to be used as conventional foods and are typically located in a designated retail area near the pharmacy.

Health and Economic Considerations

Unlike most conventional foods, ONS are formulated to address particular nutritional needs and are often used as a means to prevent and treat malnutrition; as explained above, these products are not intended to be consumed as conventional foods. ONS have been shown to help reduce healthcare costs related to malnutrition and their intended use is unique and different from conventional foods. If such products were required to conform to front-of-package nutrition information, as proposed, the intended population might be discouraged or confused over the

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intended use of these products, which could lead to poor compliance and cause them to purchase a product that does not fulfill their dietary need.

According to the Centers for Disease Control and Prevention (CDC), deaths from malnutrition have doubled from 9,300 deaths in 2018 to 20,500 deaths in 2022.⁴ Up to one in two older adults are at risk for malnutrition,^{5,6} making it a significant public health concern related to nutrition. Malnutrition is a critical, complex problem affecting individuals in all settings of care. Older adults are disproportionately affected by malnutrition, which is present in 30-50% of hospitalized patients aged 65 years and older; additionally, more than a third of community dwelling older adults are at risk for malnutrition or are malnourished.^{7,8} Malnourished individuals experience increased morbidity, complications and mortality, longer hospitalizations, and more readmissions and institutionalizations and need for ongoing services. These complications may result in increased healthcare costs as well as increased risks for functional disability, frailty, and falling. Malnutrition costs associated with older adults aged 65 years and older who are the most at risk for malnutrition, and largely dependent on Medicare, are estimated at \$51.3 billion annually.⁹

Overall healthcare expenditure for disease-associated malnutrition across eight major diseases was found to be \$156.7 billion per year according to findings from the National Health Interview Survey, the National Health and Nutrition Examination Survey, and CDC.¹⁰ In addition, malnourished patients and patients with nutrition-related or metabolic issues are frequently readmitted to the hospital.¹¹ Further, the average costs per readmission for patients with malnutrition were found to be 26-34 percent higher (\$16,900 to \$17,900) compared to those without malnutrition (\$13,400).¹²

⁴ Kaiser Health News. U.S. Malnutrition Deaths Have More Than Doubled. *U.S. News and World Report*. April 13, 2023. Retrieved from: <https://www.usnews.com/news/health-news/articles/2023-04-13/deaths-from-malnutrition-have-more-than-doubled-in-the-us#:~:text=By%20Phillip%20Reese%20%7C%20KFF%20Health%20News&text=The%20same%20trend%20occurred%20nationwide,for%20Disease%20Control%20and%20Prevention>.

⁵ Kaiser Health News. U.S. Malnutrition Deaths Have More Than Doubled. *U.S. News and World Report*. April 13, 2023. Retrieved from: <https://www.usnews.com/news/health-news/articles/2023-04-13/deaths-from-malnutrition-have-more-than-doubled-in-the-us#:~:text=By%20Phillip%20Reese%20%7C%20KFF%20Health%20News&text=The%20same%20trend%20occurred%20nationwide,for%20Disease%20Control%20and%20Prevention>.

⁶ 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.

⁷ Silver, Heidi; Kelsey Jones Pratt, Michelle Bruno, Joe Lynch, Kristi Mitchell, and Sharon McCauley. Effectiveness of the malnutrition quality improvement initiative on practitioner malnutrition knowledge and screening, diagnosis, and timeliness of malnutrition-related care provided to older adults admitted to a tertiary care facility: a pilot study. *Journal of the Academy of Nutrition and Dietetics*. 2017; 118(1): 101-109.

⁸ 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.

⁹ Snider J, et al: Economic burden of community-based disease-associated malnutrition in the United States. *JPEN J Parenteral Enteral Nutr*. 2014;38:55-165.

¹⁰ Snider, Julia; Linthicum, Mark; Wu, Yanyu; LaVallee, Chris; Lakdawalla, Darius; Hegazi, Rafaat; and Matarese, Laura. (2014). Economic Burden of Community-Based Disease-Associated Malnutrition in the United States. *JPEN*. 38. 10.1177/0148607114550000.

¹¹ Braunschweig C, Gomez S, Sheean PM. Impact of declines in nutritional status on outcomes in adult patients hospitalized for more than 7 days. *J Am Diet Assoc*. 2000;100:1316-1322.

¹² Fingar K, Weiss A, Barrett M, Elixhauser A, Steiner C, Guenter P, and Hise Brown M. All-Cause Readmissions Following Hospital Stays for Patients with Malnutrition, 2013. *HCUP Statistical Brief #218*. 2018. 1-18.



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Most people can achieve adequate nutrition and protein intake, but some require ONS to help meet their needs. Studies have shown the use of ONS can be used to treat and prevent malnutrition in hospitals and for those living in the community. Using ONS with caregiver education reduced 30-day readmission rates and length of stay in hospitals among older adults with malnutrition by 2 days on average.¹³ The NOURISH study found malnourished patients randomized to receive high-protein ONS for 90 days post-discharge had improved nutritional status and decreased mortality compared to those in the placebo group.^{14,15} Other studies have found use of ONS in hospitalized patients reduced 30-day readmission rates, reduced length of stay, reduced incidences of pressure ulcers, reduced risk of complications from chronic disease, decreased length of antibiotic therapy, and ultimately reduced health care costs.^{16,17,18}

ONS have also been shown to reduce hospitalization and medical care costs in non-hospital and community settings.^{19,20} The use of ONS as part of a nutrition-focused quality improvement program in home health agencies for patients with (or at risk of) malnutrition led to significant reductions in the relative risk of hospitalization (by 12-24%) and cost savings of \$1,500 per patient treated.²¹ Medicare patients aged 65 years and older who were provided ONS had a 16% reduction in length of hospital stay and a 15.8% cost savings.²² A review of the cost and cost-effectiveness of using standard ONS in community and care homes showed a mean cost savings of 9.2%.²³

Rationale to Exempt ONS and ORS

In the proposed rule, FDA considered whether to exempt products which may have similarities to ONS and ORS—electrolyte drinks, glucose products, and nutrition shakes that are subject to the Nutrition Facts labeling requirement—from the requirement to display a Nutrition Info box, but FDA decided against this exemption. Specifically, the preamble explains that “these products are often conventional foods and are marketed and used for a variety of purposes,

¹³ Silver, Heidi; Kelsey Jones Pratt, Michelle Bruno, Joe Lynch, Kristi Mitchell, and Sharon McCauley. Effectiveness of the malnutrition quality improvement initiative on practitioner malnutrition knowledge and screening, diagnosis, and timeliness of malnutrition-related care provided to older adults admitted to a tertiary care facility: a pilot study. *Journal of the Academy of Nutrition and Dietetics*. 2017; 118(1): 101-109.

¹⁴ Goates, Scott; Kristy Du, Carol Braunschweig, and Mary Beth Arensberg. Economic Burden of Disease-Associated malnutrition at the State Level. *PLOS ONE*. 2016; 11(9): 1-15.

¹⁵ Deutz, NE; Matheson, EM; Matarese, LE; Luo, M; Baggs, GE; Nelson, JL; Hegazi, RA; Tappenden, KA; and Ziegler, TR. Readmission and mortality in malnourished, older, hospitalized adults treated with a specialized oral nutritional supplement: A randomized clinical trial. *Clin Nutr*. 2016; 35(1): 18-26.

¹⁶ Goates, Scott; Kristy Du, Carol Braunschweig, and Mary Beth Arensberg. Economic Burden of Disease-Associated malnutrition at the State Level. *PLOS ONE*. 2016; 11(9): 1-15.

¹⁷ Philipson, TJ; Snider, JT; Lakdawalla, DN; Stryckman, B; and Goldman, DP. Impact of oral nutritional supplementation on hospital outcomes. *Am J Manag Care*. 2013; 19(2): 121-128.

¹⁸ Mullin, GE; Fan, L; Sulo, S; and Partridge, J. The Association between Oral Nutritional Supplements and 30-Day Hospital Readmissions of Malnourished Patients at a U.S. Academic Medical Center. *Journal of the Academy of Nutrition and Dietetics*. 2019; 119(7): 1168-1175.

¹⁹ Elia, M; Normand, C; Laviano, A; and Norman, K. A systematic review of the cost and cost effectiveness of using standard oral nutritional supplements in community and care home settings. *Clin Nutr*. 2016; 35:125-137.

²⁰ Arnaud-Battandier, F; Malvy, D; Jeandel, C; Schmitt, C; Aussage, P; Beaufriere, B; and Cynober, L. Use of oral supplements in malnourished elderly patients living in the community: a pharmaco-economic study. *Clin Nutr*. 2004; 23:1096-1103.

²¹ Riley, K; Sulo, S; Dabbous, F; Partridge, J; Kozmic, S; Landow, W; VanDerBosch, G; Falson, MK; and Sriram, K. Reducing Hospitalizations and Costs: A Home Health Nutrition-Focused Quality Improvement Program. *JPEN*. 2019; 0(0): 1-11.

²² Thomas DR, Zdrowski CD, Wilson MM, et al. Malnutrition in subacute care. *Am J Clin Nutr*. 2002;75:308-313.

²³ Medical Nutrition International Industry. 'Better care through better nutrition: value and effects of medical nutrition' 4th Edition. 2018. Retrieved from: https://www.medicalnutritionindustry.com/files/user_upload/documents/medical_nutrition/2018_MNI_Dossier_Final_web.pdf



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such as rehydration during or after exercise, providing energy, or general meal replacement. When these products are conventional foods and are required to bear Nutrition Facts labels, they are often used by healthy individuals and the general population; accordingly, we are not proposing to exempt such products from bearing a Nutrition Info box.”

We recognize the proposed rule contemplated that products that may be perceived as similar to ONS and ORS may be used by healthy individuals. ONS and ORS, however, are formulated for use by an individual with a disease or condition who has special dietary needs. Nonetheless, such ONS and ORS products may in some cases bear Nutrition Facts labeling, such that the inclusion of Nutrition Facts labeling in the case of ONS and ORS cannot be considered dispositive for the inclusion of front-of-package labeling. Again, ONS are scientifically formulated nutrient-dense foods designed and intended to provide supplemental (often to meet caloric or protein targets) or a sole source of nutrition for individuals who are often at risk of malnutrition or are unable to achieve adequate nutritional intake from a normal diet. Such ONS products, therefore, are often recommended by HCPs not as a casual meal replacement but for a clinical purpose. Similarly, ORS products are recommended by HCPs and are used differently than products intended for “rehydration during or after exercise” as they are intended for individuals experiencing dehydration due to diarrhea or vomiting. ORS products contain levels of glucose and electrolytes that have been extensively tested in clinical trials and shown to be effective in treating of managing mild to moderate dehydration. Guidelines supporting glucose and electrolyte levels found in ORS products have been published by the World Health Organization, the CDC, the American Academy of Pediatrics, and the European Society for Paediatric Gastroenterology Hepatology and Nutrition. In such cases, individuals recommended these products would not necessarily be considered “healthy individuals” as FDA suggests.

Further, in some instances, ONS products are specifically designed with higher caloric or protein content and specific nutrient profiles to help meet the increased nutritional needs of patients in critical states, such as those undergoing chemotherapy or hemodialysis. These products with higher calories or protein content serve a distinct purpose aiding individuals in reaching their nutritional goals and, thus, outcomes. Similarly, ORS products contain a glucose-to-electrolyte ratio necessary for individuals who need to replenish nutrients lost during dehydration due to diarrhea or vomiting. Given the specialized intended use of these products by at-risk populations, the possibility that a “healthy individual” might also consume the product should not form the basis to consider these products akin to conventional foods for the purposes of front-of-package labeling requirements.

In summary, populations who use ONS and ORS most often have nutritional goals that differ from those of general, “healthy individuals” and do so under the direction of a physician, registered dietitian, or other HCP. Additional labeling intended to help ONS and ORS consumers interpret nutrition information would be unnecessary and could cause confusion regarding the nutritional benefits of these products, which could impact compliance and hinder outcomes.

International Exemptions

Importantly, and to illustrate this point, several countries around the world have already exempted these types of products for the same reasons we have stated above. These include:



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Country	Approach	Relevant Exemptions
Canada	Mandatory	<ul style="list-style-type: none"> • Formulated liquid diets • Meal replacements • Nutritional supplements • Natural health products
Mexico	Mandatory	<ul style="list-style-type: none"> • Specialized nutrition
Brazil	Mandatory	<ul style="list-style-type: none"> • Formulas for enteral nutrition • Food supplements
Chile	Mandatory	<ul style="list-style-type: none"> • Food for special medical purposes
Colombia	Mandatory	<ul style="list-style-type: none"> • Food for special medical purposes
France	Voluntary	<ul style="list-style-type: none"> • Food for special medical purposes • Food supplements
United Kingdom	Voluntary	N/A - Business can decide on which foods the information will be most useful to consumers.
Australia/ New Zealand	Voluntary	<ul style="list-style-type: none"> • Food for special medical purposes • Formulated products for young children

HNC asks the agency to please consider exemptions made in other countries and to allow for the same or comparable products to be exempted from the front-of-package requirement in the United States.

Consumer Study

A study was conducted with participants of varying levels of prior nutrition knowledge, who were asked to view two products and determine which product was more healthful by using a “facts up front” or front-of-package nutrition information. Attention to the nutritional information was assessed via eye tracking to determine how front-of-package information influenced their

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decision-making process. Results demonstrated a negative correlation between attention to calories, fat, and sodium indicating that participants over-relied on these nutrients. The researchers acknowledged this study would indicate confusion surrounding what constitutes a meaningful change across products when the front-of-package information was added. Individuals with less nutrition knowledge were misled by calorie, sodium, and fat information displayed on the front of the pack.²⁴ Without proper education, HNC is concerned about potential consumer misinterpretation of front-of-package labeling if displayed on ONS and ORS products. For instance, consumers and patients could overlook the benefits of the ONS, such as protein and vitamins and minerals, because the positive nutrients are not displayed on the front. There could be unintended consequences where consumers and patients avoid using these products, even when recommended by their HCP, due to confusion or misunderstanding caused by seeing the fat content, for example, despite the product being specifically formulated to serve as a supplemental source of macronutrients, including dietary fat, or as sole source nutrition. Consumers and patients in need of an ORS may be concerned by the front-of-package labeling for added sugar and sodium when it is the levels of these nutrients that make them effective. This study reinforces HNC's concern that mandating front-of-package labeling for specialized nutrition products may result in consumer confusion.

Legal Considerations

ONS and ORS currently comply with FDA regulations and guidance regarding Nutrition Facts labeling, nutrition content, and structure/function claims. We believe consumers are already receiving accurate information about these products that comply with 403(q) (nutrition labeling) and 403(a)(1) (false and misleading). The proposed rule states "The NLEA, which added section 403(q) of the FD&C Act, specifies certain nutrients to be declared in nutrition labeling, including saturated fat and sodium, and authorizes FDA to require the declaration of other nutrients if we determine that the declaration will provide information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices."

Further, FDA included in the proposal "As contemplated by section 2(b)(1)(A) of the NLEA, the proposed Nutrition Info box, including its interpretive descriptions of certain nutrient levels, would present nutrition information required to be placed on the label or labeling of foods under section 403(q) in a manner that allows consumers to readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet (21 U.S.C. 343 note)."

We have not seen data from FDA, such as their focus groups, that demonstrated how ONS, ORS, or specialty foods would be handled and educated on differently from conventional foods. While FDA may have authority to require front-of-package information on conventional foods, we believe FDA does not have the same authority to require this information on specialized nutrition products, like ONS and ORS, because the information would not assist consumers in "maintaining healthy dietary practices" and would not enable consumers to understand the products' "relative significance in the context of the total daily diet." Front-of-package information on specialized nutrition products, including ONS and ORS, could cause confusion or mislead consumers. FDA cannot, under the First Amendment, compel misleading speech.

²⁴ Miller LMS, Cassady DL, Beckett LA, Applegate EA, Wilson MD, Gibson TN, et al. (2015) Misunderstanding of Front-Of-Package Nutrition Information on US Food Products. PLoS ONE 10(4): e0125306. doi:10.1371/journal.pone.0125306



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In conclusion, ONS can be used as sole source nutrition and ORS are used to replenish glucose and electrolytes lost during dehydration due to diarrhea or vomiting. As a result, the products often provide higher amounts of calories, fats, added sugar, or sodium by design. Front-of-package labeling designed for the “general population” could inadvertently discourage or create unintentional confusion for the use of such essential nutrition intended for specific patient populations. We are concerned with the prevalence of malnutrition, as one example, and any deterrent to the use of these products to address malnutrition. Such products have helped many individuals improve their lives and save on healthcare costs. We are greatly concerned by the potential for unintended consequences if front-of-package labeling is applied to such products: confusing or misleading consumers or patients who would otherwise benefit from these products, inadvertently discouraging purchase due to nutrition guidance not intended to meet their needs, and undermining recommendations made by qualified HCPs. For these reasons, HNC respectfully requests that ONS and ORS be exempt from front-of-package labeling. Such exemptions can be addressed through modification of language in the final rule, as proposed above.

HNC is available to collaborate with FDA on our request, if more information is needed, and appreciates your consideration of these comments. Please contact Berit Dockter MPP, RD, LD bdockter@healthcarenutrition.org if you have any questions.

Sincerely,

A handwritten signature in black ink that reads "Carla A. Saunders". The signature is written in a cursive style with a large initial "C".

Carla Saunders
Executive Director