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By Electronic Submission

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

Re: Proposed Rule: Food Labeling: Front of Package Nutrition Information. Docket No. FDA-2024-N-2910. 90 FR 5426 (January 16, 2025).

The Council for Responsible Nutrition (CRN)[1] appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) on its proposed rule, "Food Labeling: Front of Package Nutrition Information" (Proposed Rule). CRN supports federal government efforts to reduce the prevalence of diet-related chronic conditions in the U.S., such as empowering consumers to purchase and consume food products that support healthy dietary patterns. The agency's Proposed Rule aims to facilitate consumer understanding of nutrition information for food products "at-a-glance" by requiring use of a "Nutrition Info" box on the Principal Display Panel (PDP) of food packages that indicate the level (amount and percent Daily Value) of three nutrients – saturated fat, sodium, and added sugars – and whether those levels are "high," "medium," or "low" to help consumers determine how each food product fits into their daily diet. Saturated fat, sodium, and added sugars are nutrients that have been identified in the *Dietary Guidelines for Americans, 2020-2025* as nutrients to limit because they are

[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 180 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.

overconsumed in the U.S. population and are linked to diet-related chronic conditions. The "Nutrition Info" box is a snapshot of the Nutrition Facts panel typically located on the Information Panel where the consumer (if facing the PDP) would likely need to turn the product to view. FDA has proposed this mandatory "Nutrition Info" box on food packages marketed for adults and children 4 years and older. The agency has also proposed to exempt dietary supplements from mandatory front-of-package nutrition labeling (FOPNL) for several reasons, including that dietary supplements are intended to supplement the diet and are not a core part of the diet; they are subject to their own nutrition labeling provisions separate from foods and are required to bear a Supplement Facts label, not the Nutrition Facts label; and dietary supplements generally do not contain appreciable levels of the three nutrients to limit. CRN agrees that dietary supplements should be exempt from the FOPNL rule (21 CFR 101.6), if finalized.

U.S. consumers use dietary supplements as part of a healthy lifestyle.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines dietary supplements as products intended to be consumed orally to supplement the diet and may contain dietary ingredients including vitamins, minerals, herbs and other botanicals, amino acids, and other dietary substances, as well as concentrates, metabolites, constituents, extracts, or combinations of any of the categories of dietary ingredients. Dietary supplements are typically consumed as tablets, capsules, softgels, and chews. They also come in other forms such as gummies, liquids, and powders. The common serving size is relatively small compared to food serving sizes e.g., 1 or 2 tablets, softgels, gummies, etc. As defined, dietary supplements typically do not contain substantial amounts of macronutrients and calories as food products intended to comprise a core part of the diet. Instead, they provide micronutrients such as vitamins and minerals and other dietary substances to supplement the diet and to promote health and wellness. For example, dietary supplements provide essential nutrients, including vitamin D, calcium, potassium, and dietary fiber, which are underconsumed by the U.S. population; and the *Dietary Guidelines for Americans, 2020-2025* has identified these nutrients as nutrients of public health concern because their underconsumption is linked to adverse health conditions. Dietary supplements typically do not provide nutrients to limit, such as saturated fat, sodium, and added sugars. If they do contain these nutrients, rarely do they contribute a significant amount.

U.S. consumers use dietary supplements as part of a healthy lifestyle. CRN's 2024 Consumer Survey reports that the most popular products are vitamin and mineral supplements; and the most common reasons cited for using dietary supplements are for overall health and wellness; immune health; energy; skin/hair/nail care; and filling nutrient gaps in the diet.[2] In addition, users of dietary supplements report that supplements are essential to maintaining health and

[2] CRN-IPSOS Consumer Survey on Dietary Supplements. 2024. Available at: https://www.crnusa.org/2024survey.

are significantly more likely than non-users to report other healthy behaviors such as eating a balanced diet, exercising regularly, visiting their doctor regularly, or getting a good night's sleep. Dietary supplement consumers are likely health-conscious and accustomed to reviewing nutrition information in the Supplement Facts label to make informed decisions about supplementing their diet. It is likely that consumers of dietary supplements would go beyond glancing at the "Nutrition info" box to make purchasing decisions and may not find such a label useful, especially when the information is focused on nutrients rarely present in dietary supplements.

Dietary supplements follow nutrition labeling regulations specific to the category.

Although dietary supplements are regulated as a category of food, they are subject to separate nutrition labeling provisions at 21 CFR 101.36; are exempt from nutrition labeling provisions for food at 21 CFR 101.9; and thus, supplements bear the Supplement Facts label instead of the Nutrition Facts label. The Supplement Facts label presents the product serving size; servings per container; dietary ingredients, the quantitative amount, and percent Daily Value of each, if Reference Daily Intakes (RDIs) have been established for the dietary ingredient (nutrient), and other ingredients. The Supplement Facts label will also declare total calories, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, vitamin D, calcium, iron, and potassium when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with 21 CFR 101.9(c). Many dietary supplements, in accordance with 21 CFR 101.36, do not declare saturated fat, sodium, and added sugars on the Supplement Facts label because they do not contain any or enough of these nutrients to warrant declaration.

Dietary supplements do not typically contain nutrients to limit.

Data show the prevalence of dietary supplements with a declaration of sodium, saturated, and added sugars is low (below 2 percent). To demonstrate, CRN conducted a survey of the Supplement Online Wellness Library (OWL), our online database of dietary supplement and functional food products on market.[3] The Supplement OWL facilitates transparency into the marketplace, providing information about products, who makes them, and what ingredients are in the products. Manufacturers participating in the Supplement OWL provide up-to-date product labels for the goods they offer to consumers, including Supplement Facts and Nutrition Fact labels. As of March 2025, there are over 13,000 products bearing the Supplement Facts label in the Supplement OWL. Our survey pulls data from each unique Supplement Facts label,

[3] CRN. Supplement OWL. Available at: https://supplementowl.org. Accessed 5 March 2025.

which is provided for each variety of a product e.g., flavor and count/size. See Table 1 for more details.

Saturated Fat

Saturated fat is not typically found in dietary supplements; however, some products that contain saturated fat contribute amounts that are defined as "low" under the Proposed Rule. For example, products such as fish oils providing omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are expected to contain saturated fat as a natural constituent of the fish oil. It may be common to find a fish oil product currently available in the market that contains 2400 mg fish oil per serving and 1 g (5% Daily Value) of saturated fat, which would be "low" under the Proposed Rule. Further, some dietary supplements contain a small amount of saturated fat in the ingredients used as excipients and carriers, such as medium chain triglycerides and soybean oil. Such uses do not contribute significantly to the saturated fat Daily Value.

In fact, less than one percent of dietary supplement products on market and listed in the Supplement OWL database contain saturated fat levels that would be defined as "high;" less than one percent of products contain levels that would meet the proposed definition of "medium;" and three percent of products contain levels that would be considered "low." In addition, nearly 96 percent of products do not contain saturated fat or contain saturated fat in such insignificant levels that do not warrant declaration in accordance with 21 CFR 101.9.

Sodium

Many dietary supplements do not contain sodium as a dietary ingredient. A particular category of supplements includes sodium (from sodium bicarbonate, sodium chloride, and other sources) among other ingredients for the intended use of maintaining electrolyte balance and aiding rehydration. There is a range of sodium levels in these products, depending on the formulation; levels of sodium may fall into any of the proposed "low," "medium," or "high" ranges per serving. Electrolyte products are functional, in part, because of the levels of sodium and other electrolytes in them.

Data from the Supplement OWL indicate that less than one percent of supplement products contain sodium levels per serving that would be indicated as "high" under the Proposed Rule; less than three percent of products contain sodium levels that would be labeled "medium"; and ten percent of products contain sodium levels that would be considered "low." Nearly 87 percent of dietary supplement products do not contain sodium or contain sodium at such insignificant levels that need not be declared on the Supplement Facts label in accordance with 21 CFR 101.9.

Added Sugars

Many dietary supplements do not include added sugars. However, certain types of products contain added sugars such as certain gummies. For example, supplements in the gummy form may include 1-2g added sugars/serving, which is 2-4% of the Daily Value. Some gummy products include 5-6g added sugars/serving, accounting for 10-12% of the Daily Value. Very rarely do gummy supplements contain more than these levels of added sugars per serving. Some gummy products use sweeteners and include no added sugars.

Supplement OWL data indicate that almost zero (0.1) percent of supplement products contain amounts of added sugars per serving that would be indicated as "high" under the Proposed Rule; less than four percent of products contain added sugars in amounts that would be labeled "medium;" and less than five percent of products contain added sugars in amounts that would be considered "low." Nearly 91 percent of products contain insignificant amounts or no added sugars, so added sugars are not declared on the Supplement Facts label, which is in accordance with 21 CFR 101.9.

The vast majority dietary supplements do not contribute to sodium, saturated fat, and added sugars in the diet; therefore, nutrition labeling of many dietary supplements does not include listings of these nutrients. Mandatory FOPNL focused on these nutrients to limit imposed on dietary supplements would not be practical for manufacturers or useful for consumers. Instead, it would require supplement manufacturers to bear additional burdens of unnecessary label changes without clear public health benefit.

Table 1. Sodium, saturated fat and added sugars content of dietary supplements in a large, online database.

Products with Supplement Facts Label

	High 20% Daily Value or more	**Medium 6 – 19 % Daily Value**	**Low 5 % Daily Value or less**	**Nutrient Not Listed**	**Total Number of Products**
Sodium	57(0.43%)	326 (2.45%)	1339 (10.1%)	11,561 (87.0%)	13283
Saturated Fat	83 (0.62%)	76 (0.57%)	385 (2.90%)	12,739 (95.9%)	13283
Added Sugars	13 (0.10%)	519 (3.91%)	599 (4.51%)	12,152 (91.5%)	13283

Additional considerations related to proposed FOPNL for dietary supplements

- Consumer research on perception and understanding of FOPNL: Prior to issuing the Proposed Rule, FDA conducted consumer research, including two focus groups and an experimental study.[4] The focus groups involved participants examining the Nutrition Facts labels of mock food and beverages, such as cereal, frozen vegetable grain bowl, marinara sauce, sliced bread, coffee, soda, and orange juice. The experimental study asked participants to examine three different food products (cereal, frozen entree, canned soup) to answer questions about the product, including questions about its healthfulness and nutrient content. While it is reasonable that FDA used mock food types that are more commonly available to general consumers in its research, the lack of dietary supplement mock labels limits the extrapolation of research data to consumers that use dietary supplements. By extension, the impact of FOPNL on dietary supplements is not clear.

- Dietary supplement packaging limitations: Most dietary supplement packages are limited in size and physical space available on the product label to accommodate mandatory information; additional mandatory information, such as the proposed "Nutrition Info" box would compromise the legibility of existing mandatory information that is important for consumers.

- Alignment with global FOPNL exemptions: A number of countries that have implemented FOPNL, including the United Kingdom[5], Canada[6], and Chile[7], have exempted dietary supplements (referred to as "food supplements" or "nutritional supplements), recognizing the non-applicability of FOPNL for dietary supplements. Aligning with international authoritative bodies avoids creating unnecessary compliance burdens for global brands.

[4] FDA. Front-of-Package Nutrition Labeling. Available at: https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/front-package-nutrition-labeling. Accessed 3 July 2025.
[5] UK Department of Health. Technical Guidance on Nutrition Labelling. Available at: https://assets.publishing.service.gov.uk/media/5a8010d8e5274a2e87db7a62/Nutrition_Technical_Guidance.pdf. Accessed 3 July 2025.
[6] Health Canada. Front-of-package nutrition symbol labelling guide for industry. Available at: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/front-package-nutrition-symbol-labelling-industry.html. Accessed 3 July 2025.
[7] U.S. International Trade Administration. Chile Country Commercial Guide. Available at: https://www.trade.gov/country-commercial-guides/chile-labeling-marking-requirements. Accessed 3 July 2025.

Considerations for certain products that bear a Nutrition Facts label

In the Proposed Rule, FDA states it considered but did not exempt from proposed 21 CFR 101.6 certain products bearing the Nutrition Facts label, including electrolyte products, glucose products, and nutrition shakes. The agency states these products are consumed by the general population, not just those individuals that are healthy. However, there are varying types of such products in the marketplace with unique characteristics that FDA should consider.

Oral Rehydration Solutions (ORS)

These types of products often bear a Nutrition Facts label but may alternatively bear a Supplement Facts label. While many foods with a Nutrition Facts label use sodium and carbohydrates for flavor, ORS products use these ingredients for physiological function—to rapidly restore hydration and electrolyte balance. ORS require specific levels of sodium and carbohydrates (glucose and non-nutritive sweeteners) for functional purposes to facilitate rapid fluid absorption, rehydration, and long-lasting hydration. ORS products are utilized to support daily dehydrating moments such as during and after exposure to heat, exercise, travel, etc. With sodium being lost in the greatest amount through sweat, ORS products support a person's ability to maintain a healthy electrolyte balance. The efficacy of these products is based on the ability of carbohydrates to stimulate sodium and fluid absorption in the small intestine through fluid transport systems. The transport mechanisms link the absorption of sodium with carbohydrates from the small intestine across the luminal membrane into the bloodstream, so the sodium and carbohydrates are available to be transported systemically to cells throughout the body.

Under the Proposed Rule, the sodium and added sugars levels of ORS products may be considered "medium" or "high" but are based on well-established scientific literature on the science of hydration. Applying the proposed "Nutrition Info" box to ORS products would work against the FDA's efforts to encourage informed, health-positive choices and could mislead consumers into believing that ORS are unhealthy or should be avoided. Furthermore, ORS that are labeled as dietary supplements, which serve a similar functional purpose, are excluded from this rule as proposed.

In addition, certain ORS formulations are intended to support individuals with unique nutritional needs, such as those recovering from illness or dehydration. These ORS are recommended by healthcare professionals (HCPs) and are used differently than products intended for rehydration during or after exercise or limited exposure to heat. Their formulation, including specific sugar-to-sodium ratio, is essential for their effectiveness in aiding recovery from illness or reducing risk of dehydration. Unlike most conventional foods, these ORS are included in clinical guidelines for patient care, frequently prescribed or recommended by HCPs,

proven effective for the target population, HSA/FSA eligible (when prescribed), and may be covered by Medicaid and certain health insurance plans.

Overall, there are multiple uses of ORS, from daily hydration to supporting rehydration. ORS are specifically formulated to support fluid absorption, which necessitates certain levels of sodium and carbohydrates (sugars and non-nutritive sweeteners) to function optimally. The inclusion of the proposed "Nutrition Info" box on the PDP could mislead consumers into perceiving ORS as "unhealthy" and discourage their consumption. Therefore, FDA should consider exempting ORS from 21 CFR 101.6, if finalized.

Oral Nutritional Supplements (ONS)

Certain products that bear a Nutrition Facts label are oral nutritional supplements (ONS) specially formulated to supply a particular dietary need which exists by reason of disease or condition. Often categorized as foods for special dietary use, ONS help consumers and patients who have malnutrition, are at nutritional risk, or are experiencing involuntary weight loss to increase calories, protein, and essential nutrients in their diet. These products are not intended to be consumed as part of a normal dietary pattern, and, as such, the proposed "Nutrition Info" box could cause confusion for the intended users of these products. This confusion could lead to poor compliance or cause individuals to purchase a product that would not fulfill their special dietary need. These products are included in clinical guidelines for patient care, proven effective for the target population, HSA/FSA eligible (when prescribed) and may be covered by Medicaid and certain health insurance plans. Moreover, ONS are recommended or prescribed by heath care professionals for the specific purpose of supporting individuals with unique nutritional needs. FDA should consider exempting these specialized nutrition products from 21 CFR 101.6, if finalized.

Further, a number of countries that have implemented FOPNL, including Canada, Mexico, Brazil, Chile, Colombia, France, the United Kingdom, Australia and New Zealand have exempted comparable products (when classified as "formulated liquid diets," "meal replacements," "specialized nutrition," "food supplements," "food for special medical purpose," etc.) CRN recommends that FDA align with international authoritative bodies to avoid creating unnecessary compliance burdens for global brands.

FDA should ensure FOPNL is consistent with the Healthy Nutrient Content Claim Final Rule

Under nutrient content claims regulation at 21 CFR 101.65(d)(2), a meal product making the implied "healthy" claim is required to contain at least three total food group equivalents with no less than 1/2 food group equivalent from at least three food groups; no greater than 20 percent Daily Value of added sugars content; no greater than 30 percent Daily Value of sodium

content; and no more than 20 percent Daily Value of saturated fat content (excluding the saturated fat inherent in seafood, nuts, seeds, and soybeans in soy products (if applicable). The FOPNL Proposed Rule would allow for certain meal products that could bear the "healthy" implied nutrient content claim to simultaneously be labeled as "high" in saturated fat, which is contradictory as a product that is "healthy" is commonly expected to not contain "high" levels of a nutrient of concern. For consumers, this conflicting information would likely cause confusion. FDA should ensure that the final FOPNL rule does not conflict with labeling regulations currently in effect.

Conclusion

In closing, CRN supports the proposed exemption of dietary supplements from mandatory front-of-packaging nutrition labeling as well as an exemption for certain specialized products that bear a Nutrition Facts label. CRN appreciates the opportunity to provide comments on the Proposed Rule. We would be happy to provide additional insights if that would be helpful for the agency in finalizing the rule.

Sincerely,

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