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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: Nutrient Content Claims; Definition of Term "Healthy." Docket No. FDA-2016-D-2335.

The Council for Responsible Nutrition (CRN)[1] appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) Proposed Rule "Food Labeling: Nutrient Content Claims; Definition of the Term "Healthy" (Proposed Rule)[1]. CRN applauds FDA's intention to empower and inform consumers to make healthful dietary choices for themselves and their families with the Proposed Rule updating the "healthy" nutrient content claim. In the Proposed Rule, FDA identifies the need to address diet-related and preventable chronic diseases such as cardiovascular disease and type 2 diabetes; further, the agency states overweight and obesity, which are associated with poor eating and physical activity behaviors, are major contributors to preventable diet-related chronic diseases in the U.S.[2] The "healthy" claim could enable consumers to quickly identify products that have the appropriate nutrient content to help support good health if the definition provides flexibility for a variety of products that are innovative, convenient, affordable, and nutrient dense to bear the "healthy" claim. It is important to note that as a voluntary claim, the "healthy" claim does not imply that food products that do not bear the claim are by any means "unhealthy" or unqualified to contribute to healthy dietary practices.

[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] 87 Fed. Reg. 59170 (Sept. 29, 2022).

I. Introduction

Current federal nutrition guidance, the Dietary Guidelines for Americans 2020-2025 (DGA), recommends individuals consume adequate fruits, vegetables, whole grains, fat-free or low-fat dairy, and a variety of lean protein while staying within limits for calories, saturated fat, sodium, and added sugar [2]. American diets do not currently align with the DGA recommendations and strategies such as FDA's revision of the term "healthy" are intended to help Americans shift towards healthier dietary practices. A key DGA guideline emphasizes customizing and enjoying nutrient dense food and beverage choices to reflect personal preferences, cultural traditions, and budgetary considerations. More than one approach is possible to facilitate the shift towards healthier eating and the ability of individuals to find products they enjoy that align with their preferences.

FDA's Proposed Rule requires products bearing the "healthy" nutrient content claim to contain meaningful amounts of one or more food groups recommended in the DGA and derives food group equivalents (FGE) from the Healthy U.S.- Style USDA Food Pattern. Although FDA's food groups-based approach is reasonable and reflects DGA principles, it limits the types of products that could contribute to helping Americans make dietary changes. A two-pronged approach would provide for a variety of products that support healthy dietary practices to bear the "healthy" nutrient content claim, and thus deliver a range of options that meet diverse consumer needs.

The food groups-based approach contemplates only food products that could be derived from whole foods and beverages, and limits opportunities for innovation of nutrient dense products that could be healthful in a diet, including formulated foods and dietary supplements. The Proposed Rule indicates that currently 5% of packaged food products are labeled as "healthy." FDA states it intends for the "healthy" criteria to be "appropriately flexible to allow for industry innovation" and increase the number of "healthy" products available to consumers to help meet dietary recommendations.[3] If so, FDA should not limit the definition of the "healthy" implied nutrient content claim to food group equivalency but consider adding criteria for nutrient dense formulated foods and dietary supplements in support of this goal. These products can play a role in healthful diets that help prevent diet-related chronic diseases.

While CRN agrees with FDA that the food groups-based approach would "help ensure foods bearing the "healthy" claim contain a variety of important beneficial nutrients, and, therefore, help Americans meet recommended nutrient intakes and maintain healthy dietary patterns,"[4] we encourage the agency to consider the opportunities provided by products appropriately formulated to contain beneficial nutrients to help Americans meet nutrient needs. Whole foods and beverages should be considered first, but they do not need to be the only options. Some nutrients are difficult to obtain in sufficient quantities in conventional foods and beverages, e.g., vitamin D, (while staying within calorie limits) and some foods and beverages are not consumed by individuals due to lifestyle, personal preferences, inaccessibility, and other reasons.

Moreover, older adults, one of the fastest growing demographics in the U.S., have age-related challenges that impact the ability to prepare and consume conventional nutrient dense foods. Older adults experience decreased food consumption due to reduced energy needs; changes in appetite,

[3] *Id* at 59176.
[4] *Id* at 59175.

sense of taste, and sense of smell; physical impairment such as inability to chew or swallow food; and decreased ability to consume and/or absorb nutrients related to use of medication and their side effects [3]. Healthy formulated foods and dietary supplements have a role in complementing conventional foods and beverages to help meet the needs of diverse individuals and populations groups. Indeed, FDA's Proposed Rule includes fortified soy beverages in the "dairy" food group as an option for individuals who do not consume dairy for assorted reasons. We encourage the agency to extend this flexibility to the types of nutrient dense products that could bear the "healthy" nutrient content claim.

There are a number of nutrients that Americans do not consume enough of and their intake should be specifically encouraged in the "healthy" nutrient content claim regulation to help meet recommended amounts. The Scientific Report of the 2020 Dietary Guidelines Advisory Committee (Advisory Committee) indicates that Americans (age 1 and older) under consume a range of essential vitamins, minerals, and dietary components relative to the Estimated Average Requirement (EAR) or Adequate Intake (AI) [4]. The "shortfall" nutrients are vitamins A, C, D, E, K, calcium, magnesium, dietary fiber, choline, and potassium. Vitamin D, calcium, dietary fiber, and potassium were identified as nutrients and dietary components of public health concern because low intake is linked to negative health impacts. Further, the Scientific Report highlights iron, folate, and iodine as nutrients of public health concern for pregnant women. The DGA encourages consumption of beneficial fatty acids such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) found in seafood at varying levels and FDA's advice about eating fish supports the DGA recommendation by highlighting the health benefits of EPA and DHA, among other nutrients, that support child brain development [5]. The under consumed nutrients, nutrients of public health concern for the general U.S. population and pregnant women, as well as nutrients encouraged in the DGA should all be considered nutrients to encourage for supporting healthy nutrient intake levels and dietary practices. We suggest these nutrients be incorporated into the criteria for the "healthy" nutrient content claim for formulated foods and dietary supplements (see below).

The Advisory Committee also reported that USDA Food Patterns, including the Healthy U.S.-Style Pattern, the Healthy Vegetarian Pattern, and the Healthy Mediterranean-Style Pattern, do not meet nutrient adequacy goals (90 percent of the RDA (Recommended Dietary Allowances) or AI) for iron (for females of various age groups and women who are pregnant), vitamin D, vitamin E, and choline [4]. The USDA Food Patterns provide less than 90 percent of the RDA for iron for females ages 4-8 years, 19-30 years, 31-50 years, and less than 75 percent of the RDA for women who are pregnant. For much of the population, the USDA Food Patterns provide 55-70 percent of the RDA for vitamin D, less than 80 percent of the RDA for vitamin E, and less than 85 percent of the AI for choline [4]. Because these nutrients are not provided in adequate amounts in the USDA Food Patterns, including the Healthy-U.S.-Style Pattern that is the basis for FDA's proposal, other options to meet adequacy should be considered, including formulated foods and dietary supplements.

Formulated foods and dietary supplements can be nutrient dense options that could potentially help close the nutritional gap for Americans, without adding significantly to intakes of saturated fat, sodium, and added sugar. Nutrition bars, gels, powders, shakes, meal replacements, and dietary supplements are among products that could be designed to encourage consumption of under consumed essential nutrients and dietary components, while also meeting consumer needs and preferences.

While there is no statutory definition for a "meal replacement" in the U.S., meal replacement products are foods formulated with specific amounts of calories and essential nutrients to help support and achieve a healthy weight. Thus, they can be part of a nutrient dense, energy balanced diet to help individuals achieve healthy weight goals through modification in eating behaviors, emphasizing intake of essential nutrients to support healthy weight while limiting total caloric intake. International regulatory authorities, including Health Canada, have recognized meal replacements as products that can replace one or two of the main meals of the daily diet [6-8]. Meal replacements are also internationally recognized for the intended use in energy restricted diets for weight reduction. If consumed in place of nutrient poor conventional meals with excess added sugar, saturated fat and sodium, meal replacements can contribute to a healthy diet and can be part of solutions to reduce overweight and obesity impacting more than two-thirds of U.S. adults. These products are available in easy-to-consume formats (i.e., bars and shakes) and provide protein-rich macronutrient composition to induce sustained satiety as well as dietary fiber, vitamins, and minerals. These key attributes help increase adherence to energy balanced diets intended to help individuals achieve healthy weight goals.

II. FDA should establish criteria for food products with added nutrients.

In addition to food groups, formulated foods and dietary supplements are nutrient dense products that can contribute to overall consumption of a variety of nutrients important for maintaining health, including nutrients that are under consumed and/or of public health concern, while supporting dietary practices that help to prevent chronic disease. We recommend FDA add criteria for products with added nutrients that could bear the "healthy" nutrient content claim.

A. Nutrients to encourage

The Proposed Rule states, "By requiring products to contain a certain amount of a food group, the proposed rule will help ensure foods bearing the "healthy" claim contain a variety of important beneficial nutrients and, therefore, help Americans meet recommended nutrient intakes and maintain healthy dietary patterns."[5] By extension, criteria could be added to ensure that products with added nutrients contain a variety of nutrients to meet recommended nutrient intakes. The criteria for a product with added nutrients to bear the "healthy" nutrient content claim could include:

- Contains a minimum number of nutrients to encourage providing at least 10% of the Daily Value (DV), where applicable. Nutrients to encourage would include: (1) nutrients under consumed by the general U.S. population; (2) nutrients of public health concern for pregnant women; and (3) omega-3 fatty acids encouraged by the DGA and FDA. Collectively, the nutrients to encourage include vitamins A, C, D, E, K, calcium, magnesium, dietary fiber, choline, potassium, iron, iodine, folate, EPA, and DHA.
- Meets limits for saturated fat, sodium, and added sugar (see below for discussion about these limits)

[5] *Id.*

B. Amounts of nutrients to encourage

The existing criteria for the "healthy" nutrient content claim include a requirement for products bearing the claim to contain at least 10 % DV (good source) of one or more of the nutrients to encourage. Products that provide a "good source" of nutrients to encourage should help consumers meet recommended nutrient intakes. We recommend maintaining consistency with the 10 % DV minimum requirement for nutrients to encourage. For DHA and EPA, which do not have established Dietary Reference Intakes (DRIs), we recommend a minimum amount of 50 mg EPA and DHA per serving to be consistent with DGA recommendations and FDA's advice about eating fish.

The DGA recommends at least 8 ounces of seafood per week based on a 2,000-calorie diet and 8 to 12 ounces of seafood lower in mercury and higher in EPA and DHA per week for those who are pregnant and breastfeeding. FDA supports the DGA recommendations with its advice for pregnant and breastfeeding women to eat fish that are lower in mercury 2 to 3 times per week (equivalent to 8-12 ounces of fish). The recommendations are underpinned by evidence that fish provides key nutrients during pregnancy, breastfeeding, and early childhood to support brain development, including omega-3 fatty acids EPA and DHA. Fish lower in mercury with the highest levels of EPA and DHA include salmon. A typical serving of Atlantic salmon (farmed, cooked) provides 590 mg EPA and 1,240 mg DHA [9]. With two servings per week, the daily amount of EPA and DHA is around 500 mg. Ten percent of this daily amount is 50 mg EPA and DHA, which could serve as the minimum amount requirement for these specific nutrients to encourage.

C. Nutrients to limit

1. Meal replacements

A meal replacement product (typically a shake or bar) is intended to replace one or more conventional meals per day for weight management. Meal replacements are typically formulated to provide a significant amount of protein and micronutrients while containing less calories compared to conventional meals. In addition to the excellent nutrient profile, the convenience of preparation and ease of calculating calorie consumption have made meal replacement products conducive to achieving weight loss or weight maintenance while meeting nutrient needs. Nutrient dense meal replacement products on the market typically contain 170 – 350 calories, 17 – 30 % DV for added sugar, 7 – 25 % DV for sodium, and 5 – 10 % DV for saturated fat per serving. These ranges are reasonably within one-third of the percent DVs for these nutrients based on a 2000-calorie daily diet consisting of three meals a day and are similar to FDA's proposed limits for a "meal product" with 1 FGE dairy + 1 FGE whole grain + 1 FGE fruit, vegetable, or protein: 10 % DV for added sugar, 30 % DV for sodium, and 25 % DV for saturated fat, although a higher limit for added sugar up to 30 DV % may be needed given that it is a source of carbohydrates in meal replacement products and enhances palatability, thus supporting consumer adherence to meet healthy weight goals. In 2017 – 2018, the average intake of added sugars was 17 teaspoons for adults aged 20 and older, which is equivalent to 71.4 g or 143 % DV of added sugar per day (4.2 g sugar per teaspoon)[10]. Therefore, permitting added sugar of up to 30 % DV (15 g) in a meal replacement would be expected to reduce the overall daily sugar intake compared to the current average.

2. Other formulated foods and dietary supplements

The limits for saturated fat, sodium, and added sugar in products with added nutrients should be low but achievable. Because they may contain added macronutrients and/or micronutrients, these products require certain amounts of added sugar, saturated fat, and sodium to maintain palatability, depending on the form. Some of these products may be compared to a mixed product as described in the Proposed Rule, as they contain a variety of nutrients that are typically provided by multiple food groups; however, they do not neatly equate to any single food group. We suggest the limits for added sugar, sodium, and saturated fat in these nutrient dense products be the same as FDA's proposed limits for a mixed product consisting of ½ FGE dairy and ½ FGE whole grain: 7.5 % DV for added sugar, 10% DV for sodium, and 7.5 % DV for saturated fat. These limits are the most flexible of the food group combinations and are appropriate for products with added nutrients that may be provided by a variety of food groups.

III. FDA should include a variety of protein sources in the "Protein" food group.

The Proposed Rule includes game meat, seafood, egg, beans, peas, soy products, nuts, and seeds in the "Protein" food group. We suggest that other sources of protein be included in the "Protein" food group including protein powders, isolates, and concentrates from whey, soy, pea, and other pulse. The DGA recognizes protein from products made from soy flour, soy protein isolate, and soy concentrate. In addition, with growing interest in plant-based diets, and increased availability of other legume- and grain-derived proteins, all plant-based proteins should be considered part of the "Protein" food group. More sources of lean protein recognized as part of the "Protein" food group would help achieve the goal of encouraging lean protein consumption.

To facilitate consumption of a variety of lean proteins, FDA should specify protein Food Group Equivalents (FGE) for plant-based flour, isolate, and concentrate. FDA proposes 1 oz of "beans, peas and soy products" as the minimum requirement for the protein FGE.[6] The recent Food Patterns Equivalents Database 2017-2018 indicates that 1-oz equivalent of soy product is defined as ½ oz or 14.17 g of soy flour, isolate or concentrate (refer to Table 13) [11]. We suggest FDA aligns with the Food Patterns Equivalents Database when determining protein FGE for soy-derived flour, isolate, and concentrate. Further, FDA should consider developing FGE for protein from other plant-derived flours, isolates, and concentrates.

IV. Products that bear an authorized health claim or qualified health claim should be eligible for the "healthy" nutrient content claim.

Some food products and dietary supplements are formulated with specific food components/substances to deliver health benefits, including to fill nutritional gaps, or to help reduce the risk of a nutrition-related disease or a health condition. Products bearing authorized health claims and/or qualified health claims must meet nutrient content requirements, and such claims must be supported by scientific evidence. In addition, products bearing such claims must meet the requirements for disqualifying nutrient levels (total fat, saturated fat, cholesterol, or sodium) as specified in 21 CFR 101.14. FDA should make clear that products that meet the requirements to bear health claims may also bear the "healthy" nutrient content claim if they meet the specified criteria.

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[6] *Id* at 59183.

V. FDA should clarify whether dietary supplements are covered by the final rule.

Dietary supplements contain added nutrients and are typically not able to meet the proposed criteria based on food group equivalency. If FDA takes the food groups-only approach and does not provide an alternative approach for dietary supplements, then the agency should clarify for industry whether dietary supplements are intended to be covered by the final rule. If dietary supplements are not covered, the agency should exempt dietary supplements from 21 CFR 101.65(d) and clarify that exemption would not preclude these products from using the term "healthy" on the label or in labeling in a manner that is not otherwise false and misleading.

VI. FDA should clarify the "nutrition context" of the "healthy" nutrient content claim.

We encourage FDA to clearly distinguish between the use of the term "healthy" (or related terms listed in 21 CFR 101.65(d)(3)) on a product label in non-nutritional contexts and when "healthy" is used in a nutritional context, making the use of the term a nutrient content claim subject to the Proposed Rule requirements. As the agency recognizes in the Proposed Rule preamble, the term "healthy" can be used in several different contexts "beyond the nutritional properties of a food."[7] We are concerned, however, that the broad language describing the updated scope of the rule and included in proposed 101.65(d)(1), explanation of the updated scope in the preamble, and examples of "healthy" nutrient content claims suggest otherwise – causing company and consumer confusion as to when use of the term "healthy" is intended to be a "healthy" nutrient content claim subject to FDA's proposed criteria. FDA notes that the Proposed Rule defines "healthy" as a nutrient content claim "only when it is used in the nutritional context."[8] "Nutritional context," however, is not clearly defined and the broad preamble explanation language and examples do little to guide a company as to when use of the term creates a "healthy" nutrient content claim.

In particular, we encourage FDA to provide further examples, parameters, and information on when the use of the term "healthy" is considered a nutrient content claim, especially for the following contexts:

- Further define "nutritional context" to provide clear guidance on when use of the term would be a nutrient content claim, as well as additional examples of uses that do not create a nutrient content claim;
- Clarify that "healthy" when used in a structure/function claim, health claim, and qualified health claim does not constitute a nutrient content claim; and
- Exempt use of company and brand names from the final rule scope.

A. FDA should clearly define "nutritional context."

FDA proposes revising § 101.65(d)(1) to cover use of the term "healthy" where the claim "suggest[s] that a food may help consumers maintain healthy dietary practices due to its nutrient content where there is also implied or explicit information about the nutrition content of the food." In contrast, under current § 101.65(d)(1), for "healthy" to be a nutrient content claim it must be used "in connection with an explicit or implicit claim or statement about a nutrient (e.g., healthy, contains 3 grams of fat)."

[7] *Id* at 59181.
[8] *Id.*

FDA suggests this revision was made to make clear that "healthy" is a nutrient content claim where the term "healthy" is used to characterize the food itself and where there is also implied or explicit information about the nutrition content of the food. FDA notes that it wants "to ensure that the regulation only reaches claims that are made in a nutritional context," but admits the scope of the rule has been expanded, removing qualifications like "in connection," because the agency believes "the existing criteria may be too narrow and not reach all information about nutritional context."[9] Because so many product labels, however, bear statements about nutrients in the product, we believe it is critical that FDA provide more context around when the term "healthy" is used to characterize the food or otherwise used in a "nutritional context." These parameters should be precisely and narrowly defined to avoid suggesting that any use of the term "healthy" when information about the product's nutrient content is also included on the label is a "healthy" nutrient content claim. Labels must be reviewed as a whole and use of the term "healthy" should not disqualify the use of nutrient claims and descriptors, unless the use of the term "healthy" in conjunction with the nutrient information clearly communicates that the food helps consumers maintain healthy dietary practices because of the food's nutrient content.

B. FDA should explicitly note that structure/function claims, health claims, and qualified health claims are not "healthy" nutrient content claims.

We seek clarification that the use of the term "healthy" as part of FDA authorized health claims, qualified health claims for which FDA has issued a letter of enforcement discretion, and structure/function claims as defined by 21 CFR § 101.93, are not "healthy" nutrient content claims simply because the referenced claim uses the term "healthy." This should be the case regardless of whether claims are also made in the label or labeling about nutrients found in the product.

For example, a label bearing the claim "supports healthy bones" and a claim about the presence of calcium and vitamin D in the product (regardless of where it appears on the label and the way in which the nutrient amounts or levels are characterized) should not be considered a "healthy" nutrient content claim. Under 21 CFR § 101.93, structure/function claims describe the role of a nutrient or dietary ingredient on the structure or function of the body or characterizes the mechanism of action to maintain a body's structure or function. Use of the term "healthy" in the context of a structure/function claim does not characterize the food; rather, the term is generally used as an adjective to describe the condition of the bodily structure or function. By their very nature, however, structure/function claims often reference a specific nutrient or nutrients and/or the label may reference the amount of that nutrient or other nutrients found in the product. FDA affirmation that the use of the term "healthy" in a structure/function claim is not intended to be subject to the Proposed Rule is one example of where FDA should provide additional guidance around when "healthy" is used outside of a nutritional context.

For health claims and qualified health claims, FDA notes that the Proposed Rule does not address "healthy" when used as a part of an implied health claim but does not address how "healthy" and related terms could be used as part of an authorized health claim or qualified health claim subject to an enforcement discretion letter. Further, by regulation, health claims language must enable the public to understand the significance of the nutrients discussed in the health claim "in the context of a total daily diet."[10] Model language for some health claims use terms related to "healthy" -- e.g., "Adequate calcium

[9] *Id* at 59182.
[10] 21 CFR 101.14(d)(v).

as part of a ***healthful*** diet, along with physical activity, may reduce the risk of osteoporosis in later life" (emphasis added).[11]

FDA should specifically address that the term "healthy" and related terms when used as part of an authorized health claim or qualified health claim subject to enforcement discretion or used to meet the requirements of 21 CFR § 101.14(d)(v) does not create a "healthy" nutrient content claim, even where claims about a product's nutrients are made in connection with the health claim or qualified health claim, or elsewhere on the label.

Similarly, the phrase "use as part of healthy/healthful diet" may be used on labeling of food as part of use instructions intended to provide proper consumption guidance. This instruction may be used in conjunction with statements about the nutrient content of the food, e.g., "high in protein." CRN requests FDA clarify that the use of "healthy" as part of use instructions intended to provide proper consumption guidance (e.g., Use as part of a healthy diet) on a label that also refers to the nutrient content of the food would not constitute a "healthy" nutrient content claim. Use of such instructions is similar to use of "part of a healthful diet" in authorized health claims and are intended to help ensure consumers are informed of the balanced way to incorporate products into their overall diet.

C. FDA should exempt use of company and brand names from the final rule scope.

Another area of concern is FDA's broad proclamation that the term "healthy" or related terms in a company or brand name would be considered an implied "healthy" nutrient content claim if other information puts that term into a nutritional context. The Proposed Rule goes on to note that a brand name using the term "healthy" on a label with the nutrient content claim "low sodium" would be enough to satisfy these criteria. Similar to our concerns with other types of claims, a brand or company name alone on a label that also includes nutrient information, whether that be in the form of nutrient content claims or other claims about the level or amount of a nutrient should not be considered a "healthy" nutrient content claim. Under these criteria, any brand or company name that currently uses the term "healthy" or related terms could risk making an implied nutrient content claim. Further, no quantified data has been provided by FDA in its economic analysis that is specific to the cost of rebranding or changing company names. This could significantly raise the Proposed Rule costs for businesses. We ask that FDA determine business costs for rebranding and/or changing company names and provide further tailored guidance and examples of when "healthy" and related terms in a company or brand name would be a "healthy" nutrient content claim or exempt company and brand names from the healthy definition, provided the name is not otherwise false or misleading in the context of the entire label.

VII. Conclusion

The "healthy" nutrient content claim facilitates identification of food product choices that help consumers meet recommended intakes of important nutrients and dietary components and build dietary practices that support good health. FDA's regulation defining this claim should be appropriately flexible to facilitate manufacturers in providing healthy, innovative products that meet diverse consumer needs and preferences, including nutrient dense formulated foods and dietary supplements.

[11] 21 CFR 101.72(e).

An additional approach based on nutrients to encourage and nutrients to limit is needed to address formulated foods and dietary supplements that may bear the "healthy" nutrient content claim. If FDA does not provide an alternate to the food groups-based approach, the agency should clarify whether dietary supplements are intended to be covered by the final rule. If dietary supplements are not covered, the agency should exempt dietary supplements from the "healthy" nutrient content claim regulation. Finally, FDA should clearly and narrowly define the "nutrition context" of the "healthy" nutrient content claim to avoid misinterpretations of the term "healthy" when appropriately used in other contexts, in a manner that is truthful and not misleading, including in structure/function claims, health claims, qualified health claims, general consumption guidance, and company and brand names.

Thank you for considering our comments.

Sincerely,

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References:

1. Food and Drug Administration. Proposed Rule. Food Labeling: Nutrient Content Claims; Definition of Term "Healthy." 87 FR 59168-59202 (September 29, 2022).

2. 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.

3. U.S. Government Accountability Office. Report to Congressional Requesters. Nutrition Assistance Programs: Agencies Could Do More to Help Address the Nutritional Needs of Older Adults. Accessed 22 November 2022. Available at: https://www.gao.gov/assets/gao-20-18.pdf.

4. 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.

5. Food and Drug Administration. Advice about Eating Fish for Those Who Might Become or Are Pregnant or Breastfeeding and Children Ages 1 - 11 Years. Available at: https://www.fda.gov/food/consumers/advice-about-eating-fish.

6. Canada: Food and Drug Regulations B.24.200. Available at: https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/section-B.24.200.html

7. Europe: Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy restricted diets for weight reduction. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01996L0008-20070620&qid=1399628018023&from=EN

8. Australia and New Zealand: Australia and New Zealand Food Standards Code. Standard 2.9.3: Formulated Meal Replacements and Formulated Supplementary Foods. Available at: https://www.foodstandards.gov.au/code/Documents/2.9.3%20Supp%20foods%20v157.pdf

9. Omega-3 Fatty Acids: Fact Sheet for Health Professionals. Office of Dietary Supplements. Updated 18 Jul 2022. Available at https://ods.od.nih.gov/factsheets/Omega3FattyAcids-HealthProfessional.

10. Centers for Disease Control and Prevention. Get the Facts: Added Sugars. https://www.cdc.gov/nutrition/data-statistics/added-sugars.html. Last reviewed 28 November 2021. Accessed on 6 February 2023.

11. Bowman SA, Clemens JC, Friday JE, and Moshfegh AJ. 2020. Food Patterns Equivalents Database 2017-2018: Methodology and User Guide [Online]. Food Surveys Research Group, Beltsville Human Nutrition Research Center, Agricultural Research Service, U.S. Department of Agriculture, Beltsville, Maryland. October 2020. Available at: http://www.ars.usda.gov/nea/bhnrc/fsrg.