February 16, 2023

Submitted electronically at www.regulations.gov

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

RE: Docket No. FDA-2016-D-2335 for "Food Labeling: Nutrient Content Claims; Definition of Term `Healthy.'

Dear Sirs and Madams:

SNAC International submits this comment in response to the Food and Drug Administration's (FDA's), proposed rule on "Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy'", which was published in the *Federal Register* on September 29, 2022. SNAC International is the international trade association for the snack food industry representing snack manufacturers and suppliers. SNAC International represents over 400 companies worldwide including manufacturers of potato and vegetable chips, tortilla chips, pretzels, popcorn, kettle corn, cheese snacks, crackers, meat snacks, pork rinds, nuts, snack mixes, corn snacks, fruit snacks, snack bars, granola, rice and other grain-based snack cakes, cookies, and various other snacks.

Founded in 1937, SNAC International and its member companies have worked tirelessly to provide consumers with a range of products to meet their individual needs. With more Americans incorporating "healthy" snacks into their diets, manufacturers are innovating to provide snacks with fiber, whole grains, vegetables, and legumes that include less sodium, added sugar, and saturated fat. Examples include pulse and legume snacks, such as chick-pea and lentil-based chips. Dehydrated fruit and vegetable chip products are also innovative additions to the snack food market that are lower in sodium and saturated fat, and a source of other essential micronutrients. Other snack foods like ready-to-eat popcorn are a good source of whole grains. An increasing number of consumers are taking a holistic view of their health and developing diets that suit their own personal needs. They often look to the snack category as a convenient, innovative source for delivering key nutrients while also satisfying their own dietary restrictions and aspirations.

As indicated in our comments to the Agency in 2017 and 2021, SNAC International members have an abiding interest in the "healthy" definition rulemaking. We appreciate the Agency's efforts to update the definition for the nutrient content claim "healthy" to be consistent with current nutrition science, including the proposal to remove the thresholds for total fat and cholesterol and allow more flexibility

for products with inherent levels of saturated fat like nuts, seeds, and oils. Our members are also in support of the Agency's decision to include food groups to encourage in the new definition. However, we are concerned that the proposed rule's interpretation of "healthy" is overly restrictive and does not provide sufficient guidance to help consumers identify better-for-you products within the snack category or to be implementable by manufacturers in a way that will encourage innovation and more healthful eating by consumers. As the Agency moves forward to a final definition of "healthy," we respectfully request it considers the following changes to allow for more practical and approachable recommendations for food makers and for our consumers.

Proposed Approach

SNAC members propose that FDA adopt criteria for "healthy" nutrient content claims that would provide greater flexibility for nutrient dense foods to qualify, including by making the following changes:

- **Nutrients to Limit**: Establishing more flexible criteria for nutrients to limit, which should be based on reference amount or serving size rather than tied to the specific food group in the product;
- **Nutrients to Encourage**: Allowing, as an alternative to the food group contribution criteria, a food to qualify if it contains meaningful amounts of one or more nutrients to encourage, consistent with the current definition;
- **Foods with Small Reference Amounts**: Establishing modified criteria for foods with small reference amounts like snack foods; and
- **Food Group Equivalents**: Allowing contributions from multiple food groups to be aggregated; making certain revisions to the fruit, vegetable, and grains groups; and establishing a clearer framework with more details and information on how to conduct food group equivalent calculations.

We discuss each of these recommendations in more detail below. We also provide as Appendix 1 the full set of criteria that SNAC proposes FDA adopt. These criteria are consistent with those being proposed by the Consumer Brands Association.

1. **Nutrients to Limit: FDA should establish more flexible criteria for nutrients to limit, which should be based on reference amount size rather than tied to the specific food group in the product.**

FDA should revise the thresholds for the nutrients to limit to recognize that in many categories of foods, there is more room within a healthy dietary pattern to accommodate additional amounts of added sugars and sodium than the levels proposed.

a. Added Sugars

Added sugars is a component in some snacks, such as whole grain and vegetable crisps, trail mixes, seasoned nuts, and fruit pouches. As proposed, the added sugars threshold would exclude nutritious snack options like hummus crisps with < 1g added sugar, which would not meet the 0% DV added sugars threshold set for the vegetable food group.

The restrictiveness of the proposed added sugars criteria is exemplified by calculating the maximum added sugars consumption that would occur if a person consumed only "healthy" food products based on four eating occasions per day. If most "healthy" snacks must contain no more than 5% daily value (DV) added sugars per RACC (with some at 0% DV), and meals must contain 0-10% DV depending on the food group components, then taking FDA's assumption in the proposed rule that the typical consumer eats three meals and a snack per day,[1] this would mean a total intake of no more than 35% DV added sugars in diets that consist only of healthy foods.

Additionally, FDA's 0-5% DV criteria for added sugars across individual foods groups and mixed products[2] does not follow the 2020-2025 Dietary Guidelines for Americans (DGA), which recommends limiting added sugar consumption to 10% of total calories or 200 calories (based on a 2,000-calorie diet), which is equivalent to 50 g added sugars. With four eating occasions, each one could contribute 13 g of added sugars within the 50 g added sugars daily value; yet FDA has proposed limits that are between 0 and 2.5 grams per eating occasion for individual and mixed foods and no more than 5 grams per meal. As a result, the proposed standards are unnecessarily limiting within a healthy dietary pattern. SNAC members request the following revised added sugars thresholds for foods with smaller RACCs (≤30 g / 2 Tbsp) and larger RACCs (>30g / 2 Tbsp), respectively:

- Individual or mixed foods, small RACC (RACC ≤30g / 2 Tbsp): 10% DV added sugars
- Individual or mixed foods, (RACC >30g / 2 Tbsp): 20% DV added sugars

Importantly, we recommend that FDA establish nutrients to limit criteria that are based on the size of the RACC (or for meals and main dishes, the serving size) rather than the specific food group that the product contains. This is consistent with how FDA's nutrient content claim criteria, including the existing sodium criteria for the healthy claim, is generally distinguished between foods with small RACCs and larger RACCs.[3] This approach would be more consistent with the RACC and serving size of the product and would better reflect each food's contribution to the overall diet. From there, main dishes and meals

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1 87 Fed. Reg. at 59177.

2 We note that in Table 9 of the preamble, there is a reference to an added sugars limit of 7.5% DV for mixed products with ½ FGE each dairy and whole grain, but in the proposed codified section, the chart shows 5% DV for a mixed product with ½ FGE each dairy and whole grain.

3 *See, e.g.,* 21 CFR 101.13(h)(1), applying a different standard for nutrient content claim disclosures for foods with RACCs that are 30 g/2Tbsp or smaller; 21 CFR 101.60(b)(2), applying a different standard for low calorie claims for foods with small RACCs vs. other foods; 101.65(d), applying different sodium criteria for purposes of the healthy definition for foods depending on the RACC size.

could be allotted greater thresholds for nutrients to limit (i.e., 25% DV for main dishes and 30% DV for meals, the latter of which mirrors the proposed "meals" standard for sodium). These levels continue to be consistent with dietary recommendations. For example, taking FDA's assumption in the proposed rule of four eating occasions per day comprised of three meals and a snack (where a snack is a small RACC food), consumers eating exclusively healthy foods would not exceed the established daily value for added sugars.

b. Sodium

As with added sugars, we believe there is an ability to allow for modestly higher amounts of sodium in "healthy" foods than FDA has proposed, consistent with the requirements of a healthy diet. We also believe an approach that provides slightly greater flexibility is more likely to result in the public health changes FDA seeks to achieve with the rulemaking, including encouraging innovation in food products by setting a more realistic threshold and encouraging Americans to eat more healthful products because consumers would be more likely to accept products that reflect a more gradual reduction in sodium. FDA has recognized the importance of a gradual approach in its Voluntary Sodium Reductions Guidance.[4] The proposed sodium thresholds are 25-50% lower than those in the current "healthy" criteria, which is not aligned with the much smaller decrease in the Recommended Daily Intake for sodium of just 4% since the healthy criteria were first issued.

We ask that FDA align the nutrients to limit thresholds for sodium and added sugars. In particular, we ask FDA to establish sodium thresholds of:

- Individual or mixed foods, small RACC (RACC ≤30g / 2 Tbsp): 10% DV sodium
- Individual or mixed foods, (RACC >30g / 2 Tbsp): 20% DV sodium

And as with added sugars, we propose correspondingly greater thresholds for main dishes (25% DV) and meals (30% DV). These criteria reflect appropriate stepwise increases between the categories that are commensurate to the increase in RACC/serving size in each larger category.

We note that our proposed standard for small RACC foods of 10% DV represents a meaningful 20% decrease compared to the current sodium standard for small RACC foods[5]. This reduction also exceeds the roughly 12% decrease in population-wide sodium intake that FDA is seeking to achieve in its voluntary draft guidance on short-term sodium reductions.[6]

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[4] Guidance for Industry: Voluntary Sodium Reduction Goals | FDA (Oct. 2021) ("Reduction in sodium levels should progress gradually to allow time for product reformulation").

[5] Our proposed threshold of 10% DV for small RACC foods is equivalent to 230 mg per RACC. By comparison, under the current healthy definition, the sodium criteria for foods with small RACCs is 480 mg or less per 50 g. Taking a snack food with a RACC of 30 g, the current standard requires sodium to be 288 mg or less per 30 g, so a revised standard of 230 mg would represent a decrease of 20% compared to the current criteria.

[6] Guidance for Industry on Voluntary Sodium Reduction Goals (Oct. 2021) (fda.gov).

c. Saturated Fat

With respect to saturated fat, we are proposing a standard of 5% DV for small RACC foods and 10% DV for individual and mixed foods with larger RACCs, to reflect that under our proposed approach a food could qualify based on either nutrients to encourage or food group contribution. Under this approach, it would not make sense for the nutrients to limit criteria to be based on which food group a food contains, with higher amounts allowed for dairy or fish than other food groups. And yet a standard of 5% DV per RACC for small RACC foods would still meaningfully limit saturated fat content.

SNAC members support the proposed flexibility for nuts and seeds that have inherent saturated fat content, where the saturated fat content inherent in nuts and seeds would not be counted toward the thresholds. The proposed rule also states that FDA is seeking comment on whether nuts and seeds with relatively higher amounts of saturated fat should be eligible for the "healthy" claim, acknowledging the multiple qualified health claims pertaining to nut consumption and reduced disease risk. When it comes to "healthy" eligibility, SNAC recommends FDA provide flexibility to accommodate nuts and seeds that have inherent saturated fat. Nuts are eligible for qualified health claims in recognition of their role in a healthy dietary pattern; to exclude them due to this same inherent saturated fat content would be inconsistent and confusing to consumers.

2. <u>Nutrients to Encourage</u>: As an alternative to the food group contribution criteria, FDA should allow a food to qualify if it contains meaningful amounts of one or more nutrients to encourage, consistent with the current definition.

SNAC members recommend that FDA retain the current provision, which has been in place for decades, that allows foods to meet the healthy definition if they contain a meaningful amount of the "nutrients to encourage" found on the Nutrition Facts panel; specifically, protein, fiber, Vitamin D, potassium, calcium, and iron. The DGA acknowledges that "current inadequate intake of nutrient-dense foods and beverages across food groups has resulted in underconsumption of some nutrients and dietary components," such as fiber, vitamin D, potassium, iron, and calcium.[7] FDA's proposal to eliminate the nutrients to encourage criteria is based on the agency's stated goal of disincentivizing the indiscriminate fortification of foods only for the purpose of qualifying as healthy. We agree that foods should not be indiscriminately fortified solely to qualify as healthy. But foods that bear a healthy claim are required to comply with FDA's existing fortification policy, which already discourages indiscriminate fortification of foods that are not inherently nutrient dense.[8] We recommend that FDA maintain this requirement in the revised definition to make clear that any food that bears a healthy claim must comply with the FDA fortification policy. Further, FDA has not provided information suggesting there is an existing problem with fortification of foods for the purpose of "healthy" eligibility. SNAC members suggest that if the

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[7] *Dietary Guidelines for Americans, 2020-2025*, p. 36, https://www.dietaryguidelines.gov-/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf.

[8] 21 CFR 101.65(d)(2)(iv).

agency has concerns about food fortification, FDA should instead update the fortification policy, rather than disallowing the use of the healthy claim on nutritious foods.

SNAC therefore recommends that FDA maintain the nutrients to encourage thresholds as an alternative to the food group equivalent criteria. Indeed, FDA is proposing to adopt a food group approach based on the rationale that food groups are a proxy for the nutrients they contain. It therefore would be appropriate to continue to recognize nutrients to encourage. Consistent with the current definition, SNAC requests that FDA provide that individual foods containing at least 10% DV per RACC of at least one nutrient to encourage would qualify as healthy, provided they also meet the nutrients to limit criteria.

3. **<u>Foods with Small Reference Amounts</u>: FDA should establish modified criteria for foods with small reference amounts like snack foods.**

SNAC members believe FDA should provide modified criteria for products with small reference amounts customarily consumed (RACCs) (i.e., RACCs that are 30 g/ 2 Tbsp or less). All varieties of snack products including chips, pretzels, popcorn, extruded snacks, fruit and vegetable-based snacks (e.g., dried fruit chips), grain-based snack mixes, nuts, salsas, dips, hummus and trail mixes have RACCs of 30 g or 2 Tbsp or less. Under the proposed rule, these foods often would not be able to qualify as healthy because they could not provide a full food group equivalent per RACC, especially where the FGE is defined as an amount larger than the RACC. For example, it is mathematically impossible to provide ½ a cup of vegetables in a 2 Tbsp serving of salsa, therefore these small RACC products would categorically be excluded from making healthy claims solely based on their serving size.

To recognize their smaller serving size, we recommend FDA modify the criteria for products with small RACCs to require a smaller contribution to the food group equivalents. Specifically, a small RACC food should be deemed to meet the FGE requirements if it either contains 1/4 composite FGE or contains as its first ingredient one of the food groups to encourage. In the salsa example, ¼ FGE from the vegetable group equals 1/8 cup, which is equal to 2 Tbsp. Our proposed standard of ¼ FGE would require all of the 2 Tbsp RACC of salsa to contribute to a food group. Accordingly, ¼ FGE is a robust standard for foods with small RACCs. As another option, we ask that FDA measure the food group equivalents for small RACC products by using the first ingredient approach. This is consistent with the U.S. Department of Agriculture's (USDA's) "Smart Snacks in Schools" (or "Competitive Foods")[9] nutrition standards, which provides that all competitive foods, regardless of serving size, sold to students on the school campus during the school day must meet nutrition standards which include having as the first ingredient a grain, fruit, vegetable, dairy, or protein food; in addition to nutrients to limit.

The proposed criteria we are requesting for the food group equivalents – where if the first ingredient contributes to a food group to encourage, the food would be considered to meet the food group equivalent criteria – would offer several benefits. This approach would be easier for FDA and

[9] 7 CFR 210.11(c)(2)(ii)-(iii).

manufacturers to implement since it can be determined based on a review of the label; it is consistent with other regulations such as the Competitive Foods in Schools standards; and it solves the challenges created by the current proposal when the reference amount is inherently smaller than the food group equivalent proposed, while still ensuring the food would contain a meaningful amount of the food group. For example, it would allow a hummus or salsa to qualify if the first ingredient is chickpeas (a protein food) or tomatoes (a vegetable), respectively, without a requirement to quantify the amount in terms of volume.

4. **<u>Food Group Equivalents</u>: The food group equivalent criteria require a number of key changes in order to be implementable for nutrient-dense foods.**

    a. **FDA should allow contributions from multiple food groups to be aggregated.**

The proposed requirement that at least one, two, or three food group equivalents *from distinct food groups* must be present across individual foods, main dishes, and meals (or ½ FGE from two distinct groups for mixed products) is overly rigid and does not reflect the practical ways in which recipes are designed, nor does it reflect each food's collective contribution to food groups in a dietary pattern. It also does not align with federal dietary guidance, which recommends consumers focus on their dietary pattern as a whole rather than focusing on food groups in isolation. And as a result, it poses food design challenges that mean the requirements are unlikely to encourage innovation in the nutritious snack category.

Snacks are unique in that while often nutrient-dense, they may not be able to provide one or more individual food group(s) in certain prescribed amounts given their mix of ingredients. For example, a mix of dried fruits and nuts may not contribute exactly ½ FGE for both fruits and nuts, particularly if one component is present at a greater amount in the blend. SNAC members recommend that FDA should consider a food's collective or total contribution to one or more food groups. For example, rather than having to contain ½ FGE of two different food groups, a mixed product (or an individual food) should meet the food group requirements if it contains a total of one FGE from one or more groups. This would avoid the potential for arbitrary distinctions when a food contains multiple food groups but not in the precise combination required by the proposed rule.

    b. **FDA should count dried fruits and vegetable powders toward the food group equivalents; and use a revised standard for the grains group of 8 grams whole grains per ounce equivalent.**

        i. **Inclusion of Fruit and Vegetable Powders**

SNAC recommends that FDA determine that dried fruits and vegetables, including powdered fruits and vegetables, should count toward the fruit and vegetable food groups. In FDA's guidance, *Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals*, FDA states that fruit and vegetable

powders that are not made from juices "are essentially whole fruits and vegetables that have been processed to change the physical form of the fruit or vegetable and to remove moisture."[10] Moreover, the guidance states that fruit and vegetable powders, "contribute to the diet the same way that sugars found in whole fruits or vegetables do, and do not have to be declared as added sugars".[11] Therefore, powdered fruits and vegetables that are not derived from juice should be eligible to contribute toward the fruit and vegetable food groups when determining the food group contribution. This is particularly important to our members utilizing these powders for extruded snacks. As discussed further below, we also urge FDA to provide guidance on how to calculate the contribution of a dried vegetable/fruit powder to the fruit and vegetable food groups.

Additionally, in response to FDA's request for additional information, we have prepared a side-by-side assessment of fresh, dried, and powdered legumes to support the inclusion of dried/powdered fruits, vegetables, and legumes under the "healthy" definition. (Appendix 2)

ii. Grains Group

SNAC recommends that FDA make the following changes and clarifications related to the grains group:

- **Adjust the food group equivalent requirement for whole grains**: The food group equivalent requirement for whole grains should be at least 8 g of whole grains per ounce equivalent (or for small RACC foods, whole grains as the first ingredient). The DGA recommends six-ounce equivalents of grain foods per day, with at least half of those being whole grain. The DGA also explicitly recommend that one way to meet this recommendation is to choose foods with 8 g of whole grain or more per ounce equivalent. However, under FDA's proposed definition of healthy, foods with 8 g of whole grain per ounce equivalent that meet all other established nutrient limits for saturated fat, added sugars, and sodium, would not qualify for a "healthy" claim as currently proposed. We wholeheartedly agree that only whole grains should count towards the grain food group equivalent for the "healthy" claim. However, we recommend that the whole grain threshold set by FDA align with the recommendations in the DGA: at least 8 g per ounce equivalent. Given the assumption of four eating occasions per day and the recommended 6 ounce-equivalents of grain foods, people will have to eat multiple ounce equivalents of grain foods at certain eating occasions. It is therefore not necessary for just four foods to deliver the full recommended three ounce-equivalents of whole grain. Rather, if each of the 6-ounce equivalents of grain foods consumed per day was a source of at least 8 g of whole grains, consumers would meet the recommendation. FDA should modify the final rule accordingly.

[10] FDA Guidance for Industry: Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals (Dec. 2019), p.10, available at https://www.fda.gov/media/117402/download.
[11] *Id*.

- **Expand the listed examples of whole grain foods**: We fear that the examples of whole grain foods in the proposed rule could be interpreted very narrowly, with only a short list of whole grain foods being able to qualify as a 1 oz. equivalent of grains, or as contributing 1 FGE of ¾ oz. eq. of whole grains. In the proposed rule FDA defined a 1 ounce-equivalent as ½ cup cooked whole grain brown rice, whole grain pasta or cereal; 1 oz. dry whole grain pasta or rice; 1 medium (1 oz.) slice of whole grain bread, tortilla or flatbread; or 1 oz. of ready-to-eat whole-grain cereal. This definition potentially excludes a wide variety of foods that are inherently whole grain (whole wheat flour, whole oat flour, popcorn) or made from whole grains (whole wheat bagels, whole grain crackers, brown rice crisps etc.). SNAC recommends expanding the definition by utilizing language from the DGA and measuring compliance with the whole grain criteria in grams present per reference amount. This would ensure clarity and consistency and open up a variety of culturally relevant categories to be eligible for claims, regardless of form.

c. FDA should establish a clearer framework with more details and information on how to conduct food group equivalent calculations.

In the proposed rule, FDA says it is relying on the definitions of food group equivalents in the DGA, but the proposed rule includes very limited guidance and examples of what counts toward particular food groups. The list of foods FDA provides that would count towards various food groups read as though it is an exclusive list rather than a list of examples. FDA should make clear the listed foods are examples only, and that other foods not specifically listed may be eligible. Because these food groups will be used as the basis for a binding regulation, due process requires additional clarity on what counts as a food group equivalent for each category.

For the fruit, vegetable, and protein food groups, there is no guidance on how to convert various forms of these foods into a ½ cup or 1 oz equivalent, taking into consideration the changes in density that occur from processing steps like drying, concentrating, chopping, pureeing, grating, cooking, and many others. A standard based on volume is incredibly complex to implement because this is not how food manufacturers measure ingredients. We urge FDA to consider whether this standard can be implemented by companies and to provide guidance on how to conduct the necessary calculations to determine whether the FGE criteria are met. We urge FDA to:

- Provide a standard methodology, calculator, and/or approved database that manufacturers can use to determine FGEs for their products;
- Provide weighted FGE credit for ingredients with higher soluble solids content such as purees, pastes, and concentrates;
- Clarify, either in the final rule or through the requested methodology, that manufacturers can determine specific FGEs based on the volume and weight averages of specific ingredients in the product, and that manufacturers can take into consideration cooking yields in their final determinations of FGE; and
- Provide guidance on whether FGEs can be rounded.

- To account for differences in moisture or food form across the different food types, SNAC recommends that FDA clarify that standardizing ingredients to their fresh or "single strength" equivalent will serve as a basis for food group calculations.

As an example, consider a product that includes a dried bean powder. Just as a consumer would hydrate whole beans before consuming them, it is reasonable to apply a similar calculation for the dried bean powder to determine its food group contribution. However, depending on the starting moisture content of the dried bean powder and the specific bean variety, its contribution, to nutrient content and caloric profile would likely vary. We therefore urge FDA to consider these differences in food form or moisture content in developing guidance on FGE calculations.

5. **<u>Scope of Definition</u>: FDA should limit the proposed definition to the "healthy" implied nutrient content claim.**

SNAC members request that FDA clarify that the definition of "healthy" applies only to terms defined as synonyms for a healthy nutrient content claim (e.g., "healthier") and only in those circumstances where the requisite "nutritional context" is present on the label. We ask FDA to confirm the rule does not apply to other labeling claims, such as health claims, structure/function claims (e.g., "Heart Healthy"), other nutrient content claims, or other undefined claims (e.g., "nutritious" or "wholesome").

SNAC also requests that FDA reconsider its position that the inclusion of front-of-pack nutrition icons such as Facts Up Front, MyPlate, or other symbols on the label, or other terms such as "made with whole grains" that do not reference nutrients, would be considered "nutritional context" that would result in the term healthy on the label subject to the rule's requirements. We disagree that these labeling elements would create such a nutritional context. The Facts Up Front program represents the standardized and factual display of nutrient information about a food and nothing more. Other claims, such as those about whole grain or fruit content, do not characterize the nutrient content.[12] We urge FDA to make clear that the scope of the rulemaking is limited and narrow in nature and that doesn't deem particular foods as "unhealthy," or "bad," nor does it apply in any broader regulatory context outside of the nutrient content claim definition.

6. **<u>Compliance Date</u>: FDA should make clear that products bearing the term "healthy" used in compliance with the existing regulation may be lawfully sold and shipped in interstate commerce until the compliance date**

SNAC strongly supports the proposed 3-year compliance period, which is important for our members to have sufficient time to reformulate products where needed, and revise labels. SNAC urges FDA to state clearly and unequivocally that following the issuance of the final rule, and during the 3-year compliance period, the term healthy may continue to be used consistent with the existing regulation, and products

[12] 21 CFR 101.65(b)(3).

bearing the term healthy may continue to be sold and shipped in interstate commerce and would be considered compliant with the Federal Food, Drug, and Cosmetic Act.

Relatedly, we ask that FDA provide for an effective date that is the same as the compliance date, i.e., 3 years after issuance of the final rule, in order to help make clear that existing uses of healthy under the current regulation may continue until the compliance date. This is allowed under FDA's administrative regulations, which require that the effective date be at least 30 days after publication of the final rule, but don't restrict longer effective dates. See 21 CFR 10.40. FDA should also recognize it will exercise enforcement discretion for products that comply with the new revised healthy rule to allow such products to bear a "healthy" claim prior to the compliance date.

7. **<u>Recordkeeping</u>: FDA should provide additional clarity regarding recordkeeping requirements.**

SNAC members ask that FDA provide additional clarification regarding the rule's recordkeeping requirements. For example, FDA should clarify that records kept to verify the food group contributions are limited in nature and need only include the specific information regarding the food group component information, rather than the full recipe which is considered confidential information. Similarly, SNAC members agree that manufacturers should be permitted to demonstrate compliance using the records they best believe meet the requirements and are not required to produce any specific form or document. This approach aligns with FDA's recordkeeping system for nutrition labeling of added sugars and other nutrients for which no analytical test method exists. We also note that to the extent FDA adopts our proposed approach regarding nutrients to limit, this would significantly reduce the recordkeeping burden.

8. **<u>Legal Considerations</u>: FDA should revise the final rule in a way that satisfies the agency's legal obligations under the First Amendment and Administrative Procedure Act (APA)**

To satisfy the First Amendment, a restriction on commercial speech like the one at issue here would need to meet exacting legal standards. In particular, the final rule would need to "directly and materially" advance a "substantial" governmental interest and be "no more extensive than necessary to serve that interest."[13] FDA has stated that it expects "a small number (0 to 0.4 percent of people that try to follow current dietary guidelines) of . . . consumers would use the 'healthy' implied nutrient content claim to make meaningful, long-lasting food purchasing decisions."[14] The agency's statements suggest that the proposed requirements may not directly and materially advance FDA's stated goals of reducing chronic disease and increasing the availability of nutrient dense options. Further, as seen by the comments above, there are a number of key ways in which the proposed rule would pose obstacles to companies wishing to reformulate to make more healthful products, suggesting the goal of increasing the availability of nutrient dense options would be out of reach.

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13 *Central Hudson Gas & Electric Corp. v. Public Service Comm'n*, 447 U.S. 557 (1980).

14 87 Fed. Reg. 59168, 59195 (Sept. 29, 2022).

We ask FDA to carefully consider whether the restrictions in the proposed rule are no more extensive than needed, particularly in the areas discussed above where a healthy dietary pattern could accommodate more flexibility in added sugars, sodium, and food groups, than proposed; and where the proposed rule would exclude foods encouraged as healthful by dietary guidance. Further, we ask FDA to market test the revised requirements to ensure they do not arbitrarily exclude nutrient dense foods, such as small RACC foods, in violation of the APA.

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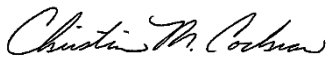
We look forward to the Agency's work on this important topic, including the final definition and the corresponding icon, and actively engaging in the regulatory process and dialogue on this very important topic. If there are any questions, please feel free to reach out to Colleen Farley, SNAC International's Director of Advocacy & Governance, at cfarley@snacintl.org.

Respectfully,



Christine Cochran
President and CEO
SNAC International

APPENDIX 1

Proposed Alternative Healthy Criteria

		Individual or Mixed Food Small RACC (≤30g or 2Tbsp) Requirements per RACC	**Individual or Mixed Food RACC >30g Requirements per RACC**	**Main Dish 6 - <10oz. serving size Requirements per labeled serving size (LSS)**	**Meal ≥10oz. serving size Requirements per LSS**	**Oils and Oil Based Spreads and Dressings**
Nutrients to Limit	Sodium Limit	10% DV 230 mg /RACC	20% DV 460 mg /RACC	25% DV 575 mg /serv	30% DV 690 mg /serv	5% DV 115 mg /RACC
	Added Sugars Limit	10% DV 5g /RACC	20%DV 10g /RACC	25% DV 12.5g /serv	30% DV 15g /serv	0-2% DV 0-1g /RACC
	Saturated Fat Limit (excluding that in nuts and seeds if applicable)	5% DV 1g/ RACC	10% DV 2g/ RACC	15% DV 3g/ serv	20% DV 4g/ serv	25% total fat for oil-based spreads; 20% total fat for oils and dressings
AND						
Components to Encourage	**Food Group Equivalent**	First ingredient (other than water, broth, stock, or similar solution) OR 1/4 composite FGE	First ingredient (other than water, broth, stock, or similar solution) OR 1/2 composite FGE	2 composite FGEs	3 composite FGEs	N/A
	OR					
	Nutrient(s) to Encourage*	≥10% DV 1 Positive Nutrient	≥10% DV 1 Positive Nutrient	≥10% DV 2 Positive Nutrients	≥10% DV 3 Positive Nutrients	N/A

*protein; fiber; vitamin D; potassium; iron; calcium

Food Group Equivalent Assumptions

Food Group	Food Group Equivalent
Vegetables	½ cup equivalent vegetable
Fruits	½ cup equivalent fruit
Grains	8 grams whole grain
Dairy	¾ cup equivalent dairy
Protein Foods	Game meats 1 ½ oz equivalent
	Seafood 1 oz equivalent
	Egg 1 oz equivalent
	Beans, peas, and soy products 1 oz equivalent
	Nuts and seeds 1 oz equivalent

APPENDIX 2

Data Supporting the Nutritional Equivalence of Whole and Powdered Legumes

Nutrition Information for Chickpeas

	US Standard Food Database USDA	Commercial Ingredients			USDA (Flour)
	Whole Chickpea Raw Seed USDA 16056	Chickpea Flour	Chickpea Meal	Chickpea Grits	Whole Chickpea Flour (Besan)-USDA 16157
	% Dried Weight Basis				
Protein (g)	22	25	25	25	25
Total Fat (g)	7	8	8	8	7
Total Ash (g)	3	3	3	3	3
Total Carbohydrate (g)	68	71	71	71	64
Total Dietary Fiber (g)	13	20	20	20	12
Iron (g)	0.005	0.0022-0.0066	0.0022-0.0066	0.0022-0.0066	0.005
Potassium (g)	0.778	0.4420-0.8839	0.4420-0.8839	0.4420-0.8839	0.943

Nutrition Information for Black Beans

	USDA Standard Food Database	Commercial Ingredients	
	Black Bean Raw (USDA 16014)	Black Bean Flour	Black Bean Grits
	% Dried Weight Basis		
Protein (g)	24.3	24.3	24.3
Total Fat (g)	1.6	3.3	3.3
Total Ash (g)	4.0	4.4	4.4
Total Carbohydrate (g)	70.1	74.0	74.0
Total Dietary Fiber (g)	17.4	25.4	25.4
Iron (g)	0.006	0.0044 - 0.0077	0.0044 - 0.0077
Potassium (g)	1.66	0.9945 - 1.1602	0.9945 - 1.1602

Nutrition Information for Navy Beans

	US Standard Food Database USDA	Commercial Ingredients	
	Navy Bean Raw (USDA 16037)	Navy Bean Flour	Navy Bean Grits
	% Dried Weight Basis		
Protein (g)	25.4	24.3	24.3
Total Fat (g)	1.7	3.3	3.3
Total Ash (g)	3.8	4.4	4.4
Total Carbohydrates (g)	69.1	72.9	72.9
Total Dietary Fiber (g)	17.4	25.4	25.4
Iron (g)	0.006	0.002-0.006	0.002-0.006
Potassium (g)	1.3	0.54-1.16	0.54-1.16