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

September 25, 2023

Re: Dietary Guidance Statements in Food Labeling: Guidance for Industry [Docket No. FDA-2023-D-1027]

Dear Sir or Madam,

Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) draft guidance for industry on dietary guidance statements in food labeling. As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. More information about our organization is available at www.FMI.org.

Executive Summary

FMI supports FDA's focus on improving dietary patterns in the United States to help reduce nutrition-related chronic disease and advance health equity. FMI members are committed to reaching consumers with evidence-based messaging to empower all Americans to make and have access to healthy choices, in alignment with the goals of the National Strategy announced following the 2022 White House Conference on Hunger, Nutrition and Health.

We welcome guidance from FDA on dietary guidance statements in labeling. This is a category of claims that has in the past been the subject of relatively little guidance, yet it is an area that presents an opportunity to facilitate helpful communication to consumers about the role of particular foods in constructing healthful diets. We agree with FDA's recognition that the legal standard governing dietary guidance statements is that such claims must be "truthful and not misleading."

At the same time, we have significant concerns that the draft guidance has taken an overly restrictive approach that goes well beyond providing guidance on the factors that need to be considered to ensure dietary guidance statements are truthful and not misleading. The draft guidance would impose a paradigm similar to what is required for health claims or nutrient content claims, on a category of claims – dietary guidance statements – that is not subject to these requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA). The recommendations in the draft guidance also go significantly beyond what the Dietary Guidelines for Americans (DGA) would require to promote certain recommended food items as being part of a healthy diet by imposing rigid recommendations related to nutrients of concern and food groups. We ask FDA to reconsider the proposed approach and hew more closely to the DGA recommendations, which don't impose specific recommended parameters when encouraging consumption of food groups within a healthy dietary pattern. Such an approach would also be more consistent with the underlying legal standard that dietary guidance statements must be truthful and not misleading. Below we summarize our comments on the draft guidance, and then lay out our comments in more detail.

1. **Definition of "Dietary Guidance" Statement**
    a. FDA explains in the draft guidance that dietary guidance statements are those that represent or suggest that an individual food or food group may contribute to or help maintain a nutritious dietary pattern. FDA should clarify that the scope of what constitutes a dietary guidance statement subject to the guidance is narrow and does not include, for example, a statement that characterizes the amount of a food group, such as "made with 8 g whole grains" or "contains ¼ cup fruit", or a statement such as "Dietitian's Pick" on a shelf-edge tag. These claims do not contain both elements of the proposed definition of a dietary guidance statement (i.e., a food/food group and discussion of a healthy dietary pattern). Accordingly, they are subject to the general "truthful and non-misleading" legal standard but are not dietary guidance statements.
    b. FDA should not abandon its prior precedent wherein a dietary guidance statement could characterize the role of a food group or category of foods (but *not* a specific food component or substance) in mitigating risk of disease, as this type of statement is found throughout federal dietary guidance and it would do a disservice to consumers to exclude such claims from the category of dietary guidance statements, particularly given FDA's focus in its nutrition policy initiatives on reducing the impact of nutrition-related chronic disease.

2. **Scope of Statements Covered by Guidance**
    a. We urge FDA to clarify that the guidance is limited to dietary guidance statements that appear on the label and in product labeling, and does not extend to advertising. Further, it is critical for FDA to consider and make clear whether and how the guidance applies beyond the physical package to information shared in other channels, such as websites, grocery store aisles, shelf-tags, in-store signage, apps, and social media. In order to encourage consumption of recommended foods and food groups and facilitate the building of healthy

dietary patterns, it is critical that the food industry, including dietitians and other nutrition professionals that are employed by retailers or food companies, is able to communicate truthful and non-misleading information to consumers. The wide variety of settings in which dietary guidance statements could be made underscores the need for flexibility and the difficulty of applying a one-size-fits-all approach of the type outlined in the draft guidance.

3. Recommendations on Source of Statements

a. The draft guidance states that dietary guidance statements should be based on "key or principal recommendations" from a consensus report, and states that consensus reports could include those published by U.S. federal government agencies or U.S. scientific bodies or U.S. health organizations outside the federal government. Yet all of the examples in the draft guidance are governmental agencies. In the past, FDA has recognized that dietary guidance could be based on the recommendations of a health professional organization such as the American Heart Association, and that such a statement would not constitute a health claim merely because the organization's name references a health or disease condition.[1] We ask FDA to make clear that non-governmental authoritative bodies such as the American Heart Association or a clinical organization can likewise provide an appropriate basis for a dietary guidance statement.

4. Meaningful Amounts of Recommended Food or Food Groups

a. A food need not contain a full FGE from a single group to make a significant positive contribution to the overall diet. Rather, it might have a smaller serving size, or contribute smaller amounts to multiple different groups to encourage, and still be a nutritious choice. Additionally, for some foods, their role in a healthy dietary pattern is not based on their food group content. For example, foods like spices; or water and unsweetened coffee, tea, or other similar beverages, do not typically contribute to food groups but are nevertheless valuable components of a healthy dietary pattern, as recognized in federal dietary guidance. We do not believe there is a feasible one-size-fits-all approach to the amount of a food group that should be present in order to support a truthful and non-misleading dietary guidance statement.

b. The difficulty of a one-size-fits-all approach is illustrated by the fact that some foods recommended by the DGA, such as calorie free beverages like bottled water and coffee, do not contain a food group. Further, the recommended minimum food group equivalents do not reflect what is considered a "significant" amount of a recommended food under the DGA (for example, generally 8 grams

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[1] FDA provided the following example of a dietary guidance statement: "Highlighted items are consistent with the general dietary recommendations of [insert name of health professional organization]. These guidelines are [describe all nutrient recommendations that comprise the group's guidelines]." Guidance for Industry: A labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods (Apr. 2008).

whole grains, ¼ cup fruit/vegetable, ½ cup dairy, and ½ of other FGEs). We therefore encourage FDA to reconsider its proposed approach for minimum food group amounts and to adopt a more flexible approach rather than trying to address all situations with a minimum food group amount.

c. In the alternative, if FDA maintains an FGE approach, FDA should revise the proposed FGE recommendations to be consistent with the DGA and establish exemptions accordingly for certain beverages and other foods that do not require a food group component to be the subject of a dietary guidance statement. It also will be critically important for FDA to provide clarity on how to calculate a food's FGE content, including where a food contains dried, concentrated, or otherwise processed ingredients in a food group, such as lentil powder, fruit puree, etc.

5. Nutrients to Limit / Disclosure Levels

a. There should be no disqualifying levels for nutrients, as dietary guidance statements are not health claims or nutrient content claims. Promotion of food groups can help consumers make choices that fit into their overall dietary pattern and meet nutrition recommendations, without the need for strict nutrient thresholds.

b. By establishing disqualifying levels for nutrients and minimum food groups, FDA would be recommending that dietary guidance statements be treated similarly to how health claims are regulated – as this is the only other category of claims that has broad disqualifying levels for nutrients. Yet these are two very different categories of claims. Further, the statute expressly allows FDA to set disqualifying nutrient levels for health claims and disclosure levels for nutrient content claims; no such authorization is provided for dietary guidance statements.[2]

c. In the alternative, if FDA nevertheless moves forward with recommended nutrient thresholds, they should be treated as suggested disclosures rather than disqualifying levels, and should align with the current disclosure levels that are already part of the regulatory framework for nutrient content claims (found in 21 CFR 101.13(h)), in order to avoid inconsistencies and consumer confusion. If the same panel of the label where the dietary guidance statement appears also bears other nutrient content claims that are accompanied by the disclosure under 101.13(h), only one disclosure per panel (accompanying the largest claim on the panel) would suffice, consistent with the regulations in 101.13(h)(4)(iii). Further, when Facts Up Front icons are included on the front of package with product calories, saturated fat, sodium and added sugar levels, the Facts Up Front icons should suffice as disclosure of these nutrient levels with no need for additional statements related to these nutrients.

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[2] 21 U.S.C. 343(r)(3)(A)(ii); see 21 CFR 101.14 (a)(4).

6. **Process for Issuing Final Guidance**
    a. FMI respectfully requests that before moving forward with a final guidance on dietary guidance statements, FDA should first finalize updates to the criteria for the nutrient content claim "healthy." The agency has proposed a similar framework for these two categories of claims, but there are a number of significant concerns and areas where clarification is needed, such as around how to calculate food group equivalents and how to account for small RACC foods, that need to be addressed before FDA recommends a similar framework for dietary guidance statements.
    b. We encourage FDA to closely coordinate with the USDA Food Safety and Inspection Service (FSIS) to ensure that the guidance would apply consistently across USDA/FSIS regulated products and would be appropriate for such products. We also encourage coordination and alignment with USDA's Center for Nutrition Policy and Promotion (CNPP) on use of MyPlate.

Detailed Comments

1. **Overall Approach**

FMI generally supports the Agency's commitment to empower consumers with more informative and accessible labeling to choose healthier diets. Dietary guidance statements that help customers determine how foods and food groups can contribute to nutritious dietary patterns should focus on the contribution to the overall diet, without disqualifying nutrient levels or precise food group minimums. The Dietary Guidelines for Americans, as the key consensus report upon which dietary guidance statements would be based, does not recommend that consumers follow rigid nutrient thresholds or food group amounts when constructing a healthy and balanced pattern of eating. The draft guidance effectively recommends limiting dietary guidance statements to only the types of foods that many consumers likely already understand to be healthful choices, such as whole fruits and vegetables and plain, unsweetened dairy products. Such an approach would limit the ability to make truthful and non-misleading statements that have the potential to improve nutrition literacy and consumer understanding as to what an overall nutritious dietary pattern looks like. We urge FDA to avoid establishing a one-size-fits all approach, as such an approach fails to capture the flexibility engrained within the DGA, and also greatly limits the utility of dietary guidance statements as a category of claims to educate consumers.

a. Definition of "Dietary Guidance" Statement

FDA explains in the draft guidance that dietary guidance statements are those that represent or suggest that an individual food or food group may contribute to or help maintain a nutritious dietary pattern. FDA should clarify that the scope of what constitutes a dietary guidance statement subject to the guidance is narrow. For example, we ask FDA to expressly clarify that a statement such as "made with whole grains" or "8 g whole grains" or "contains ½ cup fruit" or "made with real fruit" is not a statement subject to the guidance because it does not discuss or

imply anything about the food's role in contributing to or maintaining a healthy dietary pattern. Likewise, a statement that appears in labeling such as "Dietitian's Choice" is not subject to the guidance because it does not highlight a particular food group. Other examples that should not be considered within the scope of "dietary guidance" because they do not include both elements of such claims: Statements encouraging consumption of a product based on specific nutritional attributes (e.g., "grab a yogurt for protein and calcium"); statements about how a food can fit into a diet or recommendations for use that do not expressly refer to the food's role in a healthy dietary pattern ("grab a yogurt post-workout" or "grab a yogurt on the go"); or statements that refer to effects on the healthy or normal structure of function of the body (e.g., "eating xx as part of a balanced diet can provide [yy benefit]"). These types of statements are subject to the general "truthful and non-misleading" legal standard but are not dietary guidance statements within the meaning of the draft guidance and we ask FDA to confirm this in the final guidance.

We also ask FDA to clarify, consistent with past precedent, that use of the term "healthy" in a dietary guidance statement will not be considered an implied "healthy" nutrient content claim when the statement does not imply the absence or presence of a nutrient in a particular amounts. For example, FDA has previously clarified that "Eat lots of fruits and vegetables for a healthy diet" is not subject to the "healthy" nutrient content claim criteria and we ask FDA to reiterate this point in the final guidance.[3]

More broadly, though, with the proposed definition, FDA would be reversing past agency precedent where dietary guidance statements could contain one element of a health claim – i.e., a reference to either (1) a specific food or food component, or (2) a disease condition – but not both. For example, FDA has offered the following as an example of a dietary guidance statement that is *not* considered a health claim: "Consuming at least 3 or more ounce-equivalents of whole grains per day can reduce the risk of several chronic diseases".[4] FDA has explained that this statement is not a health claim, but rather is dietary guidance "because it cannot reasonably be understood to be about a specific substance."[5] FDA explained that a claim about a food or food group (rather than a specific substance) and a disease condition, did not contain all elements needed for the health claim requirements to apply. Similarly, FDA has explained that the following statement would be considered dietary guidance rather than a health claim because there is no characterization between a substance and the disease referenced in the name of the organization: "The National Cancer Institute Recommends that you eat five servings daily of fruits and vegetables."[6]

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3 Food Labeling: Nutrient Content Claims, Definition of Term: Healthy, 59 Fed. Reg. 24232 (May 10, 1994).

4 FDA Food Labeling Guide (Jan. 2013), question H4 and H5, https://www.fda.gov/media/81606/download.

5 *Id.*

6 Food Labeling: Health claims; general requirements, 58 Fed. Reg. 2478 (Jan. 6, 1993). However, the claim "The National Cancer Institute recommends that you eat five serving daily of fruits and vegetables to increase your intake of fiber" would be a health claim because it references a specific nutrient (fiber) and a disease (cancer). *Id.*

In the draft guidance, FDA appears to be abandoning this precedent without sufficient justification. The agency states that dietary recommendations have evolved from those based on specific nutrient-disease relationships to those that take into account the entirety of the diet. Yet it is not the case that disease risk no longer factors into dietary guidance. The DGA 2020-2025 are filled with discussion of how to reduce the risk of chronic diseases throughout all stages of life, even stating, "The aim of the *Dietary Guidelines* is to promote health and prevent disease". We therefore do not agree that there is merit to FDA's position that dietary guidance statements cannot reference a disease condition given that federal dietary guidance is replete with such references. The important rule-of-thumb, consistent with past FDA statements, is that the statement could not contain both a reference to a disease condition and a specific food or food component, or it would trigger the health claim requirements. Instead, dietary guidance statements should be about a category of foods (e.g., "carrots" generally rather than a specific product), or a food group.

Further, as discussed further below, FDA's recommendations in the draft guidance would treat dietary guidance statements similar to health claims – including recommending disqualifying nutrient levels and reliance upon a "consensus report" – while at the same time restricting the ability to discuss the role of a food group in reducing the risk of disease conditions (e.g., fruits and vegetables reduce risk of cancer), which is a reversal of the agency's historic statements and precedent on this category of claim. We therefore urge FDA to revisit the approach and ensure consistency with the agency's historic statements on dietary guidance.

b. Scope of Statements Covered by Guidance

As an initial matter, FDA should make clear the guidance does not apply to materials that constitute advertising. Additionally, many food retailers and product suppliers employ registered dietitians and nutrition professionals to create meaningful dietary guidance statements, tips, ideas, and solutions for consumers that align with federal recommendations. This type of content is evident across the food industry and can most often be found in grocery store aisles, on shelf tags, in-store signage, as well as on websites, apps, social media and other channels beyond what is on the package label.

With respect to these types of off-label statements, the scope of the guidance must be clarified to ensure the ability to continue to communicate truthful and non-misleading information in the food industry, without disqualifying levels, for general food and food group encouragement. For example, an in-store end cap display or online category headline for whole grain cereal options should be able to encourage consumers with a guidance statement such as: "Include whole grains as part of your day" with a link to more information at MyPlate.gov, without referencing individual item disclosure levels. Dietary guidance statements and other general nutrition statements about the inclusion of foods and food groups in overall healthy dietary patterns beyond what appears on food product labels should continue to be permitted in this way. Likewise, articles and other communications authored by dietitians identifying ways to consume more of particular food groups or nutrients should not be subject to the criteria in the

guidance; otherwise, the guidance would hamstring the ability of professionals to educate consumers on how to make stepwise changes in their diets to implement the DGA.

Further, some retailers have developed programs with dietitians that identify foods that may fit into a healthy dietary pattern or that meet specified nutrient and other criteria that are publicly available. These programs have existed for years and have garnered significant consumer use and understanding. We urge FDA to clarify that such programs are not subject to the guidance. Consumers can readily access the criteria for such programs and an FDA recommendation to use only the agency's criteria is overly and unnecessarily restrictive when applied to these existing and longstanding programs.

2. Recommendations on Source of Statements

The draft guidance states that dietary guidance statements should be based on "key or principal recommendations" from a consensus report, and states that consensus reports could include those published by U.S. federal government agencies or U.S. scientific bodies or U.S. health organizations outside the federal government. Yet all of the examples in the draft guidance are governmental agencies. In the past, FDA has recognized that dietary guidance could be based on the recommendations of a health professional organization such as the American Heart Association, and that such a statement would not constitute a health claim merely because the organization's name references a health or disease condition.[7] We ask FDA to make clear that non-governmental authoritative bodies such as the American Heart Association or a clinical organization can likewise provide an appropriate basis for a dietary guidance statement when the statement in question is supported by competent and reliable scientific evidence.

We also caution FDA against taking an overly restrictive approach in terms of the appropriate sources for dietary guidance statements that could stifle truthful and non-misleading information. The recommendation that dietary guidance statements should be based on a consensus report is similar in nature to what is required for health claims under the "significant scientific agreement" standard – yet dietary guidance statements are not subject to this standard under the statute. A standard requiring a consensus report also fails to recognize the role of emerging science and the ability to appropriately qualify and tailor the claim to the scientific evidence. These are bedrock First Amendment principles, including under the FDA framework for qualified health claims, and we urge FDA to not depart from them in guidance.

3. Meaningful Amounts of Recommended Foods or Food Groups

Our members have concerns that it is not practical or helpful to establish a one-size-fits-all approach to the amount of a food group that should be present in order to support a truthful

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[7] FDA provided the following example of a dietary guidance statement: "Highlighted items are consistent with the general dietary recommendations of [insert name of health professional organization]. These guidelines are [describe all nutrient recommendations that comprise the group's guidelines]." Guidance for Industry: A labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods (Apr. 2008).

and non-misleading dietary guidance statement. Indeed, the DGA emphasize the importance of not focusing on food groups in isolation, but rather looking at them as part of an overall dietary pattern:

> "Researchers and public health experts, including registered dietitians, understand that nutrients and foods are not consumed in isolation. Rather, people consume them in various combinations over time—a dietary pattern—and these foods and beverages act synergistically to affect health. The Dietary Guidelines for Americans, 2015-2020 puts this understanding into action by focusing its recommendations on consuming a healthy dietary pattern. The 2020-2025 Dietary Guidelines carries forward this emphasis on the importance of a healthy dietary pattern as a whole— rather than on individual nutrients, foods, or food groups in isolation."

The difficulty of a one-size-fits-all approach to food group contributions is illustrated by many of the concerns we discussed in our comments to FDA on "healthy", including the following:

- **The recommended minimum food group equivalents do not reflect what is a "significant" amount of a recommended food under the DGA** (generally 8 grams whole grains per ounce equivalent, ¼ cup fruit/vegetable, ½ cup dairy, and ½ of other FGEs, etc.). These amounts reflect substantial and meaningful amount that will help consumers meet DGA recommendations over the course of a day and encourages industry to reformulate to include more under-consumed food groups.
    - To take grains as an example, the DGA recommends that one way to meet the recommended intake of grains (6 ounce-equivalents of grain foods per day, at least half of which are whole grains) is to choose foods with 8 grams of whole grain per ounce equivalent. However, under FDA's proposed guidance, foods with 8 g whole grain per ounce equivalent would not qualify for a dietary guidance statement. If FDA maintains a food group approach, FDA should amend the whole grain equivalent recommendation so that it is aligned with the 8 g whole grain per ounce equivalent recommended in the DGA.
    - With respect to dairy, ½ cup of yogurt, for example, would be equivalent to the 4 oz/ 170 g reference amount that FDA has established for yogurt and that serves as the basis for the labeled serving size.
    - Likewise, an amount of ¼ cup fruit or vegetable could be appropriate to support a dietary guidance statement, depending on the context of the statement. For instance, a parfait ¼ cup fruit with ½ cup dairy would represent a meaningful contribution to both the fruit and dairy groups and it would be appropriate to make a claim about these food groups and their role in a healthy dietary pattern.

- **Not all foods need to contain a significant amount of a food group to be the appropriate subject of a dietary guidance statement**. Some foods recommended by the DGA, such as calorie free beverages like bottled water (still, carbonated, flavored, unflavored, with or without added vitamins or minerals), tap water, plain or flavored unsweetened coffee (whether roasted and ground, whole bean, instant, powdered, or

ready-to drink), and unsweetened tea in any form, do not contain a food group, yet should still be eligible to be promoted as a recommended food as part of a healthy dietary pattern consistent with the DGA.

- **The food group equivalents should be based on a combined contribution to multiple food groups**, as this is more consistent with the Dietary Guidelines focus on the overall eating pattern rather than focusing on food groups in isolation. For example, for some foods, like a frozen entrée or a 100% juice blend with fruit and vegetable juice, the combined contribution is more relevant than the amount of each single food group.

- **The food group equivalent criteria should be met if a food's first ingredient (or second ingredient if the first ingredient is water or broth) is in one of the food groups to encourage**. This approach is consistent with USDA standards for Smart Snacks in School, which require a food to meet nutrients to limit criteria and to contain as the first ingredient a grain, fruit, vegetable, dairy, or protein food (or if the first ingredient is water, the second ingredient is one of the listed food groups).[8] The "first ingredient" approach is also used under the Dietary Guidelines to help consumers identify whole grain-rich foods, and accordingly will be helpful in educating consumers about how to identify healthful foods by looking at ingredient lists. [9]

- **Foods with small reference amounts customarily consumed (RACCs) should be subject to a proportionally smaller FGE and nutrients to limit recommendations**. Under the proposed guidance, foods like salsa, hummus, dips, cottage cheese, most other cheeses, whole grain croutons, some crackers/cereals with a 15 g RACC, and avocado could not qualify to bear dietary guidance statements because their RACC is too small for them to contain a full FGE in the RACC. As discussed above, FDA should instead consider the FGE recommendations to be met if either the proposed FGE minimums are met, or if the first ingredient (or the first ingredient after water for foods other than beverages) is a food in one of the food groups to encourage. Such an approach would appropriately recognize the proportionally smaller contribution to dietary patterns made by foods with small RACCs and would avoid arbitrary results where foods are ineligible for a dietary guidance statements simply because they are commonly consumed in small quantities.

For these reasons, we urge FDA to reconsider its proposed approach of creating one-size-fits-all recommendations for minimum food group amounts. Such an approach fails to reflect the DGA's emphasis on dietary patterns as a whole. We ask FDA to adopt a more flexible approach rather than trying to address all situations with a minimum food group amount.

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[8] 7 CFR 210.11(c)(2)(ii)-(iii).

[9] See page 32 of the DGA ("Choose 100% whole-grain foods for at least half of all grains consumed. The relative amount of whole grain in the food can be inferred by the placement of the grain in the ingredient list. The whole grain should be the first ingredient—or the second ingredient after water. For foods with multiple whole-grain ingredients, they should appear near the beginning of the ingredient list.").

In the alternative, in the event FDA maintains the FGE concept, FDA should revise the proposed FGE recommendations to be consistent with the DGA and establish exemptions that reflect the recommendations in the DGA for certain beverages and other foods that do not require a food group component to be the subject of a dietary guidance statement.

4. Nutrients to Limit / Disclosure Levels

a. No Disqualifying Levels

Dietary guidance statements that help customers determine how foods and food groups can contribute to nutritious dietary patterns should focus on the contribution to the overall diet, without disqualifying or disclosure nutrient levels. A dietary guidance statement is not a nutrient content claim or a health claim. All foods that contain under consumed foods and food groups can help people meet recommendations and should be able to bear dietary guidance statements.

By establishing restrictive disqualifying nutrient levels, many products that are recommended by the DGA and contribute significant amounts of food groups would be disqualified from communicating dietary guidance statements. This means the draft guidance creates barriers for many claims that are truthful and not misleading. Disqualifying levels do not align with the Dietary Guidelines. The DGA do not state specific levels of nutrients to limit that people should avoid; instead they encourage shifts in consumer behavior towards "lower amounts" of saturated fat, sodium and added sugars to help build healthier dietary patterns. Yogurt is a great example of this. The DGA encourage low-fat or fat-free yogurts and do not recommend a particular level of added sugars at which yogurt is no longer an appropriate contributor to the dairy group.

With the proposed approach, FDA would be recommending that dietary guidance statements be treated similarly to how health claims are regulated – as this is the only other category of claims that has broad disqualifying levels for nutrients. Yet these are two very different categories of claims. Further, the statute expressly allows FDA to set disqualifying nutrient levels for health claims and disclosure levels for nutrient content claims; no such authorization is provided for dietary guidance statements. [10]

Moreover, the levels proposed are quite restrictive – more restrictive than FDA's existing nutrient disqualifying level/disclosure level requirements for these same nutrients for health claims and nutrient content claims. As one example, a frozen meal with 6 g (12% daily value) added sugars per serving would not appear to meet the added sugars threshold in the draft guidance and therefore would not be recommended to make a dietary guidance statement even if it

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[10] 21 U.S.C. 343(r)(3)(A)(ii); see 21 CFR 101.14 (a)(4).

contained moderate amounts of sodium and saturated fat and contributed meaningfully to one or more food groups.

This seems backwards and inappropriate when of the three types of claims, dietary guidance statements are the only ones for which the statute does *not* authorize FDA to establish disqualifying or disclosure levels for nutrients. The nutrient levels for health and nutrient content claims are generally set at 20% of the daily value, whereas products bearing a dietary guidance statement would be held to more restrictive levels for saturated fat (no more than 10% DV per RACC with an exception given to nuts and seeds), sodium (no more than 15% DV per RACC), and added sugars (no more than 10% DV per RACC). These restrictive levels blur the line between guidance on individual foods and guidance on overall diet. The noted inconsistencies will cause consumer confusion, education challenges, and implementation difficulties. These levels also fail to provide incentives for food companies to reformulate products and/or innovate around food groups.

For these reasons we urge FDA to remove the recommended nutrient levels from the final guidance and instead provide more measured guidance advising companies to assess whether the product as a whole is consistent with the dietary guidance that forms the basis for the statement. This type of approach is more in line with the flexible "truthful and non-misleading" legal standard that governs these claims.

b. Disclosure Levels

In the alternative, if FDA nevertheless moves forward with recommended nutrient thresholds, they should be treated as recommended disclosure levels, rather than disqualifying levels, and should align with the current disclosure levels that are already part of the regulatory framework for nutrient content claims (found in 21 CFR 101.13(h)), in order to avoid inconsistencies and consumer confusion.

If the same panel of the label where the dietary guidance statement appears also bears other nutrient content claims that are accompanied by the disclosure under 101.13(h), only one disclosure per panel (accompanying the largest claim on the panel) would suffice, consistent with the regulations in 101.13(h)(4)(iii). Further, when Facts Up Front icons are included on the front of package with product calories, saturated fat, sodium and added sugar levels, the Facts Up Front icons should suffice as disclosure of these nutrient levels with no need for additional statements related to these nutrients.

5. Categories of Products Eligible for Dietary Guidance Statements

We ask FDA to expressly state that dietary guidance statements may be made in the labeling of foods for infants and young children. Such a clarification is consistent with the DGA 2020-2025, which for the first time provided dietary recommendations for infants and young children. Additionally, the existing daily reference values established for these age groups, and the

available data on eating patterns of these age groups present an excellent opportunity to create criteria specific for these populations.

We also request that FDA reconsider its position on the use of dietary guidance statements on dietary supplements. The draft guidance states that because the DGA encourage Americans to meet nutrient requirements through the consumption of whole foods, dietary supplements should not bear dietary guidance statements. Yet the DGA recognize that dietary supplements can be useful in providing one or more nutrients that may otherwise be consumed in less than recommended amounts or when it is otherwise not possible to meet needs for one or more nutrients, for example, during specific life stages such as pregnancy. We therefore believe dietary supplements should be able to bear appropriate, substantiated, truthful and non-misleading statements to aid consumers in selecting products that are appropriate for their individual dietary and nutritional needs, and ask FDA to provide guidance along those lines.

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FMI thanks FDA for the opportunity to submit comments on this important topic. Please do not hesitate to contact FMI with any questions.

Sincerely,

Dana Mullen Graber
Senior Counsel, Legal and Regulatory Affairs

Krystal Register, MS, RDN, LDN
Senior Director, Health & Well-being