October 8, 2018

Leslie Kux  
Associate Commissioner for Policy  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD  20852

Re: FDA-2018-N-238; The Food and Drug Administration’s Comprehensive, Multi-Year Nutrition Innovation Strategy; Public Meeting; Request for Comments

Dear Ms. Kux:

On behalf of the National Association of County and City Health Officials (NACCHO), I am writing to provide comments in response to the Food and Drug Administration’s (FDA) Comprehensive, Multi-Year Nutrition Innovation Strategy. NACCHO represents the nation's nearly 3,000 local governmental health departments. Local health departments develop policies and create environments that make it easier for people to be healthy and safe, including advising the public on healthy eating practices, increasing access to affordable healthy foods, and ensuring the public has the knowledge and resources to choose a healthy diet.

Overall, NACCHO appreciates the agency’s commitment to align food labels with dietary advice. This effort offers a critical opportunity to create greater transparency for consumers in the service of public health and to foster innovation that drives reformulation and the availability of healthier foods. NACCHO encourages the FDA to use this opportunity to both promote healthful foods and to prevent misleading labeling that hampers Americans’ ability to make healthful dietary choices.

**General Principles that Connect Sound Labeling Policy to Public Health Goals**

Contrary to the sound recommendations of the 2015 Dietary Guidelines for Americans, Americans under-consume healthful foods: in particular, fruits and vegetables, low-fat dairy, and whole grains. Americans also over-consume unhealthful foods with added sugars, saturated fats, and sodium. Labeling transparency is a valuable tool for assisting consumers in making healthful choices and should assist consumers in following dietary advice, as the Nutrition Labeling Education Act directs.
Consumers should be confident that foods marketed as better for their health are indeed healthful choices. The stakes are high: 70% of adults and 33% of children and teens are now overweight or obese.\(^1\),\(^2\) Approximately 45% of adults have diabetes or prediabetes.\(^3\) In addition, about 75 million American adults (32%) have high blood pressure—that’s 1 in every 3 adults,\(^4\) and about 1 in 3 American adults has prehypertension.

Every time a consumer goes looking for healthier food and is sold a food or beverage that undermines their health, that is a missed opportunity to reduce diet-related disease. Many consumers who dutifully try to follow dietary advice nonetheless struggle with excess weight gain, high blood pressure, prediabetes, and other preventable diet-related health problems. Data from the International Food Information Council show that health, as well as weight loss, are core considerations for most consumers in making food choices. Consumers pay attention to labels: more than half of consumers look at the Nutrition Facts Panel or ingredient list “often” or “always” when making a purchasing decision, and approximately 40% say they consider other labeling statements about health or nutrition benefits.\(^5\)

Labels thus provide actionable information at the point of decision, connecting dietary choices to health. Yet products across the marketplace attempt “permission” marketing, in which a health halo is intentionally created to make food and beverages appear more healthful than they are. Specifically, consumers should not be misled that processed foods touting images of fruits and vegetables are adequate dietary substitutes for fresh fruits and vegetables. For this reason, it is critical that the FDA’s initiative should seek to correct misleading or inaccurate labeling claims and should not enable unhealthy foods to unfairly compete with fresh fruits and vegetables, which occupy too little space in Americans’ diets.

As the FDA designs its program, the agency should consider whether its labeling strategy will help to clarify what is in the products and what is not included in them, and whether it will effectively encourage consumers to fill grocery carts with fresh fruits and vegetables that bear

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no labels at all. For these reasons, NACCHO believes that the FDA should focus on the following topics as part of the Nutrition Innovation Strategy:

1) The FDA should strengthen the definition of “healthy” and review a full range of options for front-of-package nutrition labeling programs.

2) The FDA should improve labeling of whole grains to improve transparency for consumers and encourage healthful reformulation of grain-containing foods.

3) The FDA should improve transparency by addressing deceptive labeling.

4) The FDA should improve standards of identity and ingredient lists and complete its critical work on nutrition education and sodium reduction.

The FDA’s initiative will be most effective if the agency limits misleading claims and undertakes other reforms in the service of a clear and powerful vision of a better marketplace for consumers and companies alike.

1) The agency should strengthen the definition of “healthy” and review a full range of options for front-of-package nutrition labeling programs.

As part of its interest in “modernizing claims,” the FDA seeks public comment on the possibility of using an easy-to-find symbol to denote the claim “healthy” on food labels. NACCHO supports an effort to create a national standardized, front-of-package symbol system to help consumers quickly identify healthier foods.

While an FDA-defined healthy logo holds potential to be useful for consumers, NACCHO is concerned that a standardized “healthy” symbol, available to manufacturers for voluntary use, would be less helpful than a more comprehensive symbol system that conveys information about both the healthier and unhealthier attributes of foods. While a “healthy” logo may guide consumers to a few healthier choices within a food category, it would not allow them to discern which foods should be avoided or eaten less often — information that is critical to people’s ability to follow the advice in the Dietary Guidelines for Americans, such as to eat less saturated fat, added sugars, and sodium. Moreover, a “healthy” symbol that is primarily available for packaged foods would have the potential to make these foods appear more attractive relative to unpackaged alternatives, such as fresh fruits and vegetables, which are significantly under-consumed.

This problem would be exacerbated if the standard for “healthy” is too lax, allowing products high in refined grains or added sugars to be mislabeled as healthy. Should the FDA proceed with a healthy logo, the agency should consider ways to integrate the effort with existing labeling systems and provide additional information to consumers about the nutrition content of foods. This could include guidance on integrating the healthy logo with additional front-of-package elements, such as the information about calories, saturated fat, sodium, and added sugars, which are provided through the industry’s “Facts Up Front” initiative.
Consumer testing of a range of systems, as well as existing research and labeling rules on front-of-package systems around the globe, should guide the FDA’s review, and should include an evaluation of their impact on both consumer choices and reformulation. NACCHO encourages the FDA to begin by strengthening the definition of “healthy” as it has already proposed. The revised “healthy” definition should include limits on added sugars and require that grain-containing foods be 100% whole grain. It should also consider both food and nutrient criteria but maintain maxima for saturated fat, sodium, and added sugar in “healthy foods.”

If the FDA makes additional changes as to the healthful ingredients permitted on labels using the term “healthy,” it should consider only the foods that make up the core of a healthy eating pattern in their nutrient-dense forms. If “healthy” is not carefully defined, the claim could encourage consumers to select unhealthy foods rather than under-consumed whole fruits and vegetables.

2) The FDA should improve labeling of whole grains to improve transparency for consumers and encourage healthful reformulation of grain-containing foods

Clearer labeling of grains on processed foods is an important and promising area that could create new clarity for consumers and revitalize incentives to improve the healthfulness of these foods. The FDA should consider, as part of its Nutrition Innovation Strategy, how better to support consumers in following the Dietary Guidelines advice for consumption of whole grains. The Dietary Guidelines recommend that Americans “make at least half of your grains whole.” Yet Americans in every age group are not following this advice, under-consuming whole grains and over-consuming refined grains.

Consumers are increasingly seeking to increase their intake of whole grains. The marketplace is responding: market analysts predict the global market for whole grain and high fiber foods will expand by nearly 50% over the next five years, reaching $46.2 billion by 2022. However, labeling on grain-containing products remains afflicted by a lack of clarity. A study published in 2016 by the FDA in collaboration with several academic institutions showed that older adults are confused by package information about whole grain products. These results accord with

those of a national online survey commissioned by the Center for Science in the Public Interest in 2011 that included more than 1,000 participants. The survey, which was sent to the FDA in 2012, showed that consumers overestimated the amount of whole wheat in a product when shown the front of product packages that emphasized the word “wheat,” including when “wheat” was accompanied by depictions of dark-colored crackers, heads of wheat, or the term “stone ground.”

A result of this confusion is that while some companies are innovating in the marketplace to offer products with whole grains that appeal to consumers, incentives for these innovations are blunted by the fact that consumers often cannot tell which grain products are whole grain, and which are refined grains. Hearty-looking (and sometimes artificially colored) “wheat” breads and “multigrain” breads add to the confusion by containing labeling claims and images that suggest they contain whole grains when they may include none or negligible amounts. Whole grain content is not disclosed in the Nutrition Facts panel, and even the ingredient list may not be informative if it contains confusing names, fails to specify which grains are whole grains, or lists multiple refined grains after whole grain, which together could add up to make refined grain the predominant ingredient.

NACCHO therefore urges the agency to prioritize the issue of whole grain labeling. To prevent misleading claims and encourage healthful innovation, the FDA should:

- Define “whole grain claims” to clearly include use of the terms “whole wheat,” “whole grain,” “made with whole grain,” “multigrain,” a declaration of the whole grain content by weight; the term “wheat” on a wheat-based bread, pasta, or other product that is typically made from wheat, use of depictions of wheat or grains, or any similar descriptive phrases, terms, or representations suggesting the product contains whole grains; and
- Require that foods making such whole grain claims prominently and uniformly disclose either the percentage of whole grains and refined grains or the grams of both refined and whole grains per serving. The form of the disclosure should be based on the results of consumer testing.

3) The FDA should improve transparency by addressing deceptive labeling.

NACCHO urges the FDA to focus its reform efforts primarily on ensuring that healthful-sounding claims cannot be made on unhealthy products. Food stores are filled with sugary cereals, frozen novelties, and pastries carrying claims that they are “good” or “excellent” sources of vitamins and minerals. Cereals, candy, and salty snacks tout healthful ingredients like berries, fruit, or kale, even when they contain minuscule amounts of these healthful ingredients. When consumers purchase and consume these generally unhealthy products based on misleading claims, producers of truly healthy foods lose market share, undermining healthful innovation.
Existing rules to prevent such abuses are weak: health claims may not be made on products high in total fat, saturated fat, cholesterol, and sodium, but can be made on products made primarily of refined grain or high in added sugars.\textsuperscript{10} Regulation of nutrient content and structure/function claims is weaker still, as these claims generally can be made on unhealthy products with no more than a weak disclosure provided for nutrient content claims on foods high in total fat, saturated fat, cholesterol, or sodium (but there is no disclosure for products high in added sugars).

Moreover, structure/function claims do not require FDA approval, although for consumers such claims are often indistinguishable from health claims. The FDA has the authority to regulate structure/function claims under its general authority to prevent misleading labeling. Alternatively, the agency could deem at least some of these claims to be implied health claims, as it has done in the instance of labeling claims related to maintaining heart health.\textsuperscript{11}

The FDA currently lacks a framework to prevent claims for healthy ingredients from being made on unhealthy products, such as claims that a product is “made with” whole grains, fruits, vegetables, nuts, and dairy made on products high in saturated fat, added sugars, and sodium. In addition to its general authority to prevent misleading claims, the agency has the authority to deem such claims to be implied nutrient content claims to the extent that they are known to contain a particular nutrient (e.g., "contains oat bran" = "a good source of dietary fiber").\textsuperscript{12}

The FDA expressed an interest in exploring claims for products that offer fruits, vegetables, low-fat dairy, and healthy oils, for which American diets typically fall short of recommendations.\textsuperscript{13} The FDA also has sought how claims could or should signal that a product contains a “meaningful amount” of these food groups.\textsuperscript{14} To create more clarity for consumers, NACCHO encourages the FDA to consider requiring clear, transparent declarations on foods making fruit and vegetable claims that would allow consumers to understand how these products do, or do not, contribute to a healthy dietary pattern.

The Dietary Guidelines recommend that consumers eat a variety of vegetables and increase their consumption of fruits, with a focus on whole fruit.\textsuperscript{15} Despite such advice, Americans in

\begin{itemize}
  \item \textsuperscript{10} 21 CFR § 101.14
  \item \textsuperscript{12} 21 CFR 101.65(c)(2).
  \item \textsuperscript{14} Gottlieb, S. “Reducing the Burden of Chronic Disease.” National Food Policy Conference, Consumer Federation of America, March 29, 2018, Capital Hilton, Washington, DC.
\end{itemize}
every age group consistently fail to consume the amount of fruit and vegetables recommended in the DGA. The Centers for Disease Control and Prevention found that only one in ten adults meet the federal fruit or vegetable recommendations. More than half of consumers in the IFIC 2018 Food and Health Survey report eating less fruits and vegetables than what they believe experts recommend.

FDA should review the most frequently employed deceptive labeling claims with implications for public health, including “made with” and “contains real fruit” claims, the use of misleading images of whole fruits and vegetables when only minuscule amounts are in a serving, the use of misleading titles for categories of foods that are unhealthy or are minimally nutritious foods. The agency should consider whether, taken as a whole, such labels, images or claims are misleading or deceptive, and should use its full range of regulatory options, including enforcement, as well as developing new clarifying guidance or regulations where needed.

NACCHO urges the FDA to address this issue by:

- Requiring that foods making fruit and vegetable claims (through words or depictions) disclose the quantity of fruits and vegetables per serving in household measures. The declaration should be specific to the type of fruit or vegetable depicted or mentioned in claims, to avoid creating a lack of transparency that unfairly depicts that more desirable or expensive ingredients predominate in a food when they do not.
- Foods that contain fruit or vegetables that are not in their whole or cut form (without added sugar or sodium) should not be counted towards the amount of fruit in the declaration (for example, powders, concentrated fruit juice, or purees). A required disclosure should additionally indicate that the “The Dietary Guidelines for Americans recommends that at least half of your daily amount of fruit intake should be from whole fruits.”
- If a food is lacking in fruits and vegetables and contains only fruit or vegetable flavoring, it should bear a disclosure: “Contains no real fruits/vegetables.”

There are a number of specific additional steps that the FDA should take to update labeling requirements and address deceptions in the marketplace that currently impede healthful

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choices. The FDA currently lacks a framework to prevent claims for healthy ingredients from being made on unhealthy products, such as claims that a product is “made with” whole grains, fruits, vegetables, nuts, and dairy made on products high in saturated fat, added sugars, and sodium.

In addition to its general authority to prevent misleading claims, the FDA has authority to deem such claims to be implied nutrient content claims to the extent that they are known to contain a particular nutrient (e.g., "contains oat bran" = "a good source of dietary fiber").19 NACCHO urges the FDA to strengthen the rules for health, nutrient content, structure-function, and other “health halo,” claims to ensure these claims are not made on unhealthy products, by:

- Updating 21 CFR § 101.14 to include a disqualifying level of added sugars for health claims that comport with its Daily Value for added sugars, as the FDA indicated that it plans to do in its Nutrition Facts Panel Final Rule.
- Updating nutrient content claim disclosures for unhealthful nutrients, at 21 CFR § 101.13, to require a comparable disclosure for foods high in added sugars.
- Preventing claims for healthful ingredients like fruits, vegetables, and whole grains from misleading consumers into believing products high in saturated fat, added sugars, or sodium are healthy. This can be done either by initiating a rulemaking under the FDA’s general authority to prevent misleading claims, or by deeming such claims to be implied nutrient content claims.
- Issue regulations or take enforcement actions to define use of the term “low sugar” as a nutrient content claim. Because the FDA has not defined “low sugar” by regulation, the use of this term (or similar phrases like “lightly sweetened,” “just a tad sweet,” “sorta sweet”) that imply low sugar content should therefore be prohibited under 21 C.F.R. §101.13(b). A reasonable consumer would likely believe that a product labeled with any variation of the term ‘lightly sweetened’ contains a small amount of sugar and is a healthier option. Yet products labeled “lightly sweetened” sold today may contain as much as 20 grams of sugar, or 40 percent of the Daily Value for added sugars.
- Relatedly, the FDA should require a specific disclosure if a product boasts “0 grams” or “no” trans fat but is above a certain threshold for saturated fat, added sugars, or sodium, as most artificial trans fat is now gone from foods and this can create an unwarranted health halo on some unhealthful foods.
- IFIC consumer survey data indicate that "natural" is the most influential of all label claims and is used by nearly 40% of consumers when making purchasing decisions. The FDA should move forward to clarify the definition of “natural” and require a prominent disclosure defining the meaning of the term natural from a consumer perspective and clarifying what it does, and does not, mean in terms of ingredients and manufacturing processes.

19 21 CFR 101.65(c)(2).
4) **FDA should improve standards of identity and ingredient lists and complete its critical work on nutrition education and sodium reduction.**

**Modernizing Standards of Identity**

NACCHO urges the FDA to finalize its proposed rule from 2005 expressing general principles for modernizing standards of identity. In particular, NACCHO supports principle #4, which states that the standards of identity “may be used as a vehicle to improve the overall nutritional quality of the food supply.” FDA should focus its consideration of standards of identity on the ways in which individual standards may be revised to better reflect public health priorities. Specifically, FDA should provide flexibility to manufacturers to implement modest reductions in saturated fat and sodium without changing the name of their products, such as:

- Eliminating milkfat minimums where they appear as part of a standard of identity, including for certain cheeses (21 CFR Part 133), cacao products (21 CFR Part 163), frozen desserts (21 CFR Part 135), and milk and cream (21 CFR Part 131). In particular, FDA should prioritize milkfat minimums for the most commonly consumed cheeses (mozzarella, cheddar, and American), as cheese is a major contributor of saturated fat to the American diet and a calorically dense food.

Other requests for modification of the standards of identity should be considered by the FDA on a case-by-case basis, in a manner similar to that applied to the petition for potassium chloride use. In considering such petitions, the FDA should consider the principles laid out in its 2005 proposed rule. The agency should also consider evidence of consumer acceptance of the ingredient in the given product, and any likelihood of consumer confusion that might result from the changes.

**Modernizing Ingredient Lists**

NACCHO supports efforts to modernize ingredients lists to make them more readable and consumer-friendly. The FDA should take regulatory and enforcement action to ensure the readability of ingredients lists. The FDA should establish a minimum type size and allowable type styles, require use of upper- and lower-case letters, and include contrast requirements similar to those required for the Nutrition Facts panel, and other conspicuity measures.

**Implementing Menu Labeling and the Nutrition Facts Label Education Campaigns**

NACCHO has long supported providing additional consumer information through menu labeling and applauds the agency for conducting consumer-awareness education campaigns for menu labeling and the updated Nutrition Facts Panel. NACCHO urges the agency to dedicate adequate funding and resources towards these efforts. Such campaigns will maximize these consumer education tools and assist consumers in making informed choices, support healthier eating, and increase healthier food options.

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20 Food Standards; “General Principles and Food Standards Modernization,” 70 FR 29214 (May 20, 2005).
NACCHO urges the FDA to finalize and release its menu labeling materials. Other materials that would be useful could highlight the succinct statement on menus and menu boards providing context about calories in a daily diet as a way to educate the public on the ballpark target for 2,000 calories per day. The FDA should also highlight the additional nutrition information that is available upon request, which information can be of importance for people with diet-related diseases.

For both menu labeling and Nutrition Facts efforts, NACCHO encourages the agency to educate health professionals in collaboration with local health departments and major public health coalitions and organizations that represent constituencies such education, nutrition, and other health professionals. I look forward to future discussions about how FDA can best disseminate this information to NACCHO members.

**Sodium Reductions**

NACCHO strongly supports inclusion of sodium reduction in the FDA’s Nutrition Innovation Strategy. As the FDA notes, “[r]educing sodium in the diet is the single most effective health action related to nutrition.”\(^{21}\) The typical sodium intake—about 4,000 milligrams per day\(^{22}\), much higher than the recommended limit of 2,300mg. This is a major cause of high blood pressure, or hypertension. An estimated 46 percent of U.S. adults\(^{23}\) suffer from that condition, which increases the risk of heart disease and stroke. Together, coronary heart disease and stroke kill about 500,000 people annually in the United States.\(^{24}\)

Given successful population-wide sodium-reduction efforts in several other countries and the variation in sodium concentration within similar types of foods, the FDA’s proposed sodium-reduction targets are eminently feasible and could even be strengthened. The agency’s modest

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two-year sodium-reduction targets should be finalized, as promised, by 2019 given the urgent need to start reducing the harm from excessive sodium in food supply. The FDA should also continue its work toward finalizing the ten-year sodium-reduction targets as soon as possible, since far more significant reductions could be accomplished, and ten years gives industry ample time to plan and reformulate its products.

**Conclusion**
Thank you for the opportunity to provide these comments. I look forward to continuing to work with the FDA on ways to increase access to nutrition information for all Americans.

Sincerely,

Lori Tremmel Freeman, MBA
Chief Executive Officer