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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852


On behalf of the American Public Health Association, a diverse community of public health professionals who champion the health of all people and communities, I appreciate the opportunity to submit comments on the Food and Drug Administration’s comprehensive, multi-year Nutrition Innovation Strategy.

We support FDA’s intention to find new ways to reduce the burden of chronic disease through consumer empowerment and industry innovation to create more nutritious foods. A growing body of evidence shows that the public makes routine use of nutrition labeling. Improvements in ingredient lists, nutrition education, use of the term “healthy” and qualified claims would also be widely used. We offer some specific recommendations:

1. **Providing opportunities to make ingredient information more helpful to consumers must be based in sound science.**

Renaming ingredients on food labels should not lead to consumer confusion about the healthfulness of the product. For example, if FDA substitutes “potassium salt” for “potassium chloride,” it will be important to determine whether the consumer avoids this product because “salt” is an ingredient they may have been advised to avoid. In simplifying the ingredient list, FDA should also consider:

- How do those with low literacy and health literacy perceive the “simplification” in the terminology?
- Does the change in terminology lead to products with fewer unnecessary additives, artificial colorings and artificial flavorings?
- What is the best strategy for labeling multiple sources of whole grains or sources of sugars to best inform the consumer?

FDA should also consider proposals to substitute terminology on a case-by-case basis, as it is essential that the ingredient list not become a vague, uninformative and unclear list that lacks clear identification as to the nature of a particular ingredient. FDA may find more example opportunities to make the ingredient list more helpful to consumers by looking to Health...
Canada’s innovative changes including grouping all sources of sugar in brackets after the name “sugars” and listing all food colors by their individual common names. We also recommend that FDA consider allowing the use of simple vitamin letter names as opposed to chemical names.

2. **Consumer education as well as consumer testing are essential elements of the success of any changes in the nutrition label, claims or terminology for ingredients.**

We commend the proposed FDA education campaign for consumers on the updated Nutrition Facts Label and recommend that FDA proceed with simple, focused and positive messages that include explanations of the major changes to the nutrition label, especially:

- **Added sugar vs. total sugar:** total sugar is important in diabetes and weight management and all fermentable carbohydrates are important in dental caries;
- **Portion sizes and serving sizes:** clarifying what is a serving and how many servings per food group are recommended;
- **All labeled nutrients:** to prevent focus on single nutrients to determine healthy diet and provide context to consumers to help them understand what nutrients and in what amounts they need given their health or disease status; and
- **Motivational messages for individuals with low health literacy, limited incomes and familiarity with nutritious cooking.**

3. **FDA should revise the definition of “Healthy” before creating “Healthy” icons.**

Before developing an icon to depict foods that meet the “healthy” criteria, FDA should provide a clear definition of “healthy.” We recommend FDA:

- Establish separate “healthy” criteria for various food groups;
- Address the presence of disqualifying nutrients;
- Consider the source of beneficial nutrients (i.e. naturally occurring or fortification); and
- Limit the term to fortified foods that meet the existing 10 percent DV requirement to adhere to the agency’s fortification policy in 21 C.F.R. 104.20.

As part of the criteria defining “healthy,” we recommend the term reflect the 2015-2020 Dietary Guidelines for Americans recommendations with an emphasis on healthy eating patterns that include fruits, vegetables, lean and plant-based proteins and low-fat dairy products, rather than an emphasis on individual nutrients unless identified in the DGAs.

As the FDA develops a clear definition for the term “healthy,” it is important to identify initially products that will be included under the decided-upon criterion, and which foods will be excluded. We encourage the FDA to develop the criterion with a thorough understanding of the impact this will have on consumers’ food choices.

We recommend FDA reconsider the use of the “healthy” label if the food products do not contain fruits, vegetables, whole grains, calcium containing foods, and/or healthy proteins. The definition for “healthy” and the determination of which foods may carry the “healthy” icon should consider the number of servings of a food group in the product rather than just on
the nutrients contained in the product. To be consistent with the DGAs, “healthy” products should contain high amounts of beneficial nutrients and low amounts, if any, added sugar, refined starches, sodium and saturated fats.

We recommend special consideration be given when defining the term “healthy” to differentiate “healthy” as it applies to persons without and those with a chronic disease, (i.e. hypertension, diabetes, allergies, or renal disease). For example, FDA should require disclosures of phosphorus and potassium, as these nutrients increase risks for people with chronic kidney disease. FDA should also consider how to provide the consumer with more information on why a product is labeled “healthy.” We recommend that the broad use of the term “healthy” and any accompanying icon include consumer testing to determine consumer understanding. Furthermore, testing will help determine if the “healthy” icon effectively encourages consumers to choose more nutritious foods. If neither consumer understanding nor behavior improve, FDA should redesign the “healthy” icon to ensure the label leads consumers to healthier food choices and eating patterns. Special consideration should be made in consumer testing for consumers with limited literacy, health literacy and numeracy where an icon may be most informative. A strong education effort, as FDA has proposed, is essential to support consumer understanding of the term “healthy.”

4. **Modernizing the standards of identity can provide more flexibility for the development of healthier products.**

In reviewing the current standards of identity FDA should focus on consumer trends and public health goals (i.e. does maintaining a SOI prevent innovation such as in milk and dairy substitutes, low fat and low sodium products?). To help consumers understand and educators explain what ingredients foods contain, FDA and USDA should work together to pursue and establish common standards for the food label, school meals and nutrition crediting for foods in school meals.

On a case-by-case basis, FDA should consider how changes in SOIs will improve the nutritional profile of food products. Manufacturers should be able to submit public petitions to allow for adding or subtracting ingredients such as sodium, saturated fats or sugar to enhance the healthfulness of foods. FDA should pay attention to how product changes to lower one ingredient may lead to increases in another ingredient that is more or equally harmful. For example, lowering trans fatty acids may lead to increases in saturated fat that have equally negative cardiovascular impacts.

5. **Consumers should be confident that foods marketed as better for them are indeed more healthful choices.** Qualified health claims on foods can be misinterpreted by consumers and, therefore, need to be carefully and efficiently examined for scientific rigor and validity.

There is little evidence to show that qualified health claims on products aid consumers in making healthier food choices. Furthermore, reviews of these claims are extremely time consuming and alternatives, such as structure function claims, are commonly used among manufacturers.
If qualified health claims are continued to be approved, it is recommended to test consumer understanding of qualified health claims. Consumer testing would be essential to measure consumer understanding of a qualified health claim and the requisite behavior change related to the health claim. Regardless of changes in the efficiency of the review process for evaluating qualified health claims, sufficient scientific data should be presented to support the claim.

6. New or enhanced labeling statements or claims could spur innovation of healthier foods and motivate more healthful consumer food choices.

We strongly recommend that new or enhanced food labeling statements are required to be supported by strong, evidence-based science. Evidence should also demonstrate that the claim or statement increases consumer knowledge. These statements should provide information that improves major health concerns of Americans and motivates manufacturers to bring forth healthier products. To this end, we agree with the American Society for Nutrition recommendation that “FDA would need to define what is a ‘meaningful’ amount of a food group in a serving and set thresholds for nutrients to limit so that the product is consistent with existing scientific evidence-based Federal dietary guidance.” FDA should look to several countries such as Canada, New Zealand, United Kingdom, and Australia for “front of pack” labeling initiatives that promote more healthful foods and food choices.

We recommend FDA plan to disseminate its consumer-facing materials and to collaborate with partners to develop and disseminate additional materials to increase awareness of updated nutrition labeling by:

1. Integrating messages into SNAP-Ed, WIC nutrition education, Expanded Food and Nutrition Education Program, USDA’s Team Nutrition and other education programs focused on individuals with low literacy and health literacy; and
2. Incorporating messaging into community participatory programs available through faith-based organizations, federal qualified health centers and community stakeholders working on food security, food desserts, nutrition education and healthy corner stores.

This is a critical opportunity to create greater transparency for consumers and to foster innovation that drives reformulation and the availability of healthier foods. We encourage 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. Thank you for your consideration of our recommendations. We look forward to working with the agency on solutions and public education efforts that generate greater transparency on food labels in the service of the public’s health.

Sincerely,

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Executive Director