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# MEMORANDUM

**From**: Martin J. Hahn
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**Date**: August 3, 2018

**Re**: **FDA Holds Public Meeting on Nutrition Innovation Strategy**

On July 26, 2018, the Food and Drug Administration (FDA) held a public meeting to discuss issues related to the agency's comprehensive multi-year Nutrition Innovation Strategy. This public meeting and comment period follows FDA Commissioner Dr. Scott Gottlieb's unveiling of the Nutrition Innovation Strategy in a policy address on March 29, 2018 as a way to help Americans improve their nutrition as a step towards reducing chronic disease.1/ This memorandum provides a high-level summary of the issues that were raised at the public meeting.

## Overview of Nutrition Innovation Strategy

FDA Commissioner Gottlieb and Director of the Center for Food Safety and Applied Nutrition (CFSAN) Susan Mayne made opening remarks at the meeting. Dr. Gottlieb explained that FDA's goal with the Nutrition Innovation Strategy is to help advance public health by empowering consumers with information and facilitating industry innovation toward healthier foods, and that the agency is seeking ideas on how to modernize its approach and better protect public health. Dr. Gottlieb also announced at the meeting that FDA will take steps to modernize the dairy product standards of identity, including issuing a request for information (RFI) on this issue later this summer or in the early fall. The same day as the meeting, FDA issued a statement from Dr. Gottlieb addressing the need for FDA to look at the nutritional differences between plant-based foods positioned as alternatives for standardized dairy products and standardized dairy products. 2/ In particular, FDA has concerns about reports of children suffering nutritional deficiencies from

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1/ *See* HL Memo, FDA Commissioner Gottlieb Announces New Nutrition Innovation Strategy, April 5, 2018.

2/ Statement from FDA Commissioner Scott Gottlieb, M.D., on the process FDA is undertaking for reviewing and modernizing the agency's standards of identity for dairy products, *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm614851.htm.

consumption of plant-based beverages that use the standardized term “milk” that do not have the same nutritional profile as milk, such as severe protein malnutrition from consumption of rice-based beverages, and Vitamin D deficiency from soy-based beverages. FDA intends to study the consumer understanding of these plant-based products that substitute for dairy products, and in particular, whether consumers understand the different nutritional profiles of these products compared to standardized dairy products.

The meeting also included a presentation on consumer trends in the marketplace; a presentation on the evolving food landscape and industry innovation (including representatives from the Center for Science in the Public Interest (CSPI) and Chobani, as well as a professor of food policy); breakout sessions on food label claims including a potential icon for “healthy” claims, modernizing the standards of identity and ingredient lists appearing on labels, and consumer education campaigns on the Nutrition Facts label, as well as a public comment period. Below we highlight notable comments presented at the meeting. These highlights are relevant for interested parties to consider as they develop their comments to the Nutrition Innovation Strategy docket and engage with the agency on issues related to modernizing food labels.

**Notable Comments at Nutrition Innovation Strategy Public Meeting**

- Modernizing food standards. Felicia Billingslea, Director of the Division of Food Labeling and Standards at CFSAN, noted that one commenter suggested a horizontal standard (similar to 21 C.F.R. § 130.10) as an approach to address nutritional and flexibility issues with the standards of identity across all standards of identity, rather than taking a standard by standard approach. FDA noted there is also an opportunity in this space to make progress using public-private partnerships.
    - Several stakeholders voiced support for modernizing the standards of identity, including the American Bakers’ Association, which suggested evaluating standards of identity for modernization in order based on public health value.

- Modernizing ingredient lists. Several stakeholders commented on ways to modernize ingredient labels, for example, not requiring a parenthetical with a listing of all the vitamins and minerals that are sub-ingredients of enriched flour. One commenter noted it has submitted a petition to FDA requesting a simplification of the declared names of vitamins in ingredient statements, i.e., using letter names for vitamins, reasoning that the current labeling of chemical names for vitamins can confuse consumers. The American Society for Nutrition suggested listing food colors by their common name, and requiring all sugar ingredients declared in an ingredient statement to have the term “sugar” in parentheses following the ingredient declaration. CSPI also noted that current ingredient lists have problems with legibility, and adding formatting such as bullets, justification, etc., may help make ingredient statements easier to read. FDA also received suggestions to provide percent ingredient labeling for all food recommendations, e.g., “X% whole grains.”

- “Healthy” icon. FDA sought discussion on ways to make the presentation of “healthy” claims standardized and visible and effective for identifying healthy food sources, including development of a standardized icon or symbol. Some comments included:
    - Format of “healthy” icon. FDA noted it is reviewing the literature and considering all possibilities with respect to whether a proposed icon would be a summary icon, one with multiple stars, a traffic light system, a hybrid icon, or the use of words. Although

senior FDA officials have indicated in meetings with industry that the agency is not interested in pursuing stoplight labeling absent a statutory requirement to do so, stoplight labeling was mentioned as an example of one of the label formats FDA is considering.

- Public health impact of "healthy" icon. In response to a question about whether "healthy" denotes how much of a food should be consumed, FDA noted it is looking at the spillover effects of a potential "healthy" icon.
- CSPI position. CSPI noted that a "healthy" icon should have cross-category comparisons and interpretative information, and that the "healthy" definition should place an emphasis on whole foods.
- Consumer testing. Some stakeholders urged FDA to consider testing proposed "healthy" icons with consumers. FDA indicated that it intends to conduct consumer testing of a proposed "healthy" icon.
- Consumer education. FDA also indicated it would implement a consumer education campaign on any potential "healthy" icon, in addition to other efforts to contextualize the icon to address any "health halo" effect. Many stakeholders expressed support for a consumer education campaign on "healthy" claims.
- Context of icon. Some comments raised concerns about FDA implementing a "healthy" icon without placing the product in a broader nutritional context.
- International approaches. One commenter asked whether FDA will be considering examples from other countries in developing a "healthy" icon.

- Redefining "healthy". Although FDA emphasized this public meeting was not intended to solicit comments on the "healthy" definition, a number of commenters offered additional information on how the agency should redefine this claim. For example, a few stakeholders noted that the current "healthy" definition lacks limits on added sugars.

- CSPI comments. A representative from CSPI noted that CSPI is working on proposed legislation titled the Food Labeling Modernization Act. Generally, CSPI noted that conflicting information on food labels can be confusing for consumers and FDA can help minimize consumer confusion by restricting false and misleading claims and having a clear vision for food labeling. Some specific examples of steps CSPI thinks FDA could take include: reviewing labels for products such as fruit snacks that use misleading titles and images and possibly require such products to disclose the quantity of fruit they contain; facilitating grain labeling (i.e., "whole grain"); revising nutrient content claim disclosures to be more informative at a glance; defining terms like "lightly sweetened"; taking action to ensure "energy" claims are not confusing to consumers, for example, by disclosing caffeine content and that "energy" is synonymous with "calories"; and testing a range of front-of-pack (FOP) labeling systems.

- Sodium reduction. Dr. Gottlieb noted in his opening address that sodium reduction is still a priority for FDA, and is one example of FDA's efforts to facilitate innovation of more healthful foods. Several stakeholders indicated they are supportive of FDA finalizing the sodium reduction targets. One trade association recommended that FDA redefine the targets to clarify they are not maximum allowable levels.

- Increased intake of saturated fat. Neal Hooker, Professor of Food Policy at the Ohio State University, noted that a nationally representative estimate of *trans* fat intake indicates that

*trans* fat consumption in the U.S. is going down; however, he noted that saturated fat intake has increased.

- Defining nutrient-dense. A representative from Chobani suggested there is an opportunity for FDA to define the term "nutrient-dense" to facilitate consumer shifts to "nutrient-dense" foods in accordance with dietary recommendations.

- Dietary guidance claims. A representative from the American Society of Nutrition noted that for dietary guidance claims, FDA needs to provide exact amounts of food groups per serving when claims are based on the *Dietary Guidelines for Americans*.

- "Nondairy" and allergen-free labeling. The Food Allergy Research and Education (FARE) organization noted it was concerned about the use of the term "nondairy" as milk-allergic consumers can mistakenly believe such products are safe for their consumption. In addition, FARE noted that allergen-free labeling can be confusing to consumers, as some products bearing allergen-free labeling also bear a statement that the product "may contain" the allergen.

- Procedures for Qualified Health Claims. FDA sought comments on whether the factors discussed in FDA's 2003 guidance on Interim Procedures for Qualified Health Claims are still relevant, and if there other factors the agency should consider in evaluating health claims. Some commenters suggested that in order to evaluate a health claim, FDA has to dive into the science supporting the claim, which makes it challenging to prioritize claims for review. Another commenter suggested that there are not many approved qualified health claims due to difficulties in getting scientific support for the claim, and that FDA's efforts would be better focused on aligning food labels with the *Dietary Guidelines for Americans*.

- New standard for olive oil. The North American Olive Oil Association recommended that FDA create a new standard of identity for olive oil to help inform consumers about the quality and types of olive oil to mitigate consumer confusion.

FDA will accept written comments on the Nutrition Innovation Strategy until August 27, 2018. FDA noted that dairy standard of identity comments are welcome to this docket, however, FDA will be opening a separate docket for this issue as well.

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We will continue to monitor FDA's actions related to nutrition policy and labeling. Please do not hesitate to contact us if you have any questions on this or any other matter.