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April 26, 2017

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

Re: Docket No. FDA-2016-D-2335 for "Use of the Term 'Healthy' in the Labeling of Human Food Products; Request for Information and Comments."

Dear Sir or Madam:

The Institute of Food Technologists (IFT) appreciates the opportunity to provide comments on the "Use of the Term 'Healthy' in the Labeling of Human Food Products." Founded in 1939, the Institute of Food Technologists is committed to advancing the science of food. Our non-profit scientific society—more than 17,000 members from more than 95 countries—brings together food scientists, technologists and related professionals from academia, government, and industry.

Through food science and technology, food scientists and technologists develop and enhance access to food options in retail and foodservice establishments to support consumers' efforts to achieve the recommendations of the 2015-2020 Dietary Guidelines for Americans (DGA).

IFT believes that labeling of an individual food as "healthy" has the potential to be misleading. IFT recommends that if the term "healthy" is used on food and beverage products, it should be in the context of overall diet to help promote healthy eating patterns. It is important to recognize that an individual nutrient or food product may contribute to a healthy diet, but is not enough on its own to maintain good health long term. Because dietary patterns comprised of diverse food and beverage products from a variety of food categories, as outlined in the DGA, are important to achieve healthy eating patterns, "healthy" label/labeling should only be used in the context of promoting consumption of a variety of foods and beverages. Further, it is important to consider the amount and frequency of consumption of individual foods, including those labeled as "healthy," in the context of overall eating patterns.

On this basis, IFT offers the following recommendations:

- A food-based definition of "healthy" which combines nutrient limits and a descriptive statement about how the food helps achieve dietary recommendations.
- Foods which exceed recommended limits for sodium, added sugars, and

saturated fat should be excluded from labeling as "healthy."

- Foods that are fortified with essential nutrients should not be excluded from labeling as "healthy," as long as the fortification is consistent with FDA's fortification policies and the food helps contribute to an overall healthy eating pattern.
- Raising consumer awareness and providing education about any changes in labels/labeling is essential.

IFT offers the following insights from its members in response to the specific questions posed by the Agency:

Question: Is the term "healthy" most appropriately categorized as a claim based only on nutrient content? If not, what other criteria (e.g., inclusion of foods from specific food categories) would be appropriate to consider in defining the term "healthy" for use in food labeling?

Response: A hybrid approach to use of the term, which combines nutrient limits and a descriptive statement about how the food helps achieve dietary recommendations, is needed to adequately define "healthy." Foods which exceed recommended limits for sodium, added sugars, and saturated fat should be excluded from labeling as "healthy." Products labeled as "healthy" should be able to contribute to the overall diet a meaningful amount of recommended food from a given food category, to help Americans meet the dietary recommendations. A descriptive statement should be used on food and beverage products bearing the term "healthy" to indicate their contribution to overall healthy dietary patterns. For example, potential labeling statements for such products might include: "Provides 1 serving of whole grains, part of a healthy eating pattern," or "Contributes to a healthy eating pattern, provides 1 serving of whole grains."

The definition for a "healthy" food should align with the three healthy eating patterns recommended by the 2015-2020 DGA (DHHS/USDA 2015). These healthy eating patterns are currently implemented across several different federal programs, including the National School Lunch Program and the Supplemental Nutrition Assistance Program. A failure to promote consistency in consumer-facing messaging across these programs about the definition of "healthy" could contribute to consumer confusion and inaction.

Question: What types of food, if any, should be allowed to bear the term "healthy?" Should all food categories be subject to the same criteria? Please provide details of your reasoning.

Response: The term "healthy" should not be limited to only packaged food, and allowed to be used on foods and beverages sold to consumers as prepackaged retail products, including fresh and bulk products. Foods should be allowed to bear a statement implying healthfulness in a balanced diet, if the foods can be consumed within a recommended eating pattern, as set forth in the DGA. All food categories

play a role in some capacity in a healthy dietary pattern; therefore, all food categories should be included and subject to the same criteria.

Question: Is "healthy" the best term to characterize foods that should be encouraged to build healthy dietary practices or patterns? What other words or terms might be more appropriate (e.g., "nutritious")? We encourage submission of any studies or data related to descriptors used to communicate the overall healthfulness of a food product.

Response: It would be important that any synonyms used in place of "healthy" meet the same criteria, and serve the same purpose intended as the term "healthy;" that is, the food or beverage should be able to help consumers achieve healthy dietary patterns. Additionally, considerations of the amount and frequency of consumption of individual foods and beverages, including those labeled with synonyms for "healthy," in the context of overall eating patterns are important.

Additionally, we recommend consideration be given to how use of the term "healthy" or synonyms on food packages would align with use of other terms, such as "nutritious," in online or other peripheral sales material. Further, it is important to ensure that statements and claims on labels that are being replaced by statements and claims in labeling (i.e., off-package materials used to sell the product, including online) are consistent with FDA's labeling policy.

Question: What nutrient criteria should be considered for the definition of the term "healthy?" Should nutrients for which intake is recommended to be limited be included? Should nutrients for which intake is encouraged continue to be included? **Response:** Foods which exceed recommended limits for sodium, added sugars, and saturated fat should be excluded from labeling as "healthy."

Question: If nutrients for which intake is encouraged are included in the definition, should these nutrients be restricted to those nutrients whose recommended intakes are not met by the general population, or should they include those nutrients that contribute to general overall health? Should the nutrients be intrinsic to the foods, or could they be provided in part--or in total--via fortification? Please provide details of your reasoning and provide any supportive data or information.

Response: The use of the term "healthy" on food labels should be allowable on food and beverage products that are fortified with essential nutrients, and not limited to those in which nutrients are present intrinsically, as long as the fortification is consistent with FDA's policies on food fortification and the product may contribute to an overall healthy eating pattern.

Fortification of the food supply during the past century has effectively reduced the risk of nutrient deficiency diseases such as neural tube defects, goiter, and rickets. Fortification is a public health strategy to enhance nutrient intakes of populations without increasing caloric intake. Fortification programs were originally designed to

eliminate nutrient deficiency diseases; however, now fortification programs serve to improve low dietary intakes of essential nutrients rather than a diagnosable condition (Dwyer and others 2014, 2015). For example, a study by Fulgoni and others (2011) showed that enrichment and/or fortification improved intakes of several nutrients including thiamin, folate, iron, and vitamins A and D. The Food Agriculture Organization of the United Nations (FAO) considers fortification a cost-effective method, with the potential to improve micronutrient status without any change in existing dietary patterns (FAO 2014). Further, the 2010 DGA acknowledge that "...fortification of certain foods may be advantageous in specific situations to increase intake of a specific vitamin or mineral. In some cases, fortification can provide a food-based means for increasing intake of a particular nutrient or providing nutrients in highly bioavailable forms" (USDA/DHHS 2010). Fortification of foods is a positive means to increase the nutrient contribution of many foods widely available to Americans generally, including the economically disadvantaged (IFT 2013). Foods that intrinsically contain nutrients may be altered once they are cooked or processed. Foods containing essential nutrients via fortification should still fall within the same "healthy" labeling as foods containing intrinsic nutrients, as long as the fortification is consistent with FDA's food fortification policies and the product may contribute to an overall healthy eating pattern.

Question: Are there current dietary recommendations (e.g., the Dietary Guidelines for Americans) or nutrient intake requirements, such as those described in the final rule updating the Nutrition Facts label (see 81 FR 33742; May 27, 2016) or those provided by the Institute of Medicine (IOM) in the form of Dietary Reference Intakes (DRI)

(http://www.nationalacademies.org/hmd/Activities/Nutrition/SummaryDRIs/DRITab les.aspx), that should be reflected in criteria for use of the term "healthy?" **Response:** To ensure consistency across regulatory agencies and to promote coherence in nutrition communications to consumers, a food-based definition of "healthy," which combines nutrient limits and a descriptive statement about how the food helps achieve the Dietary Guidelines would be appropriate. The DGA serves as guidance for administrators in many federal programs and as the basis for consumerfacing nutrition education programs and materials (e.g., MyPlate). Therefore, it would be important to ensure that the criteria forming the definition of "healthy" are consistent with these existing policies and programs to avoid confusion and potential inaction among consumers. Foods which exceed recommended limits for sodium, added sugars, and saturated fat should be excluded from labeling as "healthy."

Question: What is consumers' understanding of the meaning of the term "healthy" as it relates to food? What are consumers' expectations of foods that carry a "healthy" claim? We are especially interested in any data or other information that evaluates whether or not consumers associate, confuse, or compare the term "healthy" with other descriptive terms and claims?

Response: The 2016 Food and Health Survey conducted by the International Food Information Council (IFIC 2016), found that healthfulness continues to be one of the top drivers in food purchasing decisions. However, this and other research to understand Americans' definition of "healthy" in relation to food and eating styles has underscored the complex and multifaceted perceptions of consumers:

- In an open-ended question on the definition of "healthy" foods, more than one-third (35%) of respondents said that a "healthy" food is one that does not contain or has low levels of certain components such as fat and sugar. Other responses included "good for you" (18%) or "contains certain [healthful] components (17%). When given a list of attributes describing healthy eating style, 51% of consumers described "healthy eating style" as "the right mix of different foods," followed by "limited or no artificial ingredients or preservatives" (41%). However, in an open-ended response to the same question, 26% described "moderation/serving size and portions" followed by "includes certain foods I define as healthy" (25%) and "the right mix of different foods" (21%), as healthy eating styles (IFIC 2016).
- A review of qualitative studies examining consumer perceptions of "healthy" foods and diets, Bisogni and others (2012) found a diverse, complex set of definitions. The authors reported that consumers define healthy eating not only in terms of nutrients and components, but also in how foods are produced, processed and prepared (e.g., natural, homemade, and organic).

The confusion about healthy foods and dietary patterns expressed by consumers can be ameliorated by a definition of "healthy" that is consistently applied across federal policies and programs. Furthermore, given that consumers eat foods, not nutrients, a food-based definition with nutrient limits and a descriptive statement about how the food or beverage helps achieve dietary recommendations would allow consumers to evaluate choices in terms of how the products fit into their overall dietary patterns to support overall health and wellbeing.

Question: Would this change in the term "healthy" cause a shift in consumer behavior in terms of dietary choices? For example, would it cause a shift away from purchasing or consuming fruits and vegetables that do not contain a "healthy" claim and towards purchasing or consuming processed foods that bear this new "healthy" claim?

Response: The DGA emphasizes that to reduce the risk of diet-related chronic diseases and manage weight, Americans should follow healthy eating patterns and that foods and beverages be selected to achieve the ultimate goal of a balanced healthy diet that is within calorie needs and which delivers needed nutrients during the course of a day (DHHS/USDA 2015). A food-based definition of "healthy" which combines nutrient limits and a descriptive statement about how the food or beverage helps achieve dietary recommendations would allow consumers to evaluate food choices in terms of how they contribute to an overall healthy diet. This would not necessarily contribute to a shift toward processed foods, if it included all foods

contributing to dietary patterns as outlined in the DGA. Thus, in this way the definition could help consumers choose foods and beverages with the potential to build healthy diets that meet the dietary recommendations.

Question: How will the food industry and consumers regard a change in the definition of "healthy?"

Response: The DGA states that all sectors and all levels of society have a role to play in changing the food environment to help consumers shift towards healthier dietary patterns with more nutrient-dense food choices (DHHS/USDA 2015). A food-based definition of "healthy" with nutrient limits and a descriptive statement about how the food helps achieve dietary recommendations, would allow consumers to evaluate food choices in terms of how they can contribute to their overall dietary patterns, consistent with the goals of the Dietary Guidelines.

It is important that any change in labeling to include a term such as "healthy" help consumers follow healthy eating patterns by consuming a variety of food and beverage products from the food categories, as outlined in the DGA, and be mindful of the amount and frequency of each of the foods and beverages they consume.

Raising consumer awareness and providing education about any forthcoming changes in label/labeling should occur before such changes are implemented. This would include explanation of any forthcoming label changes and how they align with dietary guidance. Consumers should not be caught off guard by label changes, as there is a need to build and maintain their trust.

IFT appreciates the opportunity to provide comments on this important topic. We thank you in advance for your consideration of our comments on the use of the term "healthy" on food products. Please contact Farida Mohamedshah, Director, Food Health & Nutrition, (<u>fmohamedshah@ift.org</u>; 202-330-4986) if IFT may provide further assistance.

Sincerely,

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