

April 24, 2017

RE: 21 CFR Part 101 [Docket No. FDA–2016–D–2335]  
Use of the Term “Healthy” in the Labeling of Human Food Products

Dear FDA,

As leading nutrition scientists and health professionals with substantial expertise in diets, health, and nutrition communication and translation, we are delighted that the FDA is updating its criteria on use of the term “healthy” in the labelling of food products. Nutritional science has advanced considerably since the FDA last released these criteria. It is essential that these be updated to be consistent with the best modern science, including the 2015 Dietary Guidelines Advisory Committee Report (DGAC) and 2015 Dietary Guidelines for Americans (DGA). We list below our major comments and recommendations that we feel are critical to formulate the new criteria:

### Key Points

- **Specific healthful foods emphasized by the DGA:** Strong evidence supports health benefits of minimally processed, bioactive-rich, plant-based foods such as fruits, vegetables, beans/legumes, nuts, seeds, and whole grains; as well as fish and yogurt. The relative amounts of such foods in a product should be one strong component of criteria for allowing use of the term “healthy.” products predominantly composed of such foods should generally meet the criteria.
- **Types of fats:** The content of total fat should not be a criterion. More relevant for major health outcomes are the relative amounts of specific fats. The ratio of polyunsaturated to saturated fat, or alternatively the ratio of unsaturated fat to saturated fat, is a reasonable criterion for overall fat quality. This criterion can be consistent across food categories as long as a minimum amount of fat is contained in the food product.
- **Types of carbohydrates:** Similar to fats, the balance of more vs. less healthful carbohydrates is a reasonable criterion for overall carbohydrate quality. The ratio of total carbohydrate to naturally occurring fiber is a reasonable criterion; e.g., a ratio of 10:1 or lower. As a practical metric, this ratio captures the relative content of starch and sugars vs. bran and whole grains. This criterion can be consistent across food categories as long as a minimum amounts of carbohydrate is present.
- **Nutrients of concern:** Any criterion that incorporates micronutrients should focus on nutrients of concern, as defined in the DGAC and DGA, rather than all vitamins or minerals. This is important to prevent otherwise unhealthy products from “gaming the system” by adding micronutrients that the majority of Americans already consume in sufficient amounts. While we believe that foods and diet patterns naturally rich in vitamins and minerals may be best for preventing many chronic diseases, there is not yet strong evidence to distinguish naturally occurring vs. fortified micronutrients.
- **Sodium and added sugar:** The criteria should include limits on additives such as sodium and added sugar according to their absolute contents per serving, given the wide ranges of levels of these additives in otherwise similar foods. These criteria should also be food category-specific, with different cutpoints for different categories, e.g. similar to FDA voluntary targets for sodium reduction in food products. (Because partially hydrogenated vegetable oils are appropriately no longer considered “GRAS” by FDA, we did not include industrial trans fats here.).
- **Terminology:** We support the term “healthy” and related terms as most clear and understandable for consumers.

**Further expertise:** We emphasize our willingness to provide our efforts and expertise to work further with the FDA in your quest to update and harmonize policies and rules related to diet and health. Several of us have served on major committees whose missions were to weigh scientific evidence in order to establish national and international nutrition policy guidelines, so we have an abundance of experience and knowledge in this arena. Suboptimal diet is a leading cause of poor health in the United States, and improving dietary options and choices should be a major federal priority.

Sincerely,



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