



Council for Responsible Nutrition

1828 L Street, NW, Suite 510 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

April 26, 2017

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Use of the Term “Healthy” in the Labeling of Human Food Products; Request for Information and Comments; Extension of Comment Period. 81 Fed. Reg. 96404-96405 (Friday, December 30, 2016). Docket No. FDA-2016-D-2335.

The Council for Responsible Nutrition (CRN)¹ appreciates the opportunity to provide comments on FDA’s request for information and comments titled, “Use of the Term “Healthy” in the Labeling of Human Food Products.”

CRN recommends that FDA maintain the nutrient contribution criterion in the definition of “healthy” because there are essential nutrients for which sufficient intake is required to sustain

¹ The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN’s Code of Ethics. Learn more about us at www.crnusa.org.

body functions and reduce the risk of disease. The 2015-2020 Dietary Guidelines for Americans (DGA)² indicate that many Americans do not meet their needs for several important and essential nutrients. Foods that contribute to the adequate intake of these under-consumed should be encouraged. In particular, foods that are good sources of under-consumed nutrients should bear the “healthy” nutrient content claim to help Americans structure diets that conform to current dietary recommendations.

CRN suggests a modification to the requirements currently in 21 CFR 101.65(d)(2) specific to the “beneficial nutrients” condition to reflect new scientific findings in DGA. The DGA identified nutrients that are consumed by many individuals in amounts below the Estimated Average Requirement (EAR) or Adequate Intake levels set by the Institute of Medicine. These include potassium, dietary fiber, choline, magnesium, calcium, and vitamins A, D, E, and C. Of these under-consumed nutrients, calcium, vitamin D, potassium, and dietary fiber are considered nutrients of public health concern because low intakes are associated with health concerns. Low intake of iron is also considered to be of public health concern for young children, women capable of becoming pregnant, and women who are pregnant.

To help bring intake of under-consumed nutrients closer to recommendations, and to help Americans make healthful food choices, we suggest that FDA update the list of nutrients in 21 CFR 101.65(d)(2)(i) to be consistent with the DGA, as well as the updated Nutrition Facts label. That is, nutrients for which intake should be encouraged include iron, protein, potassium, dietary fiber, choline, magnesium, calcium, and vitamins A, D, E, and C. To satisfy the nutrient contribution criterion, a food product must contain one or more of nutrients listed above (at least two nutrients for a main dish product and at least three nutrients for a meal product) at no less than 10 percent of the Reference Daily Intake or Dietary Reference Value per reference amount customarily consumed or per labeled serving.

Foods have varying levels of intrinsic nutrients, and most foods do not provide appreciable levels of several key nutrients naturally. For example, vitamin D is found in very few foods, including fatty fish, beef liver, cheese, and egg yolks. Thus, in addition to foods that

² U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans. 8th Edition. December 2015. Retrieved from <http://health.gov/dietaryguidelines/2015/guidelines>.

naturally contain vitamin D, the DGA recommends individuals to eat more foods fortified with vitamin D, such as milk, yogurt, and breakfast cereals. It is important to recognize that fortified foods contribute to raising intakes of nutrients that many Americans are consuming in amounts below the EAR. In an analysis of data from NHANES 2003-2006, enrichment and/or fortification improved intakes of several under-consumed nutrients when compared with intakes from naturally occurring nutrients.³ The “healthy” nutrient content claim should be permitted for all foods that meet the nutrient contribution criterion (and other relevant requirements) whether the nutrients for which intake is encouraged are intrinsic to the foods or provided by fortification. A variety of foods should be able to bear the “healthy” nutrient content claim to give Americans options in constructing healthy diets.

We recognize that FDA is already exercising enforcement discretion to allow “healthy” claims for food products that contain at least 10 percent of the Daily Value of vitamin D or potassium, as long as the products meet all other relevant conditions. Again, we recommend that in addition to nutrients of public health concern, all other under-consumed nutrients should be encouraged because their adequate intake also contributes to a healthful diet.

CRN also recognizes that FDA is exercising enforcement discretion with respect to the low fat requirement in 21 CFR101.65(d)(2)(i), provided that the majority of the fat are mono and polyunsaturated fats and the amounts of mono or polyunsaturated fats are declared on the label. We agree that the low fat requirement should be updated to allow the use of the “healthy” claim on labels for products that are not low in total fat but have a fat profile makeup of predominantly mono and polyunsaturated fats, as long as the products meet all other relevant conditions.

CRN does not have specific comments regarding the current requirements for saturated fat, cholesterol, and sodium that a food bearing the “healthy” nutrient content claim must meet.

³ Fulgoni VL 3rd1, Keast DR, Bailey RL, Dwyer J. Foods, fortificants, and supplements: Where do Americans get their nutrients? J Nutr. 2011 Oct;141(10):1847-54.

Thank you for considering our comments.

Sincerely,

A handwritten signature in cursive script, appearing to read "Andrea Wong".

Andrea Wong, Ph.D.

Vice President, Scientific & Regulatory Affairs

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Haiuyen Nguyen

Director, Scientific & Regulatory Affairs