

One Minute Memo[®]



FDA Announces Initiative to Redefine “Healthy” Claim for Food Labeling

By Jay W. Connolly and Joseph Orzano

The U.S. Food and Drug Administration (“FDA”) announced in September that it is considering how to redefine the term “healthy” as a nutrient content claim for the labeling of human food products. The FDA issued a guidance for industry entitled “Use of the Term ‘Healthy’ in the Labeling of Human Food Products: Guidance for Industry” stating that FDA does not intend to enforce the regulatory requirements for products that use the term if certain criteria set forth in the guidance are met.

The FDA’s initiative to redefine “healthy” is part of an overall plan to provide consumers with information and tools to enable them to easily and quickly make food choices consistent with public health recommendations and to encourage the development of healthier foods by the industry. It follows the FDA’s May 2016 issuance of final rules updating the Nutrition Facts label and serving size information for packaged foods to reflect new scientific information, including the link between diet and chronic diseases such as obesity and heart disease. Those updates include changes to the individual nutrients that must be declared and also changes to the daily values of other individual nutrients to reflect changes in recommended intake levels, based on current science.

Current FDA regulations provide a definition for use of the term “healthy” and similar terms such as “healthful” or “health” as implied nutrient content claims on the label or in labeling of food. The definition establishes nutrient conditions for bearing a “healthy” or similar implied nutrient content claim. The nutrient conditions vary depending on the food category, but include specific criteria for nutrients to limit in one’s diet such as total fat, saturated fat, cholesterol and sodium and requirements for nutrients to encourage in the diet including vitamin A, vitamin C, calcium, iron, protein, and fiber.

The existing regulatory definition for the implied nutrient content claim “healthy” remains in effect; however, the FDA states in its new guidance that it intends to exercise its enforcement discretion (to not enforce the applicable regulatory definition) in two different situations. First, if a food labeled “healthy” exceeds the existing total fat threshold, the FDA intends to exercise its enforcement discretion if: (1) the amounts of mono- and polyunsaturated fats are declared on the label; and (2) the amounts declared constitute the majority of the fat content. Second, if a food labeled “healthy” does not satisfy the requirement that it contain at least 10 percent of the daily value of vitamin A, vitamin C, calcium, iron, protein, or fiber, the FDA intends to exercise its enforcement discretion if the food instead contains at least 10 percent of the daily value of either potassium or vitamin D. If so, the FDA states that whichever of those two nutrients is being used as the basis for eligibility should be declared on the Nutrition Facts label. This statement by the FDA is particularly important to note for regulated entities that have not yet implemented the new Nutrition Facts label, which requires the declaration of vitamin D and potassium independent from this guidance.

The guidance does not establish any rights for any person and is not binding on the FDA or the public. The FDA states in the guidance, however, that it represents its current thinking on the topic.

The FDA is now seeking information and comments on the use of the term “healthy” in the labeling of human food products. Comments may be submitted until January 26, 2017. To electronically submit comments to the docket, visit this page: [FDA “Healthy” Docket](#). For additional information and the new guidance visit this page: [“Healthy” Regulatory Information](#).

Regulated entities may wish to consider this guidance in conjunction with their work towards the applicable compliance deadline for updating Nutrition Facts labels.¹ In addition, parties to litigation over “healthy” claims may attempt to seek stays while the FDA considers the issue, as parties have done in other food labeling cases challenging “evaporated cane juice” and “natural” and related claims. Last, regulated entities should stay tuned for further initiatives from the FDA addressing other label claims. In a [September 2016 blog post](#) on the “healthy” initiative, the FDA’s Director of the Office of Nutrition and Food Labeling at FDA’s Center for Food Safety and Applied Nutrition indicated that the FDA will begin evaluating other claims to determine how they might be modernized as well.

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¹ Manufacturers will need to use the new Nutrition Facts label by July 26, 2018; however, manufacturers with less than \$10 million in annual food sales will have an additional year to comply. For more information, visit the following page: [FDA Regulatory Information on Nutrition Facts Label](#).

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