

ALERTS

Food, Drug And Device Law Alert - Effective Immediately: FDA Issues Guidance On Use Of 'Healthy' In Food Labeling

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The FDA recently issued a brief guidance, effective immediately, on the use of "healthy" in food labeling. As stated in the guidance's introduction, the FDA intends "to exercise enforcement discretion relative to foods that use the implied nutrient content claim 'healthy' on their labels which: (1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or (2) contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D." At the same time, the FDA issued a related request for information and comments on "healthy" food labeling claims, with comments due Jan. 26, 2017.

Guidance

The guidance is an effort to coordinate the FDA's position on enforcing the current food labeling regulations with the recently released update to the Nutrition Facts box and the 2015-2020 Dietary Guidelines. The guidance explains that "the science related to public health recommendations for intake of dietary fats has evolved." Instead of a focus on limiting total fat intake, nutrition science now encourages the intake of mono and polyunsaturated fats. Accordingly, the guidance states that "foods that use the term 'healthy' on their labels that are not low in total fat should have a fat profile makeup of predominantly mono and polyunsaturated fats (i.e., sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food). Thus, with respect to the current requirement that any food bearing the nutrient content claim "healthy" meet the low fat requirement (21 C.F.R. §101.65(d)(2)(i)), the FDA will not take enforcement action "provided that: (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."

With respect to potassium and vitamin D, the guidance states that they are now nutrients of public health concern, whereas vitamins A and C are no longer nutrients of public health concern. The FDA's existing regulations state any food bearing the nutrient content claim "healthy" must contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of vitamin A, vitamin C, calcium, iron, protein, or fiber. The guidance states the FDA will not take enforcement action against a food label using the term "healthy" if the food instead (or in addition) contains at least 10 percent of the DV per RACC of potassium or vitamin D. The guidance notes "if a food is basing its eligibility for bearing a 'healthy' claim on potassium or vitamin D, whichever nutrient is being used as the basis for eligibility should be

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declared in the Nutrition Facts label.”

Request for Information and Comments

The FDA also published a Federal Register notice requesting information and comments on a variety of issues related to the “healthy” claim, including:

- What types of food, if any, should be allowed to bear the term “healthy”? Should all food categories be subject to the same criteria?
- 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”)?
- 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?
- 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?
- Are there current dietary recommendations (e.g., the Dietary Guidelines for Americans) or nutrient intake requirements, that should be reflected in criteria for use of the term “healthy”?
- What are the public health benefits, if any, of defining the term “healthy” or other similar terms in food labeling?
- 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?
- Would this change in the term “healthy” cause a shift in consumer behavior in terms of dietary choices?
- How will the food industry and consumers regard a change in the definition of “healthy”?
- What would be the costs to industry of the change?

Comments are due on or before Jan. 26, 2017.

A copy of the guidance can be found [here](#) and the request for comments can be found [here](#).

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