

# FDA Issues Enforcement Discretion Guidance and Requests Public Comments on Use of “Healthy” in Food Labeling

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Food, Drugs, and Devices

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Today, the Food and Drug Administration (FDA) issued a guidance document communicating its intent to exercise enforcement discretion regarding certain uses of “healthy” in food labeling for products that do not meet FDA’s current “healthy” regulatory requirements but that contain predominantly “good fats” or are a good source of certain nutrients (“healthy” guidance).<sup>1</sup> FDA also, separately, requested public comment on the use of the term “healthy” in food labeling, including as a nutrient content claim, and in particular in response to a citizen petition that KIND LLC submitted to FDA last December requesting changes to FDA’s “healthy” regulation (“healthy” notice).<sup>2</sup> FDA has committed to redefining “healthy” to reflect current dietary recommendations and nutrition science.

This alert provides a high-level summary of the guidance document and FDA’s request for comments on the use of the term “healthy.”

## Highlights of the “Healthy” Guidance

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The “healthy” guidance communicates that manufacturers who wish to use “healthy” as a nutrient content claim in food labeling should continue to do so in accordance with FDA requirements. Under FDA’s nutrient content claim regulations, “healthy” is a nutrient content claim when it is used in connection with an explicit or implicit statement about a nutrient (e.g., “healthy, contains 3 grams of fat”).<sup>3</sup> To bear a “healthy” nutrient content claim, a processed food must, generally, be “low fat” and “low saturated fat” as FDA defines those terms, meet certain

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<sup>1</sup> See Guidance for Industry: Use of the Term “Healthy” in the Labeling of Human Food Products (Sept. 2016) on [FDA’s website](#).

<sup>2</sup> See “Use of the Term Healthy in the Labeling of Human Food Products,” *available at* <https://www.federalregister.gov/documents/2016/09/28/2016-23365/use-of-the-term-healthy-in-the-labeling-of-human-food-products> (scheduled to be published in the Federal Register on September 28, 2016).

<sup>3</sup> 21 C.F.R. 101.65(d)(2).

criteria for cholesterol and sodium content, and be a good source of one of vitamin A, vitamin C, calcium, iron, protein, or fiber.<sup>4</sup>

Most importantly, the “healthy” guidance communicates that FDA intends to exercise enforcement discretion regarding the use of “healthy” as a nutrient content claim for two categories of foods that do not meet the above criteria:

- Foods that are not “low fat,” but have a fat profile makeup of predominantly mono and polyunsaturated fats (*i.e.*, the sum of monounsaturated fats and polyunsaturated fats are greater than the total saturated fat content of food), and that declare the content of mono and polyunsaturated fats on the label.
- Foods that do not meet the current nutrient contribution requirement in the regulation, but that do provide at least ten percent of the daily value (DV) of potassium or vitamin D per reference amount customarily consumed. Because FDA revised the DVs for potassium and vitamin D in its recent rulemaking updating the Nutrition Facts label, it will allow some flexibility on this issue until the compliance date for that rule. If a food label does not yet meet the new Nutrition Facts label requirements, it may rely on the old DVs for potassium or vitamin D; however, if a food label has been updated to comply with the new Nutrition Facts label requirements, a “healthy” nutrient content claim should be based on the new DVs for potassium or vitamin D.

The “healthy” guidance explains that FDA’s enforcement policy is based in part on the fact that scientific understanding and nutrition guidance has shifted from recommending diets low in total fat to no longer recommending limiting overall fat intake, and instead prioritizing increasing intakes of polyunsaturated and monounsaturated fats and decreasing intakes of saturated fat and trans fat. FDA also notes an increased emphasis in recent years on the importance of dietary patterns as a whole -- the combination of foods and drinks that people consume over time -- rather than the nutrient makeup of a particular food. FDA intends to exercise enforcement discretion as described in the guidance until it amends its “healthy” nutrient content claim regulation to reflect current dietary recommendations and the latest nutrition science.<sup>5</sup>

## **FDA’s Request for Comments on the Use of “Healthy” in Food Labeling**

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The “healthy” notice requests information and comments from the public on the use of “healthy” in food labeling, including the pending KIND citizen petition requesting that FDA take a number of actions related to its regulation of “healthy” and additional considerations that FDA has identified as relevant to the issue. In a related blog post, FDA said that it is updating its definition of “healthy” to ensure it reflects the most recent public health recommendations, with the intent that more companies will use the claim “as a basis for new product innovation and

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<sup>4</sup> FDA has established different criteria for the use of a “healthy” nutrient content claim in the labeling of fruits, vegetables, seafood, and game meat.

<sup>5</sup> FDA issued the “healthy” guidance as a final guidance for immediate implementation without first soliciting public comment; however, the public may comment on any FDA guidance document at any time.

reformulation, providing consumers with a greater variety of ‘healthy’ choices in the marketplace.”<sup>6</sup>

FDA specifically invites comment on the requests in KIND’s citizen petition. In addition, the “healthy” notice includes a number of detailed questions on which FDA has requested public input, 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?
- 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?
- 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?
- What would be the costs to industry of the change?

The “healthy” notice solicits, in particular, consumer research or other data that evaluate how consumers perceive the word “healthy” in food labeling.

FDA will accept comments in response to the “healthy” notice until January 28, 2017. FDA will also be holding public forums to gather additional input on this issue.

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<sup>6</sup> “Making Sure ‘Healthy’ Means What It Says on Food Packages,” September 27, 2016, *available at* <http://blogs.fda.gov/fdavoices/index.php/2016/09/making-sure-healthy-means-what-it-says-on-food-packages/>.

Covington & Burling LLP continues to monitor developments in food labeling requirements and, in particular, related to the use of “healthy” claims. If you have any questions concerning the food labeling developments discussed in this client alert or other food regulatory matters, or would like assistance in preparing comments to FDA on the issues described above, please contact any of the following attorneys in our Food & Drug Practice Group or visit our [food and beverage practice website](#):

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