

What To Know About FDA's New 'Healthy' Guidance

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Late last month, the U.S. Food and Drug Administration issued a guidance document communicating its intent to exercise enforcement discretion (i.e., to not take regulatory or enforcement action) regarding certain uses of the term “healthy” in food labeling that do not comply with the FDA’s current “healthy” regulations.[1] This announcement came after recent heightened public attention about the FDA’s regulation of “healthy” following a number of warning letters to industry and a subsequent citizen petition asserting that the FDA’s “healthy” requirements do not reflect current nutrition science and asking the FDA to update those requirements.

On the same day it issued the “healthy” guidance, the FDA also requested public comment on the use of the term “healthy” in food labeling, including as a nutrient content claim, through a Federal Register notice posing a number of specific questions about consumer interpretation of “healthy” in labeling and whether and how the term should be regulated.[2]

These actions indicate that the FDA has committed to redefining “healthy” to reflect current dietary recommendations and nutrition science; however, until the FDA does so through rulemaking, the “healthy” guidance will have short-term implications for much of industry, both from an enforcement perspective and otherwise.

Highlights of the “Healthy” Guidance

Briefly, the FDA’s “healthy” guidance will allow the use of “healthy” in the labeling of food products that do not meet the FDA’s current “healthy” regulatory requirements but that contain predominantly “good fats” or are a good source of certain nutrients.

Under the 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 three grams of fat”).[3] To bear a “healthy” nutrient content claim, a processed food must, generally, be “low fat” and “low saturated fat” as the FDA defines those terms, meet certain criteria for cholesterol and sodium content, and be a good source of one of vitamin A, vitamin C, calcium, iron, protein or fiber.[4]



Jessica P. O'Connell



Miriam J. Guggenheim



Jeannie M. Perron

Most importantly, the “healthy” guidance communicates that the 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 10 percent of the daily value (DV) of potassium or vitamin D per reference amount customarily consumed. Because the 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 the 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. The 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.

Aside from these two categories of foods, 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. The 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.[5]

Highlights of FDA’s Request for Comments

The “healthy” notice requests information and comments from the public on the use of “healthy” in food labeling, including the pending citizen petition, submitted by KIND LLC, requesting that the FDA take a number of actions related to its regulation of “healthy” and additional considerations that the FDA has identified as relevant to the issue. In a related blog post, the 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 reformulation, providing consumers with a greater variety of ‘healthy’ choices in the marketplace.”[6]

The 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 the 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. The FDA will accept comments in response to the “healthy” notice until Jan, 28, 2017. The FDA will also be holding public forums to gather additional input on this issue. It is clear that the FDA intends to evaluate all uses of the term “healthy” and similar types of food labeling claims, and in particular how consumers perceive such terms when used in labeling, in determining how to update its current regulations.

Potential Short-Term Implications of the “Healthy” Guidance

Until the FDA completes its rulemaking process and finalizes new requirements for the use of “healthy” in food labeling, the “healthy” guidance allows for certain uses that do not comply with the FDA’s current requirements, which provides industry with some flexibility in how it uses that term in labeling. In addition, the FDA’s conclusion that KIND’s use of “healthy and tasty” to describe its corporate philosophy was not a nutrient content claim[7] confirms that certain uses of “healthy,” and other similar terms, are outside the scope of the FDA’s nutrient content claim regulations altogether.

This means that companies that wish to use “healthy” in the labeling of their food products should consider whether that use triggers the FDA’s nutrient content claim requirements and, if so, whether the products would qualify for enforcement discretion under the “healthy” guidance.

Companies should also be mindful of the possibility that the FDA may still issue warning letters or take other enforcement action regarding “healthy” claims that are not covered by the “healthy” guidance and do not otherwise comply with the FDA’s regulations — neither the “healthy” guidance nor the “healthy” notice provide a free pass for all uses of “healthy.”

For example, a food that is not “low fat” but that contains predominantly mono- and polyunsaturated fats could potentially bear a “healthy” claim, but only if that food complies with the other nutrient content claim requirements in the FDA’s regulations. Similarly, a food label may use “healthy” in a way that is not a nutrient content claim — for example, to provide dietary guidance or describe a corporate philosophy — but that labeling statement must still be truthful and nonmisleading.

The FDA has, notably, continued to issue warning letters citing violations of its “healthy” nutrient content claim regulations even after acknowledging the need to reevaluate those regulations.[8] And,

historically, FDA food labeling warning letters can lead to consumer litigation, as has been the case with many warning letters the FDA has issued regarding the use of “healthy” claims.

While the FDA’s “healthy” guidance is, therefore, a significant first step in allowing, and even encouraging, food labeling claims that are consistent with current federal dietary recommendations and nutrition science, it will be important to remain engaged with the FDA on this issue (for example, through comments in response to the “healthy” notice) to ensure that future regulatory changes reflect input from all relevant stakeholders.

—By Jessica P. O’Connell, Miriam J. Guggenheim and Jeannie M. Perron, Covington & Burling LLP

Jessica O’Connell is special counsel and Miriam Guggenheim and Jeannie Perron are partners at Covington & Burling in Washington, D.C. O’Connell previously served as associate chief counsel in the FDA’s Office of Chief Counsel.

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

[2] 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 Sept. 28, 2016).

[3] 21 C.F.R. 101.65(d)(2).

[4] The FDA has established different criteria for the use of a “healthy” nutrient content claim in the labeling of fruits, vegetables, seafood and game meat.

[5] The 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.

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

[7] “Statement on FDA’s Actions on Labeling of KIND Products,” available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm500184.htm>.

[8] See, e.g., FDA Warning Letter to Middlefield Original Cheese Co-op, Aug. 29, 2016, available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2016/ucm518515.htm>; FDA Warning Letter to CV. Arira Pangindo, Jan. 27, 2016, available at <http://www.fda.gov/iceci/enforcementactions/warningletters/2016/ucm484873.htm>.