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FDA's Proposed Revamp of "Healthy" Claim Requirements: What Industry Should Do Now

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The long wait is over—the Food and Drug Administration (FDA) has finally issued a proposed rule updating its regulatory definition for the implied nutrient content claim "healthy." The proposed rule, published on September 29, 2022, comes with several significant changes that will impact not only what products qualify under the revamped definition—but also what claims and labeling elements may be subject to scrutiny from the plaintiffs' bar.

The FDA's definition of the claim "healthy" has a long regulatory history—the agency first issued its regulation definition for "healthy" in 1994. At that time, the agency explained that the purpose of this claim is to highlight foods that, based on nutrient levels, are useful in constructing a diet that conforms to current dietary guidelines. That original definition—still appearing in the FDA's regulations—outlines limits on total fat, saturated fat, cholesterol, and sodium that a food must meet to use the claim "healthy" (or related terms defined in the regulation), as well as minimum amounts of nutrients for vitamin A, vitamin C, calcium, iron, protein, and dietary fiber.

But as the dietary guidelines have evolved since 1994, the definition of "healthy" remained the same. For example, salmon and avocados, both high in fats, would not be able to bear the healthy claim under the current regulation. Recognizing changes in nutrition science, in 2016, the FDA released an enforcement discretion policy that would allow foods to use a "healthy" claim if the foods: (1) are not low in total fat but have a fat profile of predominantly mono- and polyunsaturated fats; or (2) contain at least 10 percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D, even if the food does not meet the minimum nutrient requirements in the definition.

In 2016, the agency also announced its plan to redefine "healthy" in accordance with the evolving "public health recommendations for various nutrients," and in May 2021 the agency announced its intent to create a new symbol to be used on packaging to signify that a product meets the new definition of "healthy."

Proposed Rule: Key Requirements and Requested Items for Public Comment

In an effort "to be consistent with current nutrition science and Federal dietary guidance," the FDA's proposed rule leverages the *Dietary Guidelines for Americans, 2020-2025* to update the definition of "healthy." The agency has moved

away from only setting criteria for individual nutrients to a two-fold approach, considering: (1) food groups; and (2) specific nutrients to limit. This approach is intended to look at the overall nutrient content of foods—not just focusing on individual nutrients in isolation. Key requirements and changes from the existing regulatory definition include:

- **Expansion of the instances when "healthy" would constitute a nutrient content claim:** The proposal would define "healthy" as a nutrient content claim only when it is used in a nutritional context. The FDA proposes to broaden its description of what labels and labeling trigger "healthy" claims, extending this to include "healthy" not only when it appears with declarations of the presence and level of nutrients but also to "any material stating or implying that the nutrient content of the food would be helpful to consumers in structuring a diet that is supported by current dietary recommendations."

- **Requiring levels of certain amounts of food from several food groups or subgroups:** The FDA proposes several main food groups: vegetables, fruits, grains, dairy, protein foods, and oils and requires that for foods to be labeled as "healthy," a minimum amount of a food group must be contained in that food (the agency refers to this minimum amount as a "food group equivalent"). For example, the food group equivalent for the grains food group is no less than ¾ oz equivalent whole grain. The proposal also includes oils (100 percent oils, oil-based spreads, and oil-based dressings) in the definition of "healthy" if they meet certain specified requirements.

- **Retaining restrictions on saturated fat and sodium:** Consistent with the existing definition, the proposed rule retains restrictions on both saturated fat and sodium, which will vary depending on both the food group and whether the food is an individual food or a combination food (which includes mixed products, main dish products, and meal products).

- **Inclusion of added sugars:** In addition to maintaining limitations on saturated fat and sodium, the FDA is proposing to limit levels of added sugars for foods to meet the healthy definition. The proposal is to adjust the baseline values for added sugars as warranted based on considerations for different food groups. The FDA does not consider high intensity (low and no-calorie) sweeteners as added sugars.

- **Removing restrictions on total fats and cholesterol:** In recognition of current nutrition science's view that the type of fat is more relevant than overall total fat intake, the proposed rule eliminates limitations for total fat in the updated criteria for "healthy." Along with trans fats, the FDA expects the proposed limitation on saturated fats to sufficiently limit the amounts of dietary cholesterol, so restrictions on cholesterol were removed.

- **Exemption for raw, whole vegetables and fruits and water:** All raw, whole vegetables and fruits are allowed to be labeled "healthy" without additional requirements. Similarly, the FDA proposes including plain water and plain carbonated water in the definition of "healthy."

- **Recordkeeping requirements:** While the FDA will not require additional records apart from the Nutrition Facts label to verify compliance for nutrients to limit (sodium, saturated fats, and added sugars), the agency will require regulated entities to retain written records to verify that a food meets food group equivalent requirements "when it is not apparent from the label of the food." This requirement does not extend to food that is raw, whole vegetables; raw, whole fruits; water; and individual foods when the information on the label verifies that it meets the food group equivalents.

Recognizing that it may take time for industry to analyze products, update their records of product labels, and print new labels, the FDA proposes that the final rule will become effective 60 days after the date of its publication in the *Federal Register* with a compliance date three years after the effective date.

The FDA opens up a number of issues for comment, including whether nutrients to encourage should be included in the rule, the approach of using food groups to encourage as criteria for "healthy," the approach for baseline values for added sugars, and other terms synonymous with "healthy" that the agency should consider.

What Regulated Industry Should Be Doing Now

The FDA estimates that about 5 percent of all packaged foods are currently labeled as "healthy." Based on its proposal, the agency expects the availability of the "healthy" claim will be expanded in the marketplace "due to manufacturers being more willing to use the updated claim."

Based on both (1) the agency's expansion for the circumstances in which a labeling claim would be considered a "healthy" claim as well as arguably more restrictive requirements to meet the definition; and (2) the plaintiffs' bar's increasing attempts to sweep other claims (e.g., "free of") and graphic depictions within the definition of "healthy," *we expect this rulemaking to expose a much broader array of food labeling to both FDA regulatory scrutiny and potential litigation risk—so it remains to be seen whether this rulemaking will actually increase manufacturers' appetite for using a "healthy" claim*.

Every food and beverage company should consider taking two immediate next steps:

1. *Review the proposed requirements and consider commenting on the FDA's proposal, working through legal counsel or trade organizations.* From the levels of added sugars to the scope of the term "healthy," there is significant opportunity to provide the agency with additional information as it looks to finalize the rule.

2. *Evaluate food and beverage labels now—for both compliance with these potential requirements and heightened litigation risk*. While the agency is proposing to provide a compliance date that is three years after the effective date of the final rule, evaluating products and updating labels will take some time, so it is prudent to start considering whether products may comply with the proposed requirements—and monitor for any changes that appear in the final rule.

From a litigation perspective, the plaintiffs' bar has continued to target "healthy" and other allegedly related claims and labeling graphics as not comporting with a consumer's expectations of what it means for a food or beverage to be "healthy." The FDA's proposed rule may provide additional fodder to those efforts. In some jurisdictions, this risk is only compounded by recent rulings that have expanded what it may mean for a food product to be considered "healthy." For example, a California federal court recently denied summary judgment to a food manufacturer in response to a challenge under state consumer protection statutes to various health and wellness labeling representations the plaintiffs argued were false and misleading. The court ultimately concluded that, based on evidence provided by the plaintiffs, there was a material issue of fact that the products were unhealthy given the amount of added sugar—a nutrient that was not, and is still not, part of the FDA's definition for what it means to be "healthy."

Our Food, Beverage & Agribusiness Team, which provides both regulatory and litigation services to our clients, will continue to monitor developments related to the "healthy" claim definition.

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