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December 27, 2024

FDA Publishes Final Rule on “Healthy”



On December 27, 2024, the U.S. Food and Drug Administration (FDA) published a [final rule](#) updating the criteria regarding when foods may be labeled with the nutrient content claim “healthy” and derivatives thereof—“health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness.” The compliance date is February 25, 2028. Importantly, the final rule provides that foods may bear the term “healthy” in line with the new requirements soon after the rule takes effect (*i.e.*, 60 days from December 27, 2024).

What You Need To Know

- **Contains updated criteria.** To qualify as “healthy” under the final rule, a food product must now:
 - Contain a certain amount of food from one of the food group equivalents (FGEs) established by the Dietary Guidelines for Americans, 2020-2025 (Dietary Guidelines) (vegetables, fruits, dairy, grains, protein foods, and oils).
 - Meet specific limits for added sugars, saturated fat, and sodium.

For example, a vegetable product may bear a “healthy” claim if it (1) contains at least ½ cup equivalent vegetable and (2) contains no greater than 2% of the Daily Value (DV) of added sugar, no more than 10% of the DV of sodium, and no more than 5% of the DV of saturated fat.

- **Reflects current science and nutrition recommendations.** The final rule represents the first update to the definition of “healthy” in 30 years and was drafted to reflect current nutrition science and federal

nutrition guidelines. Previously, nuts and seeds, higher fat fish (such as salmon), certain oils, and water did not meet FDA’s “healthy” criteria. But under FDA’s updated “healthy” claim, these foods now qualify as “healthy.”

In particular, nutrient-dense foods recommended by the Dietary Guidelines—such as vegetables, fruits, whole grains, fat-free and low-fat dairy, lean game meat, seafood, eggs, beans, peas, lentils, nuts, and seeds (with no added ingredients except for water)—now qualify for the “healthy” claim due to their nutrient profile and positive contribution to an overall healthy diet.

- **Aims to help consumers readily identify healthy food options.** Per FDA, the updated definition aims to help consumers identify healthier food choices at a quick glance. FDA explains that current Dietary Guidelines include a focus on the importance of healthy dietary patterns and the food groups that comprise them, the types of fat in the diet, and the amount of added sugars and sodium in the diet. FDA believes that the updated “healthy” criteria identify foods that help consumers build a healthy eating pattern.
- **Largely adopts “food group equivalent” approach, but several changes merit careful review.** The final rule generally adopts the FGE approach to the “healthy” claim presented in the [2022 proposed rule](#). At the same time, the final rule contains several key changes. Several (nonexhaustive) changes of note include:
 - An increased sodium nutrient limit for mixed food products from ? 10% DV to ? 15% DV per Reference Amounts Customarily Consumed.
 - An increased added sugars nutrient limit for individual fruits, vegetables, and protein foods from 0% DV to ? 2% DV.
 - More flexibility in the proportions of FGEs required for mixed foods such that, for example, mixed foods must contain at least one FGE, with 1/4 an FGE from at least two food groups. This stands in contrast to the 2022 proposed rule which would have required 1/2 FGE from each of at least two food groups.
- **Establishes recordkeeping requirements.** The final rule requires manufacturers to maintain records for foods bearing a “healthy” claim unless the food’s mandatory labeling information makes this clear. When records must be kept, the final rule mandates that such records be kept for at least two years after the food is introduced or delivered for introduction into interstate commerce.

Looking Ahead

FDA has published several resources regarding the final rule (*e.g.*, “[Updated ‘Healthy’ Claim – Factsheet](#)” and “[Updated ‘Healthy’ Claim – Infographic](#)”) and plans to host a stakeholder webinar to provide an overview of the final rule at a later date. Additionally, FDA’s [Constituent Update](#) announcing the final rule notes that the agency is continuing its efforts to develop a symbol for manufacturers to use on labels to show that the product meets the criteria for “healthy.”

FDA’s publication of this rule occurs within the context of the Biden administration’s broader effort to address chronic disease through its [White House National Strategy on Hunger, Nutrition, and Health](#). Once the Trump administration enters office, we expect a continued focus on food regulatory actions to promote healthy eating consistent with the views expressed by current nominees for the U.S. Department of Health and Human Services Secretary and FDA commissioner.

If you have any questions concerning FDA’s final rule on “healthy,” please contact members of Perkins Coie’s food regulatory team.

Authors

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