

Insights: Alerts

The FDA's "Healthy" Labeling Rules – Is Your Brand Ready for the New Standard?

December 27, 2024

Written by **Shreya P. Desai**,

The U.S. Food and Drug Administration (FDA) recently finalized its long-awaited [rule](#) redefining the use of the term "healthy" on food packaging. While the rule technically goes into effect on February 25, 2025, businesses will have three years, until February 25, 2028, to comply. The updated rule is designed to ensure that foods labeled as "healthy" align more closely with evidence-based nutrition recommendations and promote better consumer understanding of healthy eating patterns. The rule also reflects a broader push for transparency in food labeling and consumer protection.

The FDA started regulating the use of "healthy" claims on food labels in 1994. While the agency has periodically updated guidelines related to nutrition facts labels, serving sizes, and the Daily Value (DV) of certain nutrients, its definition of "healthy" had remained outdated. The FDA kicked off an effort to align the term with current nutrition science and federal dietary guidelines in 2016 with its initiation of a rulemaking process, beginning with a request for information and public comments on what advertising foods as "healthy" should actually mean.

In September 2022, the FDA issued a proposed rule aimed at revising the definition of "healthy" to better reflect foods that support healthy dietary practices. After reviewing more than 400 public comments submitted in response to the proposal, the FDA finalized the rule, incorporating significant updates to modernize the criteria for making a "healthy" claim.

The final rule introduces several key changes, resulting in some foods that previously qualified as "healthy" no longer meeting the updated criteria. Examples of such foods include fortified white bread, highly sweetened yogurt, and highly sweetened cereals.

Though not comprehensive, highlights from the new rule include the following provisions:

- **Saturated Fat, Sodium, and Added Sugars Limits:** Products must stay within specified thresholds for these components. For example, sodium is capped at 10% of the daily value per serving.
- **Minimum Nutrient Requirements:** Foods must contain a meaningful amount of food group-based nutrients such as fruits, vegetables, grains, protein, and dairy to qualify.
- **Automatic Qualification:** Certain foods without added ingredients (other than water) automatically qualify as "healthy." These include vegetables, fruits, whole grains, beans, peas, seafood, and nuts. Water, tea, and coffee with less than 5 calories per serving also automatically qualify for the "healthy" claim.

What's at Stake?

Misusing “healthy” could result in FDA enforcement actions, including warning letters, recalls, or reputational damage. Use of the term is also closely monitored by competitors, which could bring challenges in federal court and/or the NAD for false advertising, as well as plaintiffs' attorneys, who may bring false advertising claims under state consumer protection laws.

Steps for Compliance:

1. Audit Your Product Portfolio: Determine which items meet the new criteria and identify those needing reformulation or labeling adjustments.
2. Review Marketing and Advertising: Ensure consistency between product labels and promotional claims to avoid discrepancies.
3. Stay Ahead of Enforcement: Use the FDA's recently published guidance as a roadmap to interpret gray areas in the new rules.
4. Consult Legal and Regulatory Experts: Collaborate with your Kilpatrick Advertising Team to navigate the nuances of compliance.

Bottom Line:

It has taken many years for the federal government to finally issue this new rule, and it must be noted that the incoming administration may have potentially different ideas around what constitutes “healthy” foods.

Nevertheless, advertising foods as “healthy” should be substantiated by sound science and strict compliance with the FDA's updated standards. Your labeling and advertising practices need a health check before the FDA or the marketplace does it for you.

Related People



Shreya P. Desai

t 404.815.6032

spdesai@ktslaw.com