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Legal Alerts

# Proposed Rule on "Healthy" Labeling

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Here is what you need to know about the FDA's recent proposed rule on "healthy" labeling.

- On September 29, 2022, FDA proposed an amendment to the existing regulation (21 CFR § 101.65) on when "healthy" or similar terms can be used on food and beverage products.
- The proposed rule can be found at www.regulations.gov/docket/FDA-2016-D-2335. The docket number is FDA-2016-D-2335. You may wonder about the docket number including 2016, which means that FDA has been considering a modification to § 101.65 for several years.
- This is a proposed rule, subject to public comment until December 28, 2022. Comments may be submitted electronically at the address listed above. We would be glad to assist you with interpreting the proposal and filing comments if you wish to do so.
- The purpose of this proposed rule is to update the definition for the implied nutrient claim "healthy" to be consistent with current nutrition science and Federal dietary guidance, particularly *the Dietary Guidelines for Americans 2020-2025 (Dietary Guidelines.gov)*. The Dietary Guidelines are a joint venture of the US Department of Agriculture (USDA) and the Department of Health and Human Services (HHS). FDA is part of HHS.
- Since 1994, FDA has recognized that, when a manufacturer uses labeling that describes a product as "healthy" in a nutritional context, it is making an implicit claim that the nutrient content of the food may help consumers maintain a healthy diet. That interpretation is the basis for § 101.65.
- The updated "healthy" criteria emphasize the food groups and subgroups identified in the *Dietary Guidelines 2020-2025*, as opposed to amounts of individual nutrients. The broad food categories are: (1) raw, whole fruits and vegetables; (2) individual food products; (3) combination foods, which encompass mixed products, main dish products, and meal products; and (4) plain water. Individual food products are comprised entirely or almost entirely of one food group - vegetables, fruits (not raw), grains, dairy, proteins (game meats, seafood, eggs, beans, peas, soy products, nuts, and seeds). The details, including the levels needed to support a "healthy" claim, are somewhat complex and beyond the scope of this summary. We would be glad to assist you in interpreting the implications of the proposed rule for your specific situation.
- With respect to some specific nutrients, the proposal continues to limit salt and saturated fat, although not unsaturated and polyunsaturated fat. There also is an addition of a limit on added sugar.
- The proposal also includes recordkeeping requirements. If compliance with the requirements for the "healthy" label declaration is not evident from the nutrition facts panel or other labeling, the "manufacturer" must have (and maintain for 2 years) documentation supporting compliance. It is not clear who is the "manufacturer" (e.g., as between the brand and any contract manufacturer) for recordkeeping purposes, but the responsibility probably resides with the entity responsible for the

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"healthy" claim.

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- Food & Beverage

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