

# FDA Healthy Proposed Rule

September 29, 2022

Food, Beverage, and Dietary Supplements

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On September 28, 2022, the Food and Drug Administration (FDA) issued the long-awaited [proposed rule](#) updating the criteria for when food products can be labeled with the nutrient content claim “healthy” and when the use of “healthy” would be considered an implied nutrient content claim. FDA explains that the proposed “healthy” criteria will better align with the updated Nutrition Facts label and current Dietary Guidelines for Americans.

## Background

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FDA currently considers “healthy” labeling claims to be implied nutrient content claims when they are used in connection with an explicit or implicit statement about a nutrient (e.g., “healthy, contains 3 grams of fat”).<sup>1</sup> A food can only be marketed with a healthy nutrient content claim if it complies with FDA’s regulatory requirements.

In recent years, FDA has recognized that nutrition science and federal dietary guidelines have evolved since the agency established its “healthy” definition in the 1990s. For example, current public health standards emphasize the importance of assessing overall dietary patterns, rather than the intake of specific nutrients, in determining the health impact of consumers’ food choices.

In light of these changes, and in response to a citizen petition submitted by KIND in 2015, FDA solicited public comments on updating its “healthy” definition in September 2016.<sup>2</sup> Simultaneously, FDA issued a guidance document stating that the agency would exercise enforcement discretion regarding certain uses of “healthy” in food labeling for products that did not meet FDA’s existing “healthy” regulatory requirements but that contained predominantly “good fats” or were a good source of certain nutrients.<sup>3</sup> The agency held a public meeting to solicit additional public input on “healthy” in March 2017, and accepted public comments through April 2017.<sup>4</sup>

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<sup>1</sup> See 21 C.F.R. 101.65(d)(1).

<sup>2</sup> See “Use of the Term Healthy in the Labeling of Human Food Products,” <https://www.federalregister.gov/documents/2016/09/28/2016-23365/use-of-the-term-healthy-in-the-labeling-of-human-food-products> (Sept. 28, 2016).

<sup>3</sup> See Guidance for Industry: Use of the Term “Healthy” in the Labeling of Human Food Products (Sept. 2016) on [FDA’s website](#).

<sup>4</sup> See Public Meeting to Discuss Use of the Term “Healthy” in Food Labeling on [FDA’s website](#).

## The Proposed Rule

FDA is proposing to revise the “healthy” nutrient content claim criteria to emphasize healthy dietary patterns by requiring food products to contain a certain meaningful amount of food from at least one of the food groups or subgroups recommended by the 2020-2025 Dietary Guidelines. FDA’s proposal would also impose nutrient limits for saturated fat, sodium, and added sugars on certain food categories.

The 2020-2025 Dietary Guidelines recommended a healthy dietary pattern that focuses on meeting food group needs with nutrient-dense foods and beverages which are within calorie limits. The recommendation took the view that good nutrition does not come from the intake of individual nutrients but rather from foods with a mix of various nutrients working in combination. Each food group provides an array of nutrients and the recommended amounts reflect eating patterns associated with positive health outcomes. The Dietary Guidelines specifically explained that a healthy dietary pattern includes vegetables, fruits, grains, dairy, protein foods, and oils.<sup>5</sup> FDA proposes that using food groups as the criteria for “healthy,” rather than focusing solely on a limited set of nutrients, would better identify foods that may help consumers maintain healthy dietary practices, consistent with current nutrition science and federal dietary guidance.

FDA proposes to use a measurement described as a “food group equivalent” to inform criteria for particular food products to bear a “healthy” nutrient content claim. A food group equivalent is equal to the following:

Food Group	Food Group Equivalent	Examples
(i) Vegetable	½ cup equivalent vegetable	½ cup cooked green beans; 1 cup raw spinach
(ii) Fruit	½ cup equivalent fruit	½ cup strawberries; ½ cup 100% orange juice; ¼ cup raisins
(iii) Grains	No less than ¾ oz equivalent whole grain	1 slice of bread; ½ cup cooked brown rice
(iv) Dairy	¾ cup equivalent dairy	6 oz fat free yogurt; 1 1/8 oz nonfat cheese
(v) Protein foods	1 ½ oz equivalent game meat 1 oz equivalent seafood 1 oz equivalent egg 1 oz equivalent beans, peas, or soy products 1 oz equivalent nuts and seeds	1 ½ oz venison 1 oz tuna 1 large egg ¼ cup black beans ½ oz walnuts

<sup>5</sup> The Dietary Guidelines does not categorize oils as a “food group,” but it emphasizes that oils are one of the six core elements of a healthy dietary pattern. FDA proposes to include oils as a food group for purposes of the “healthy” requirements; however, because of their specific role in healthy dietary patterns, the proposed criteria for oils differ from the criteria for other food groups.

Specifically, a food can bear a healthy nutrient content claim if it falls into one of the following categories:

1. It is a raw, whole fruit or vegetable.
2. It is plain water and plain carbonated water without any flavoring or additional ingredients.
3. It is 100% oil, an oil-based spread whose fats come from oil, or an oil-based dressing containing at least 30% oil provided the oil meets the requirements of 100% oil; and meets nutrient thresholds for added sugars, sodium, and saturated fat.
4. It is a food that contains at least one “food group equivalent” of one of the identified food groups (i.e., “food product”) and meets nutrient thresholds for added sugars, sodium, and saturated fat.
5. It is a food that contains at least ½ “food group equivalent” of specific combinations of two or more of the identified food groups (i.e., a “mixed product”) and meets nutrient thresholds for added sugars, sodium, and saturated fat.
6. It is a “main dish product” that contains at least two food group equivalents and meets nutrient thresholds for added sugars, sodium, and saturated fat.
7. It is a “meal product” that contains at least three food group equivalents and meets nutrient thresholds for added sugars, sodium, and saturated fat.

For example, a trail mix product consisting of fruit and nuts could be labeled “healthy” if it contains ¼ c-eq fruit (half a fruit food group equivalent) and ½ oz-eq nuts (half a food group equivalent of nuts and seeds) to meet the food group equivalent requirement and meets the nutrient thresholds of 0% Daily Value (DV) for added sugars, 10% DV for sodium, and excluding the saturated fat content from nuts and seeds, 5% DV for saturated fats.

Each manufacturer—other than those producing raw, whole fruits, raw whole vegetables, water, and individual foods where the standard information required on the food label provides sufficient information to verify that the food meets the food group equivalent requirements to bear the claim—must keep written records specifically showing that a food that bears a “healthy” claim meets the food group equivalent requirements for at least two years.

In addition to changes to the “healthy” nutrient content claim criteria, FDA is also proposing changes to the regulations to make clear that any information on the label or labeling that puts the term “healthy” into a nutritional context would make “healthy” an implied nutrient content claim when the term is used to characterize the food. The proposed rule broadens the description of what a nutritional context entails. The rule would no longer require that an implied nutrient content claim be used “in connection with an explicit or implicit claim or statement about a nutrient” (which many have interpreted to mean that the nutritional context had to be immediately adjacent to the implied nutrient content claim). Rather “healthy” constitutes a nutrient content claim where the term “healthy” is used to characterize the food itself and “where *there is also* implied or explicit information about the nutrition content of the food.” For example, where “healthy” appears on the front of a cereal product that is described elsewhere on the label or labeling as high in dietary fiber (e.g., on the back of the package, or on a website), the “healthy” claim would constitute a nutrient content claim. In contrast, FDA does not consider “our manufacturing processes support a healthy planet” to be in a nutritional context.

The proposed rule was rolled out as part of the [White House Conference on Hunger, Nutrition, and Health](#), as well as the release of the related [Biden-Harris Administration National Strategy on Hunger, Nutrition, and Health](#). As part of one of the strategy's pillars to empower all consumers to make and have access to healthy choices, the Administration's additional actions include, among many things, developing a front-of-package (FOP) labeling system to quickly and easily communicate nutrition information, facilitating making nutrition information easily available when grocery shopping online, facilitating lowering the sodium content of food, facilitating lowering added sugar consumption, and addressing marketing of unhealthy foods and beverages. In addition, FDA has developed a draft guidance related to Dietary Guidance Statements on food labels to help people understand how a food or food group can contribute to a healthy eating pattern. This draft guidance is part of the Administration's recently announced strategy and is expected to issue shortly.

FDA is also in the process of studying and exploring the development of a "healthy" symbol that manufacturers can use to show that their product meets the "healthy" claim criteria.

Interested stakeholders have 90 days from when the rule is officially published in the Federal Register to submit comments.

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If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Beverage, and Dietary Supplements practice:

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