

# THE JOURNAL OF FEDERAL AGENCY ACTION

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# Food and Drug Administration Publishes Draft Recommendations on Use of Dietary Guidance Statements

Miriam Guggenheim, Jessica O'Connell, and Deepti Kulkarni\*

*In this article, the authors discuss a recent draft guidance published by the Food and Drug Administration on the use of dietary guidance statements in conventional food labeling.*

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The Food and Drug Administration (FDA) has published draft Q&A guidance<sup>1</sup> on the use of Dietary Guidance Statements in conventional food labeling. This draft guidance is one piece of the FDA's larger Nutrition Innovation Strategy,<sup>2</sup> under which the FDA aims to modernize food labeling claims. The FDA has previously sought comments<sup>3</sup> on how Dietary Guidance Statements should be regulated and has generally advised that such statements should be truthful and non-misleading, but this draft Q&A guidance represents the most in-depth view on the agency's thinking to date. The FDA's recommendations in the draft guidance are intended to enhance consistency and consumer understanding of Dietary Guidance Statements and help consumers make healthier food choices.

## Dietary Guidance Statements

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Dietary Guidance Statements are voluntary labeling claims that suggest a food or food group may contribute to or help maintain a nutritious dietary pattern. Dietary Guidance Statements can be provided through written or graphic material and are based on key or principal recommendations from a consensus report, like the 2020-2025 Dietary Guidelines,<sup>4</sup> though reports from other public and private sources may also be eligible. Dietary Guidance Statements can be provided on food labels or in labeling that accompanies a food, which could include certain websites or brochures. The

FDA provides several examples of claims that would be considered Dietary Guidance Statements, including the following:

- Eat leafy green vegetables as part of a nutritious dietary pattern;
- Make half your grains whole grain; this product contains 12 grams of whole grains per serving;
- Choose fat-free or low-fat dairy products instead of full-fat dairy options; and
- Trail mix can be part of a well-balanced diet.

The FDA explains how it considers Dietary Guidance Statements to differ from certain other FDA-regulated food-labeling claims. Nutrient content claims are different than Dietary Guidance Statements because they more narrowly characterize the level of a certain nutrient in the food, such as “high in protein.” Dietary Guidance Statements are also different from the implied nutrient content claim “healthy,” though the distinction is more nuanced. The FDA explains that a “healthy” implied nutrient content claim suggests a food may help consumers maintain healthy dietary practices because of its nutrient content; the FDA’s requirements for “healthy” implied nutrient content claims are triggered when a food’s nutrient content is described as “healthy.” In contrast, the FDA says that Dietary Guidance Statements do not characterize the nutrient content of the food and instead provide a broader message about how the product contributes to a nutritious dietary pattern. According to the agency, foods that include a Dietary Guidance Statement may or may not be eligible for a “healthy” implied nutrient content claim, which means that some foods that may not bear that type of “healthy” claim could still claim to be part of a well-balanced diet through a Dietary Guidance Statement. Dietary Guidance Statements are also different than health claims because they do not characterize the relationship of a particular substance with reduced risk of a disease or condition.

If a product bears a Dietary Guidance Statement, the FDA’s position is that the product should contain a meaningful amount of the food or food groups that are the subject of the statement, or else the statement may be misleading. The draft guidance sets out “food group equivalents,” which represent a meaningful amount of food or food groups that are the subject of the Dietary Guidance Statement. For example, for food products making a Dietary Guidance

Statement related to whole grains, the product should contain at least 12 grams of whole grains. Special rules apply to mixed products where more than one food or food group is the subject of the Dietary Guidance Statement, and to main dishes and meal products. While the FDA recommends that foods bearing Dietary Guidance Statements meet these food group equivalent recommendations, the agency expressed some flexibility regarding raw, whole fruits and vegetables that do not provide the recommended equivalent.

In addition to containing a meaningful amount of a recommended food or food group, the FDA's position is that individual foods and mixed products bearing Dietary Guidance Statements generally should not exceed certain levels for saturated fat, sodium, and added sugars:

- Saturated fat should not exceed 2 grams per reference amount customarily consumed (RACC) (10 percent of the daily value), except saturated fat from nuts and seeds does not count toward this limit;
- Sodium should not exceed 345 milligrams per RACC (15 percent of the daily value); and
- Added sugars should not exceed 5 grams per RACC (10 percent of the daily value).<sup>5</sup>

However, the FDA recognizes that certain foods may exceed these thresholds but still be recommended by consensus reports. For such foods, the FDA advises that Dietary Guidance Statements can still be appropriate, but the product should disclose the amount of the relevant nutrient level present, or else say “see nutrition information for [relevant nutrient] content.” This disclosure should be placed “near” the Dietary Guidance Statement and be “visually connected” to it.<sup>6</sup>

## **Specific Food Categories**

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Finally, the draft guidance addresses the use of Dietary Guidance Statements on a few specific food categories. The FDA's position is that Dietary Guidance Statements should not be made on dietary supplements because the Dietary Guidelines encourage Americans to meet nutrient requirements through consumption of whole foods. The draft guidance currently addresses only Dietary Guidance Statements for individuals ages two and older. This does



not necessarily preclude the use of Dietary Guidance Statements on foods for infants and children under two, but the FDA says that it intends to consider providing guidance in the future on how Dietary Guidance Statements can be made for such products. Regarding plant-based milk and yogurt, the FDA advises that Dietary Guidance Statements on dairy alternatives are only appropriate when the product is fortified such that the nutrient profile resembles traditional dairy.

## Notes

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4. <https://www.dietaryguidelines.gov/resources/2020-2025-dietary-guidelines-online-materials>.
5. The FDA has established higher thresholds for main dish and meal products.
6. A disclosure would not be required when the saturated fat level is exceeded due to the saturated fat in nuts or seeds.