

Name and Address

Food labels must list:

- a. Name and address of the manufacturer, packer or distributor. Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase which states the firm's relation to the product, e.g., "manufactured for" or "distributed by."
- b. Street address if the firm name and address are not listed in a current city directory or telephone book;
- c. City or town;
- d. State (or country, if outside the United States); and
- e. ZIP code (or mailing code used in countries other than the United States).

Nutrition Facts Panel

Under the label's "Nutrition Facts" panel, manufacturers are required to provide information on certain nutrients. The mandatory (underlined) and voluntary components and the order in which they must appear are:

- total calories
- calories from fat
- calories from saturated fat
- total fat
- saturated fat
- polyunsaturated fat
- monounsaturated fat
- cholesterol
- sodium
- potassium
- total carbohydrate
- dietary fiber
- soluble fiber
- insoluble fiber
- sugars
- sugar alcohol
- other carbohydrate
- protein
- vitamin A
- percent of vitamin A present as beta-carotene
- vitamin C
- calcium
- iron
- other essential vitamins and minerals

If a claim is made about any of the optional components, or if a food is fortified or enriched with any of them, nutrition information for these components becomes mandatory.

These mandatory and voluntary components are the only ones allowed on the Nutrition Facts panel.

All nutrients must be declared as percentages of the Daily Values which are label reference values. The amount, in grams or milligrams, of macronutrients (such as fat, cholesterol, sodium, carbohydrates, and protein) are still listed to the immediate right of these nutrients. But, a column headed "% Daily Value" appears on the far right side.

Format Modifications

In some circumstances, variations in the format of the nutrition panel are allowed. Some are mandatory.

- The labels of foods for children under 2 (except infant formula, which has special labeling rules under the Infant Formula Act of 1980) may not carry information about saturated fat, polyunsaturated fat, monounsaturated fat, cholesterol, calories from fat, or calories from saturated fat.
The reason is to prevent parents from wrongly assuming that infants and toddlers should restrict their fat intake, when, in fact, they should not. Fat is important during these years to ensure adequate growth and development.
- The labels of foods for children under 4 may not include the % Daily Values for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber. They may carry % Daily Values for protein, vitamins and minerals, however. These nutrients are the only ones for which FDA has set Daily Values for this age group.
Thus, the top portion of the "Nutrition Facts" panels of foods for children under 4 will consist of two columns. The nutrients' names will be listed on the left and their quantitative amounts will be on the right. The bottom portion will provide the % Daily Values for protein, vitamins and minerals. Only the calorie conversion information may be given as a footnote.

Simplified Label Format

Some foods qualify for a simplified label format.

- This format is allowed when the food contains insignificant amounts of seven or more of the mandatory nutrients and total calories. "Insignificant" means that a declaration of zero could be made in nutrition labeling, or, for total carbohydrate, dietary fiber, and protein, the declaration states "less than 1 g."
- For foods for children under 2, the simplified format may be used if the product contains insignificant amounts of six or more of the following: calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins A and C, calcium, and iron.
- If the simplified format is used, information on total calories, total fat, total carbohydrate, protein, and sodium--even if they are present in insignificant amounts--must be listed. Other nutrients, along with calories from fat, must be shown if they are present in more than insignificant amounts. Nutrients added to the food must be listed, too.

Small Packages

Some format exceptions exist for small and medium-size packages.

- Packages with less than 12 square inches of available labeling space (about the size of a package of chewing gum) do not have to carry nutrition information unless a nutrient content or health claim is made for the product. However, they must provide an address or telephone number for consumers to obtain the required nutrition information.
- If manufacturers wish to provide nutrition information on these packages voluntarily, they have several options: (1) present the information in a smaller type size than that required for larger packages, or (2) present the information in a tabular or linear (string) format.
- The tabular and linear formats also may be used on packages that have less than 40 square inches available for labeling and insufficient space for the full vertical format.

Other options for packages with less than 40 square inches of label space are:

- abbreviating names of dietary components
- omitting all footnotes, except for the statement that "Percent Daily Values are based on a 2,000-calorie diet"
- placing nutrition information on other panels readily seen by consumers.

Insufficient Space

A select group of packages with more than 40 square inches of labeling space is allowed a format exception, too.

- These are packages with insufficient vertical space (about 3 inches) to accommodate the required information. Some examples are bread bags, pie boxes, and bags of frozen vegetables. On these packages, the "Nutrition Facts" panel may appear, in tabular format, with the footnote information appearing to the far right.
- For larger packages in which there is not sufficient space on the principal display panel or the information panel (the panel to the right of the principal display), FDA allows nutrition information to appear on any label panel that is readily seen by consumers. This lessens the chances of overcrowding of information and encourages manufacturers to provide the greatest amount of nutrition information possible.

Dual Declaration

For products that require additional preparation before eating, such as dry cake mixes and dry pasta dinners, or that are usually eaten with one or more additional foods, such as breakfast cereals with milk, FDA encourages manufacturers to provide voluntarily a second column of nutrition information. This is known as dual declaration.

With this variation, the first column, which is mandatory, contains nutrition information for the food as purchased. The second gives information about the food as prepared and eaten.

Nutrient Content Claims

The regulations also spell out what terms may be used to describe the level of a nutrient in a food and how they can be used. These are the core terms:

- **Free.** This term means that a product contains no amount of, or only trivial or "physiologically inconsequential" amounts of, one or more of these components: fat, saturated fat, cholesterol, sodium, sugars, and calories. For example, "calorie-free" means fewer than 5 calories per serving, and "sugar-free" and "fat-free" both mean less than 0.5 g per serving. Synonyms for "free" include "without," "no" and "zero." A synonym for fat-free milk is "skim".
- **Low.** This term can be used on foods that can be eaten frequently without exceeding dietary guidelines for one or more of these components: fat, saturated fat, cholesterol, sodium, and calories. Thus, descriptors are defined as follows:
 - **low-fat:** 3 g or less per serving
 - **low-saturated fat:** 1 g or less per serving
 - **low-sodium:** 140 mg or less per serving
 - **very low sodium:** 35 mg or less per serving
 - **low-cholesterol:** 20 mg or less and 2 g or less of saturated fat per serving
 - **low-calorie:** 40 calories or less per serving.

Synonyms for low include "little," "few," "low source of," and "contains a small amount of."

- **Lean and extra lean.** These terms can be used to describe the fat content of meat, poultry, seafood, and game meats.
 - **lean:** less than 10 g fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per serving and per 100 g.
 - **extra lean:** less than 5 g fat, less than 2 g saturated fat, and less than 95 mg cholesterol per serving and per 100 g.
- **High.** This term can be used if the food contains 20 percent or more of the Daily Value for a particular nutrient in a serving.
- **Good source.** This term means that one serving of a food contains 10 to 19 percent of the Daily Value for a particular nutrient.
- **Reduced.** This term means that a nutritionally altered product contains at least 25 percent less of a nutrient or of calories than the regular, or reference, product. However, a reduced claim can't be made on a product if its reference food already meets the requirement for a "low" claim.

- **Less.** This term means that a food, whether altered or not, contains 25 percent less of a nutrient or of calories than the reference food. For example, pretzels that have 25 percent less fat than potato chips could carry a "less" claim. "Fewer" is an acceptable synonym.
- **Light.** This descriptor can mean two things:
 - First, that a nutritionally altered product contains one-third fewer calories or half the fat of the reference food. If the food derives 50 percent or more of its calories from fat, the reduction must be 50 percent of the fat.
 - Second, that the sodium content of a low-calorie, low-fat food has been reduced by 50 percent. In addition, "light in sodium" may be used on food in which the sodium content has been reduced by at least 50 percent.
The term "light" still can be used to describe such properties as texture and color, as long as the label explains the intent--for example, "light brown sugar" and "light and fluffy."
- **More.** This term means that a serving of food, whether altered or not, contains a nutrient that is at least 10 percent of the Daily Value more than the reference food. The 10 percent of Daily Value also applies to "fortified," "enriched" and "added" "extra and plus" claims, but in those cases, the food must be altered.

Alternative spelling of these descriptive terms and their synonyms is allowed--for example, "hi" and "lo"--as long as the alternatives are not misleading.

Healthy. A "healthy" food must be low in fat and saturated fat and contain limited amounts of cholesterol and sodium. In addition, if it's a single-item food, it must provide at least 10 percent of one or more of vitamins A or C, iron, calcium, protein, or fiber. Exempt from this "10-percent" rule are certain raw, canned and frozen fruits and vegetables and certain cereal-grain products. These foods can be labeled "healthy," if they do not contain ingredients that change the nutritional profile, and, in the case of enriched grain products, conform to standards of identity, which call for certain required ingredients. If it's a meal-type product, such as frozen entrees and multi-course frozen dinners, it must provide 10 percent of two or three of these vitamins or minerals or of protein or fiber, in addition to meeting the other criteria. The sodium content cannot exceed 360 mg per serving for individual foods and 480 mg per serving for meal-type products.

Health Claims

Claims for 10 relationships between a nutrient or a food and the risk of a disease or health-related condition are now allowed. They can be made in several ways: through third-party references (such as the National Cancer Institute), statements, symbols (such as a heart), and vignettes or descriptions. Whatever the case, the claim must meet the requirements for authorized health claims--for example, they cannot state the degree of risk reduction and can only use "may" or "might" in discussing the nutrient or food-disease relationship. And they must state that other factors play a role in that disease.

The claims also must be phrased so consumers can understand the relationship between the nutrient and the disease and the nutrient's importance in relationship to a daily diet.

An example of an appropriate claim is: "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."

The allowed nutrient-disease relationship claims and rules for their use are:

- **Calcium and osteoporosis:** To carry this claim, a food must contain 20 percent or more of the Daily Value for calcium (200 mg) per serving, have a calcium content that equals or exceeds the food's content of phosphorus, and contain a form of calcium that can be readily absorbed and used by the body. The claim must name the target group most in need of adequate calcium intakes (that is, teens and young adult white and Asian women) and state the need for exercise and a healthy diet. A product that contains 40 percent or more of the Daily Value for calcium must state on the label that a total dietary intake greater than 200 percent of the Daily Value for calcium (that is, 2,000 mg or more) has no further known benefit.
- **Fat and cancer:** To carry this claim, a food must meet the nutrient content claim requirements for "low-fat" or, if fish and game meats, for "extra lean."

- **Saturated fat and cholesterol and coronary heart disease (CHD):** This claim may be used if the food meets the definitions for the nutrient content claim "low saturated fat," "low-cholesterol," and "low-fat," or, if fish and game meats, for "extra lean." It may mention the link between reduced risk of CHD and lower saturated fat and cholesterol intakes to lower blood cholesterol levels.
- **Fiber-containing grain products, fruits and vegetables and cancer:** To carry this claim, a food must be or must contain a grain product, fruit or vegetable and meet the nutrient content claim requirements for "low-fat," and, without fortification, be a "good source" of dietary fiber.
- **Fruits, vegetables and grain products that contain fiber and risk of CHD:** To carry this claim, a food must be or must contain fruits, vegetables and grain products. It also must meet the nutrient content claim requirements for "low saturated fat," "low-cholesterol," and "low-fat" and contain, without fortification, at least 0.6 g soluble fiber per serving.
- **Sodium and hypertension (high blood pressure):** To carry this claim, a food must meet the nutrient content claim requirements for "low-sodium."
- **Fruits and vegetables and cancer:** This claim may be made for fruits and vegetables that meet the nutrient content claim requirements for "low-fat" and that, without fortification, for "good source" of at least one of the following: dietary fiber or vitamins A or C. This claim relates diets low in fat and rich in fruits and vegetables (and thus vitamins A and C and dietary fiber) to reduced cancer risk. FDA authorized this claim in place of an antioxidant vitamin and cancer claim.
- **Folic acid and neural tube defects:** Folic acid and neural tube defects: This claim is allowed on dietary supplements that contain sufficient folate and on conventional foods that are naturally good sources of folate, as long as they do not provide more than 100 percent of the Daily Value for vitamin A as retinol or preformed vitamin A or vitamin D. A sample claim is "healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect."
- **Dietary sugar alcohols and dental caries (cavities):** This claim applies to food products, such as candy or gum, containing the sugar alcohols xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, or a combination of any of these. If the food also contains a fermentable carbohydrate, such as sugar, the food cannot lower the pH of plaque in the mouth below 5.7. Besides the food ingredient's relationship to dental caries, the claim also must state that frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. A shortened claim is allowed on food packages with less than 15 square inches of labeling surface area.
- **Soluble fiber from certain foods, such as whole oats and psyllium seed husk, and heart disease:** This claim must state that the fiber also needs to be part of a diet low in saturated fat and cholesterol, and the food must provide sufficient soluble fiber. The amount of soluble fiber in a serving of the food must be listed on the Nutrition Facts panel.