

HELPFUL REFERENCES

FDA

General Inquiries: Call toll-free 1-888-INFO-FDA (1-888-463-6332).
Food Safety Hotline: 1-800-332-4010
FDA's food label information on the Web: www.cfsan.fda.gov/label.html.

USDA

Food Safety Education and Communication Office
1400 Independence Ave., S.W., Room 1180
Washington, DC 20250
Meat and Poultry Hotline: 1-800-535-4555

To obtain camera-ready nutrition facts:

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Nutritional Labeling

GENERAL GUIDELINES



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PURPOSE

The purpose of the “Nutrition Facts” labeling is to help consumers choose more healthful diets, and motivate food companies to improve nutritional value of their products. Nutrition Labeling is mandatory for most foods offered for sale to consumers. The Food and Drug Administration (FDA) allows certain exemptions particularly for small businesses.

EXEMPTIONS TO MANDATORY LABELING

Businesses must file an annual notice with FDA that they are claiming exemption based on number of employees and units of product.

Summary of Exemption

CFR Reference

Manufactured by small business-fewer than 100 employees and fewer than 100,000 product units or retailers with annual gross sales of less than \$500,000 or with annual gross sales of food to consumers of less than \$50,000.	101.9(j)(1)
Bakery, confectionary, and deli food prepared on site	101.9(j)(2)
Foods providing no significant nutrition	101.9(j)(3)
Infant formula, Infant and junior foods	101.9(j)(4) and 101.9(j)(7)
Dietary supplements of vitamins and minerals	101.9(j)(5)
Medical foods	101.9(j)(8)
Bulk food for further processing	101.9(j)(9)
Fresh produce and seafood	101.9(j)(10) and 101.45
Custom-processed fish and game	101.9(j)(12)
Donated food	101.9(a)

A firm with less than 10 employees and less than 10,000 units sold does not have to apply to FDA for exemption.

SPECIFIC DECLARATIONS

The detailed requirements for declaring nutrition information may be found in 21 CFR 101.9 for FDA regulated foods, 9CFR 317 for meat products and 9CFR 381 for poultry products. The nutrition panel on each food product is called “Nutrition Facts” and lists the following mandatory dietary components:

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.”

There is new recent health claim approved by the FDA: “Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease”.

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

- **Calcium and osteoporosis** 21CFR 101.72
- **Fat and cancer** 21CFR 101.73
- **Sodium and hypertension (high blood pressure)** 21CFR 101.74
- **Saturated fat and cholesterol and coronary heart disease (CHD)** 21CFR 101.75
- **Fiber-containing grain products, fruits and vegetables and cancer** 21CFR 101.76
- **Fruits, vegetables and grain products that contain fiber and risk of CHD** 21CFR 101.77
- **Fruits and vegetables and cancer** 21CFR 101.78
- **Folic acid and neural tube defects** 21CFR 101.79
- **Dietary sugar alcohols and dental caries (cavities)** 21CFR 101.80
- **Soluble fiber from certain foods, such as whole oats and psyllium seed husk, and heart disease** CFR 101.81
- **Soy Protein and risk of heart disease** 21 CFR 101.82
- **Plant Sterol/stanol esters and risk of coronary heart disease** 21CFR 101.83



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

Sample label for Macaroni & Cheese

Nutrition Facts
Serving Size 1 cup (228g)
Serving Per Container 2

Amount Per Serving
Calories 250 Calories from Fat 110

	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Trans Fat 1.5g	
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

*Percent Daily Values are based on a diet of other people's misdeeds.
**Your Daily Values may be higher or lower depending on your calorie needs.

Calories: 2,000 2,500

Total Fat	Less than 65g	65g
Sat Fat	Less than 25g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

① Start Here →
②
③ Limit these Nutrients
④ Get Enough of these Nutrients
⑤ Footnote

Quick Guide to % DV
⑤
5% or less is Low
20% or more is High

- Total calories
- Calories from fat
- Total fat
- Saturated fat content
- Trans Fat
- Cholesterol
- Sodium
- Total Carbohydrates
- Dietary Fiber
- Sugars
- Protein
- Vitamin A and C
- Calcium
- Iron

Voluntary dietary components that can be listed on the label include calories from saturated fat, polyunsaturated fat, monounsaturated fat, potassium, soluble fiber, insoluble fiber, sugar alcohol, other carbohydrates, and vitamins and minerals.

All nutrients must be stated as a percentage of their “Daily Value” to show how much of a day’s ideal total of a particular nutrient THE consumer is getting.

FORMATS

Although FDA has permitted a variety of formats to be used for presenting nutrition information, the conditions under which each format may be used are specified in detail. Depending upon the product and package size, the format could be Standard, simplified or shortened.

SERVING SIZES

The nutrient content information presented in the Nutrition Facts panel is based on a serving of the food and is intended to help consumers compare products. FDA has established a system for determining serving sizes based on amounts normally consumed per eating occasion. Regulations for determining the serving size to use on a food label may be found in 21 CFR 101.12(b) and for meat and poultry products in 9 CFR 317.312

Household units – Label serving sizes are to be declared in common household units familiar to most consumers. These units are cups,



Nutrition Facts
Serving Size: 1/2 package (44g, about 1/4 cup dry mix)
Servings Per Container: 12

Amount Per Serving	Mix	Baked
Calories	190	250
Calories from Fat	45	140
	% Daily Value**	
Total Fat 5g*	8%	24%
Saturated Fat 2g	10%	13%
Trans Fat 1g		
Cholesterol 0mg	0%	23%
Sodium 300mg	13%	13%
Total Carbohydrate 34g	11%	11%
Dietary Fiber 0g	0%	0%
Sugars 18g		
Protein 3g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	6%
Iron	2%	4%

* Amount in Mix
** Percent Daily Values are based on a diet of other people's misdeeds.
*** Your Daily Values may be higher or lower depending on your calorie needs.

	Calories: 2,000	2,500
Total Fat	Less than 65g	65g
Sat Fat	Less than 25g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

tablespoons, teaspoons, piece, slice, fraction, ounce, fluid ounce, etc. The common household measure is followed by its metric equivalent in grams (g).

NUTRIENT CONTENT CLAIMS

Nutrient content claims describe the level of nutrient in a food product; also referred to as descriptors. Food manufacturers are required to use standardized definitions when making claims concerning the nutrient contents of foods. These are the core terms:



Free

These products contain 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

These foods may 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 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 foods 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.

