Extra lean: less than 5 grams of fat, less than 2 grams saturated fat and less than 95 milligrams cholesterol per serving and per 100 grams.

High

Refers to foods that contain 20 percent or more of the Daily Value for a particular nutrient in a serving.

Good source

This means that a serving of a food contains 10 to 19 percent of the Daily Value for a particular nutrient.

Reduced

Refers to a nutritionally altered food that contains at least 25 percent less of a nutrient or of calories than the regular, or reference, food. A reduced claim cannot be made on a product if its reference food already meets the requirements for a "low:" claim.

Less

Refers to foods that contain 25 percent less of a nutrient or of calories than the reference food.

Light

May mean two things:

1. A nutritionally altered product containing one-third fewer calories or half the fat of the unaltered reference food. If the food derives 50 percent or more of its calories from fat, the reduction must be 50 percent of the fat.
2. The sodium content of a low-calorie, low-fat food has been reduced by 50 percent. Also, "light in sodium" may be used on foods in which the sodium content has been reduced by at least 50 percent.

More

Refers to a serving of food that contains a nutrient that is at least 10 percent of the Daily Value more than the reference food. The 10 percent of the Daily Value also applies to "fortified," "enriched," "added" and "extra and plus" claims, but in those cases the food must be altered.

Alternative spellings of these descriptive terms is allowed, for example "lo" and "hi," as long as they are not misleading.

Healthy

Refers to foods that must be low in fat and saturated fat and contain limited amounts of cholesterol and sodium. Single item foods must provide at least 10 percent of one or more of vitamin A or C, calcium, protein or fiber. Certain raw, canned and frozen fruits and vegetables and certain cereal-grain products are exempt from the 10 percent rule if they do not contain ingredients that change the nutritional profile and in the case of the enriched grain products, conform to standards of identity, which require certain ingredients. A meal-type product, such as multi-course frozen dinners, 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 milligrams per serving for individual foods and 480 milligrams per serving for meal-type products.

Health Claims

Health claims are intended to inform consumers about reducing the risk or delaying the premature onset of a chronic disease condition by consuming certain foods as part of a healthy diet. Currently, there are 13 allowed nutrient-disease relationship claims:

1. Calcium and osteoporosis
2. Fat and cancer
3. Saturated fat and cholesterol and coronary heart disease (CHD)
4. Fiber-containing grain products, fruits and vegetables and cancer
5. Fruits, vegetables and grain products that contain fiber and risk of CHD
6. Sodium and hypertension (high blood pressure)
7. Fruits and vegetables and cancer
8. Folic acid and neural tube defects
9. Dietary sugar alcohols and dental caries
10. Soluble fiber from certain foods, such as psyllium seed husk and heart disease
11. Soy protein and coronary heart disease
12. Dietary noncariogenic carbohydrate sweeteners and dental caries
13. Sterols/stanols and coronary heart disease

Conclusion

Constructing a food label may seem intimidating at first. However, by becoming familiar with a few basic regulations and requirements, a visually appealing label can be developed that conveys the necessary product information in a uniform and easy to understand manner. Please feel free to contact the Food & Agricultural Products Center with questions about product labeling and for a review of your proposed product label by calling (405) 744-6071. You may also visit the FDA Web site (http://www.cfsan.fda.gov/label.html) for additional information.

References

General Food Labeling Requirements. 2005. Guide to U.S. Labeling Law, Vol 1. Thompson Publishing Group.

U.S. Food and Drug Administration, FDA Backgrounder, The Food Label, BG99-5, May 1999. http://www.cfsan.fda.gov/~dms/fdnewlab.html#updated

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FOOD TECHNOLOGY FACT SHEET

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Food Product Labeling Basics

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Introduction

Food packaging labels are meant to be more than just attractive artwork to catch the eye of the consumer. Properly formatted labels convey specific information in a manner that enables the consumer to make an informed purchase. Foods packaged with labels that do not meet regulatory requirements, also known as misbranded, may result in harsh penalties to the producer (see penalties sidebar). Accurate and legally complete labels make sense from the standpoints of both ethics and good business. Fortunately, constructing a label that meets regulations is simple and requires only a small amount of information and following a few rules. The purpose of this fact sheet is to provide the necessary information to enable readers to develop their own food packaging labels that meet all current legal requirements.

Required Elements of a Food Label

The Federal Food, Drug and Cosmetic Act (FD&C) requires five elements to appear on a food label:

1. Name of the food
2. Net quantity of contents
3. Name and address of the manufacturer
4. Statement of ingredients
5. Nutrition information

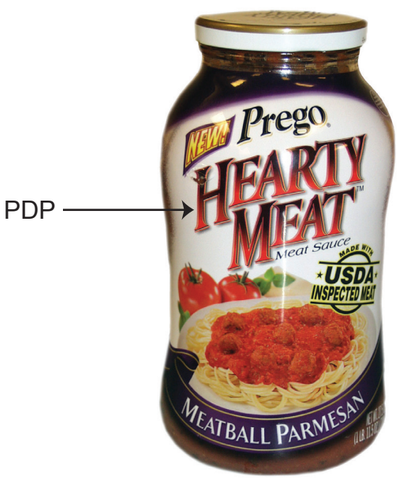
This information in its entirety may be placed together on the principal display panel, or the name of the food and net quantity may be placed on the principal display panel while the name and address of the manufacturer, statement of ingredients and nutrition information are placed on the information panel as described below.

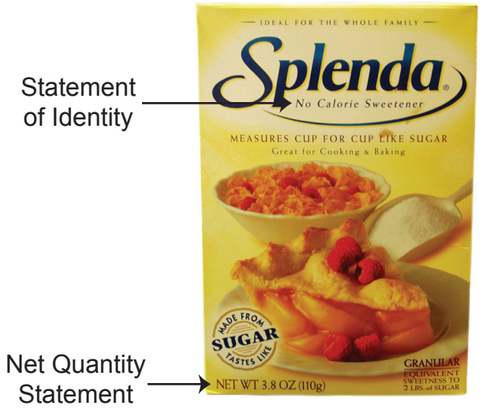
Principal Display Panel

The principal display panel, or PDP, is the portion of the package that is seen at the time of purchase by the consumer and contains information typically regarding the statement of identity and net quantity. Often food packages are designed with two or more panels that may serve as the PDP. These additional panels are referred to as alternate principal display panels, and they must also contain the statement of identity and net quantity of contents.

Name of the Food

The statement of identity is the name of the food and must appear prominently on the PDP, as well as any alternate PDP, in bold type and should run parallel to the bottom of the package. The common or usual name of the food is to be used. If one is not available, then a name that is descriptive and not misleading should be used. Examples of foods with standards of identity are jelly, mayonnaise and peanut butter. The standard of identity establishes and maintains the identity and quality of a food. It may specify lists of mandatory ingredients and authorize specific lists of optional ingredients. A complete list of foods that have standards of identity may be found in Title 21 of the Code of Federal Regulations parts 131 to 169. If the food has a standard of identity, then the name specified in the standard must be used on the PDP.





Net Quantity of Contents

The net quantity of contents is the amount of food contained within a package (excluding the weight of the package itself), and typically includes any water, syrup or liquid that has been added to the food. However, for foods where the liquid is typically discarded, such as olives or mushrooms, the drained weight should be displayed. The net contents should be displayed in both metrics (grams, milliliters, kilograms or liters) and the U.S. Customary System (ounces, pounds, fluid ounces). The metric measure may appear before or after the U.S. Customary statement, or below or above it. The measures must also match, i.e., volume measures are generally required for liquid foods (milliliters, liters and fluid ounces) and weight measures for solid, viscous or mixed solid/ liquid foods (grams and ounces).

The net quantity of contents statement should appear in the lower 30 percent of the PDP, running as a distinct line parallel to the base of the package.

Information Panel

The information panel contains information that is generally required to be placed together such as contact information for the manufacturer (see "contact information"), packer or distributor, the ingredient list and nutritional labeling. This information cannot be interrupted or visually split by non-essential information, such as artwork or a UPC symbol. The information panel is positioned directly to the right of the PDP, unless this panel is not usable. The information panel would then be the next label panel immediately to the right.

PENALTIES

The Federal Food, Drug and Cosmetic Act (FD&C) gives the Food and Drug Administration (FDA) the authority to recommend to the Department of Justice that misbranded product and accompanying labeling be seized, be the subject of an injunction or be the subject of a criminal prosecution. The FDA also has the authority to request a company recall product whose label violates the FD&C Act.

Ingredient Listing

Ingredients must be listed by their common name in descending order by predominance of weight or volume. This includes items such as preservatives, colors and flavors.

It should be noted that those ingredients that are used for a specific functional purpose, such as preservatives, must have their function listed in parentheses immediately following the ingredient. For example:

Ingredients: water, tomatoes, onions, garlic, salt, sodium benzoate (preservative)

Ingredients that comprise less than 2 percent or less of a product formula need not be listed in descending order by predominance of weight or volume. However, they must be preceded by the phrase "contains less than 2% of the following…" In cases where an ingredient may or may not be present in a product formula at a concentration of less than 2 percent, the phrasing would read "may contain less than 2% of the following …"

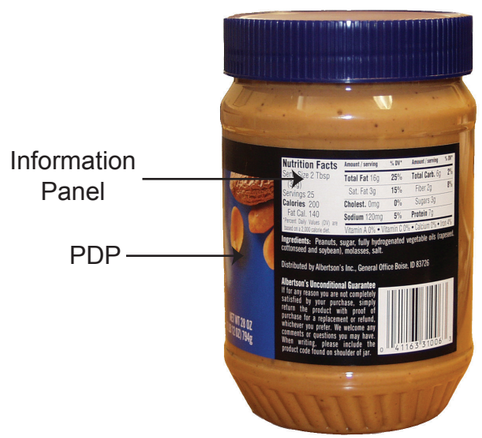
Ingredients, such as Worcestershire sauce, that are comprised of other ingredients would still be listed by predominance of weight; however, they would be followed by a parenthetical statement listing each component found in the Worcestershire sauce. For example:

The company makes a soup with ingredients in the following proportions: 15 pounds water, 8 pounds of beef, 5 pounds of potatoes, 4 pounds of carrots, 1.5 pounds of Worcestershire sauce, 1 pound of mushrooms and 0.5 pound of salt.

The ingredient listing would show:

Ingredients: water, beef, potatoes, carrots, worcestershire sauce (water, vinegar, molasses, corn syrup, salt, anchovies, spices), mushrooms, salt.

Note that water and salt both appear twice in the ingredient statement. If the company wants water and salt to be listed only once, they would need to know the amounts of water and salt that was used in the Worcestershire sauce so that those amounts could be added to the water and salt in the company's formula.



Contact Information

The FDA requires that a food label "conspicuously" identify a product's manufacturer, distributor or packer and provide their address as well. The name, city, state and zip code of the food manufacturer, distributor or packer may be listed on either the PDP or the information panel. However, it must be accompanied by the statement of ingredients and the nutrition information, unless the product is explicitly exempted from these regulations.

Nutritional labeling

The Nutrition Labeling and Education Act (NLEA) mandates all food intended for retail sale to carry nutritional labeling, with a few exceptions. Foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition facts are exceptions. Insignificant amounts are defined as those that would round to zero or less than 1 gram on the label. Examples of such foods include coffee beans, tea and some spices. Bulk-packed foods not intended for retail sale are exempt. Raw produce also is generally exempt. In addition, small businesses may be exempt from placing a nutritional label on their products based on several federal regulations; current information is available on the FDA's Web site (http://www.cfsan.fda.gov/~dms/sbel.html).

The nutrition labeling exemptions found in 21 CFR 101.9(j)(1) and 21 CFR 101.36(h)(1) apply to retailers with annual gross sales of not more than $500,000, or with annual gross sales of foods or dietary supplements to consumers of not more than $50,000. For these exemptions, a notice does not need to be filed with the FDA.

The nutrition labeling exemptions for low-volume products found in 21 CFR 101.9(j)(18) and 21 CFR 101.36(h)(2) apply if the person claiming the exemption employs fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of that product are sold in the United States in a 12-month period. For these exemptions, a notice must be filed annually with the FDA.

If any nutrient content claim (e.g., "sugar free"), health claim or other nutrition information is provided on the label or in labeling or advertising, the small business exemption is not applicable for that product.

A unique set of nutritional labeling regulations apply to foods specifically intended for infants, toddlers and medical patients.

A unique set of labeling regulations apply to foods intended for "special dietary use." These include foods for infants and toddlers, hypoallergenic foods and foods intended to be useful in maintaining or reducing body weight. Infant formula labeling regulations may be found in 21 CFR 107.10, 21 CFR 107.20 and 21 CFR 107.30. Specific requirements for infant food labeling are found in 21 CFR 105.65. Details on nutritional labeling requirements for children under 4 years of age are found in 21 CFR 101.9(j)(5). Information on reference amounts customarily consumed per eating occasion for infants and toddlers is found in 21 CFR 101.12(b). Labeling requirements for hypoallergenic foods is found in 21 CFR 105.62. Information on label statements required for foods intended to be useful in maintaining or reducing body weight are found in 21 CFR 105.66. "Medical Foods," which are foods formulated to be consumed or administered entirely under the supervision of a physician and which are intended for the specific dietary management of a disease or condition, are exempt from nutritional labeling, nutrient claim and health claim requirements.

Additional Information that May Appear on the Food Label

Nutrient Content Claims

Terms such as "low sodium" and "fat free" are referred to as nutrient claims, and there are strict guidelines regarding the concentration levels and formatting that must be followed in order to use these terms on a product's packaging.

The core terms are:

Free

Refers to products contains either no amount or a trivial "physiologically inconsequential" amount of one or more of the following: fat, saturated fat, cholesterol, sodium, sugars and calories. An example would be, "calorie free," which means less than 5 calories per serving, while "sugar-free and fat-free" both mean less than 0.5 grams per serving. Other terms that may be used instead of "free" are "without," "no" and "zero."

Low

Refers to foods that may be eaten frequently without exceeding dietary guidelines for one or more of the following nutrients: fat, saturated fat, cholesterol, sodium and calories.

Low-fat: 3 grams or less per serving
Low-saturated fat: 1 gram or less per serving
Low-sodium: 140 milligrams or less per serving
Very low sodium: 35 milligrams or less per serving
Low-cholesterol: 20 milligrams or less and 2 grams or less of saturated fat per serving
Low-calorie: 40 calories or less per serving

Other terms that may be used instead of "low" are "little," "few," "low source of" and "contains a small amount of."

Lean and Extra Lean

Refer to the fat content of meat, poultry, seafood, and game meats.

Lean: less than 10 grams of fat, 4.5 grams or less saturated fat, and less than 95 milligrams cholesterol per serving and per 100 grams.