Food Label Requirement Made Simple

A guide for the FDA food label regulations

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Introduction

TPGTEX Label Solutions is a company whose main specialty is finding solutions to any label printing issue. Over the years TPGTEX has developed many software applications to help in the creation of labels. The ***Food Labeling System*** was developed to automate the creation of food labels. The program includes a product manager that stores all needed information for the purpose of printing food labels with nutrition panel.

This document was prepared in an effort to help our customers who are small food manufacturers and processors. Like so many, they have a great food product that they worked very hard on developing. They wanted to start marketing it to local grocery store chains, gifts shops, etc. What they did not have was good information – or guideline as to what needed to be on the food label.

The FDA and USDA sites are full of information about the food label. However, most of the information is written in a way that will be hard for most people to understand. It is very long and very detailed.

This guide touches on all sections of the food label (front and nutrition Panel). Each section is explained and the most common expressions are explained as well. When ever possible, examples were added.

We hope this guide helps make things a little simpler for you.

Good Lack with your product.

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The information provided here is based on the FDA website where you can get more specific information. This guide is intended to help you sort through the main parts of the labeling requirements. It is not meant to replace the FDA guide.

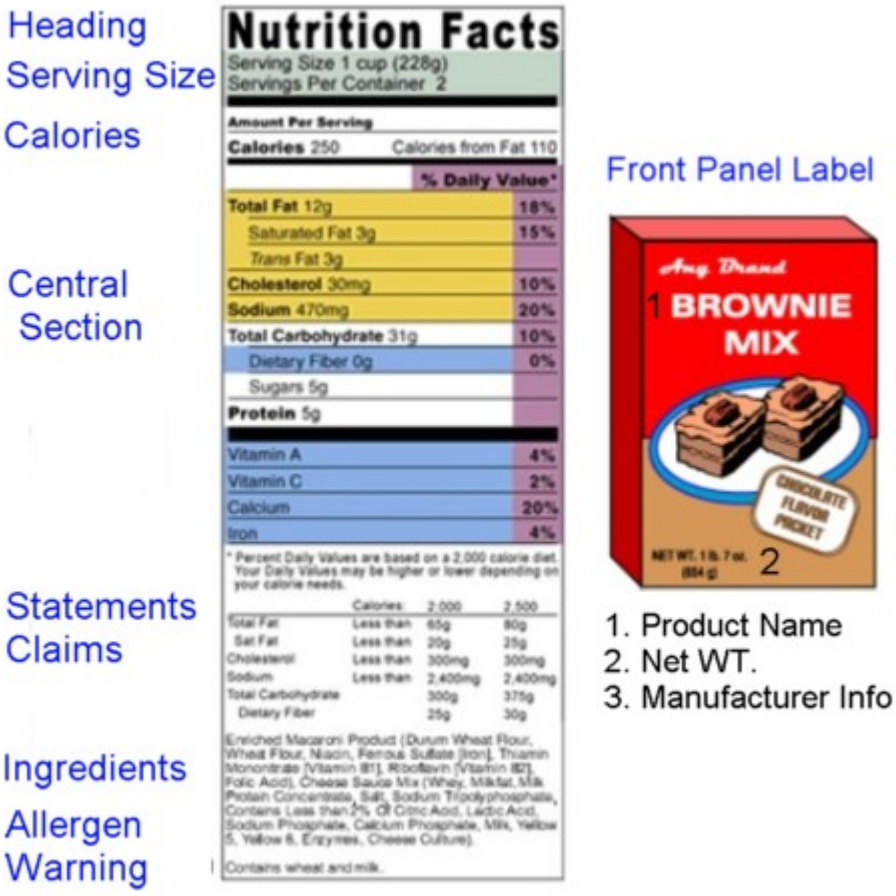
What is a food label anyway?

The purpose of the food label is to inform the consumer in a clear way what is the content of the food package.

A food label is comprised of two main parts: the front and the nutrition information.

The two parts can be together on one label or can be divided to two labels.

1. **The front part** contains the name of the product and the weight.
2. **The nutrition panel** contains all nutritional information as well as ingredient list and any statements and disclaimers.



Small Business Exemption

Small business may be exempt from some of these requirements and can apply for the exemption to the FDA.

The FDA defines small business in these terms:

> *"...low-volume products, applies 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."* Exemptions can now be filed **online.**

Heading

How large must the Nutrition Facts Heading be?

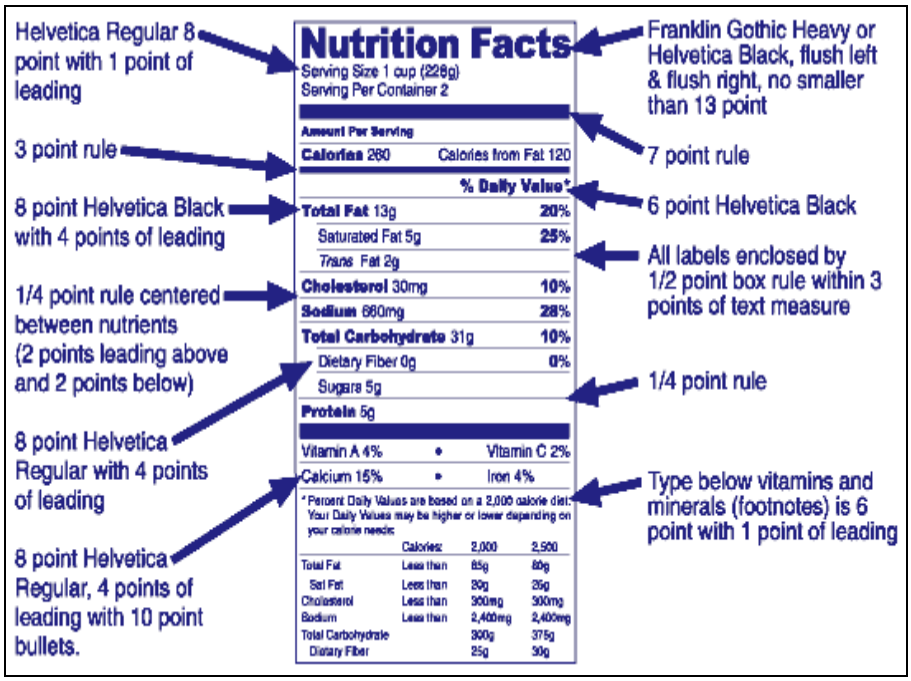
The "Nutrition Facts" heading must be in a type size larger than all other print size in the nutrition label (21 CFR 101.9(d)(2)). Minimum type sizes of 6 point and 8 point are required for the other information in the nutrition label (21 CFR 101.9(d)(1)(iii)), and there are minimum spacing requirements between lines of text (21 CFR 101.9(d)(1)(ii)(C)).

Small food packages may have different requirements.

The FDA defines small packages as:

"..Food packages with a surface area of 40 sq. in. or less.."

Font and Spacing Requirements



*Source www.fda.gov

What is the "right" Serving Size?

To determine the right serving size portions use these three simple steps:

1. **First Step**: Determine your food category using the Reference Amount Customarily Consumed (RACC) tables. Click here to go to [table 1], [table 2] - both tables can also be found on the www.gpoaccess.gov site.

2. **Second Step**: Determine appropriate serving size. If your product is sold in small units it is required to be labeled as *single serving* container. Labeling requirements for single-serving containers can be found here 21 CFR 101.9(b)(6).

3. **Third Step:** Determine the number of serving for your food package.

Serving size is expressed as a common household measure followed by the equivalent metric quantity in parenthesis (e.g., "1/4 cup (112 g)").

Common Household Measures

21 CFR 101.9(b)(5)

(5)For labeling purposes, the term ***common household measure*** or common household unit means *cup*, *tablespoon*, *teaspoon, piece*, *slice, fraction* (e.g., 1/4 pizza*), ounce* (oz), *fluid ounce* (fl oz), or other common household equipment used to package food products (e.g*., jar, tray*). In expressing serving size in household

measures, except as specified in paragraphs (b)(5)(iv), (b)(5)(v), (b)(5)(vi), and (b)(5)(vii) of this section, the following rules shall be used:

(i) *Cups, tablespoons, or teaspoons* shall be used wherever possible and appropriate except for beverages. For beverages, a manufacturer may use fluid ounces. Cups shall be expressed in 1/4- or 1/3-cup increments. Tablespoons shall be expressed as 1, 1 1/3, 1 1/2, 1 2/3, 2, or 3 tablespoons. Teaspoons shall be expressed as 1/8, 1/4, 1/2, 3/4, 1, or 2 teaspoons.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

What is "Calorie Free" Food?

> *"...Foods with less than 5 calories meet the definition of "calorie free" and any differences are dietarily insignificant.."*

Calories should always be rounded. They are either rounded to the nearest 5 or 10

How are Calories Rounded?

Calories must be rounded as follows:

50 calories or less: Round to nearest 5-calorie increment.

Example: Round 47 calories to "45 calories"

Above 50 calories: Round to nearest 10-calorie increment.

Example: Round 96 calories to "100 calories"

Additional information about this subject can be found here 21 CFR 101.9(c)(1)

The Parts of the Central Section

- **Trans Fat Labeling** - FDA is requiring that trans fatty acids be listed in nutrition labeling to assist consumers in maintaining healthy dietary practices.
- **Trans fatty acids** should be listed as "Trans fat" or "Trans" on a separate line under the listing of saturated fat in the Nutrition Facts label. Trans fat content must be expressed as grams per serving to the nearest 0.5-gram.
- **Vitamins and Minerals** - Generally, FDA only requires that the label declare the vitamins A and C, and the minerals calcium and iron.
- **Declare other vitamins and minerals** when they are added directly to the packaged food (e.g., enriched bread), but not when the enriched product is added as an ingredient to another food.
- Daily Value - This value must be calculated and presented for any nutrient that is mandatory on the label. In addition, any other nutrient that has been added and has an established DV%, need to have that value as well.
- **Nutrients not included in the required list** - manufacturers may add calories from saturated fat, polyunsaturated fat, monounsaturated fat, potassium, soluble and insoluble fiber, sugar alcohol, other carbohydrate, vitamins and minerals for which Reference Daily Intake (RDI's) have been established, or the percent of vitamin A that is present as beta-carotene. 21 CFR 101.9(c)

Be sure to consult the guide provided on the FDA site for specific information, requirements, and regulations concerning your product.

What and How Claims and Statement are Written?

The *Claims and Statement* section was created for the use of additional nutrient content claims on labels in accordance with provisions of the Nutrition Labeling and Education Act of 1990.

Antioxidant: An antioxidant nutrient content claim can only be made for nutrients for which there is an established RDI.

Note: The antioxidant nutrient must meet the requirements for nutrient content claims for High claims, Good source claims, and More claims, respectively (in 21 CFR 101.54(b),(c),or(e)).

Example: To use a high claim, the food would have to contain 20% or more of the Daily Reference Value (DRV) or RDI per serving. For a good source claim, the food would have to contain between 10-19% of the DRV or RDI per serving.

Example of correct usage: *"high in antioxidant vitamins C and E"*

Fiber: You can use "high", "good source" or "more". However; if the food is NOT "low" in total fat, then the label *must include* the level of total fat per labeled serving.

Sugar Free: food that contains less than 0.5 g of sugars. Terms such as "free of sugar", "no sugar", "zero sugar", "without sugar", "sugarless", "trivial source of sugar", "negligible source of sugar", "dietarily insignificant source of sugar" can also be used. However; If the food is NOT also low or reduced in calorie that fact must be disclose.

Fat Free: food contains less than 0.5 grams fat per serving. RAW serving. 3

Descriptive Terms: Each term can only be used if the nutrient it refers to is contained in the food product at a minimum percentage or above.

"high potency": food contains 100 percent or more of vitamins or minerals (RDI).

Example of correct usage: *"Botanical X with high potency vitamin E."*

- "more", "fortified", "enriched", "added", "extra", and "plus" : food contains at least 10 percent more of the RDI. Used in the description of protein, vitamins, minerals, dietary fiber, or potassium.

- "rich in", or "excellent source of": food contains 20 percent or more of the RDI or the DRV.

- "good source", "contains", or "provides": food contains 10 to 19 percent of the RDI or the DRV.

- "light" can be used only if the consumer would generally recognize it as a food that is improved in its nutrient value compared to other average products of its type.

- "reduced", "less", "fewer", and "light" : the label must state each of the following (these are called "accompanying information"):

1. The percentage or fraction by which the food has been modified,
2. The reference food, and
3. The amount of nutrient (that is the subject of the claim) that is in the labeled food and in the reference food.

What is a Disclosure Statement?

Disclosure statement *"... is a statement that calls the consumer's attention to one or more nutrients in the food that may increase the risk of a disease or health-related condition that is diet related. The disclosure statement is required when a nutrient in a food exceeds certain prescribed levels."*

"...disclosure statement is required when a NCC is made and the food contains one or more of the following nutrients in excess of the levels listed below per Reference Amount Customarily Consumed (RACC), per labeled serving, or, for foods with small serving sizes, per 50 grams."

Total Fat	13.0 grams
Saturated Fat	4.0 grams
Cholesterol	60 milligrams
Sodium	480 milligrams

Be sure to consult the guide provided on the **FDA site** for specific information, requirements, and regulations concerning your product.

The Ingredient List

- List ingredients in descending order, sorted by weight. The ingredient with most weight is listed first, and the ingredient with the least weight is listed last.
- list the common or usual name for ingredients unless there is a regulation that provides for a different term. For instance, use the term "sugar" instead of the scientific name "sucrose."

  Example - INGREDIENTS: Apples, Sugar, Water, and Spices

- Trace ingredients do not need to be listed if a substance is an incidental additive and has no function or technical effect in the finished product. *Sulfites are considered to be incidental only if present at less than 10 ppm.*
- Chemical preservatives that are added to a food, must be included using both the common or usual name of the preservative and the function of the preservative by including terms, such as "preservative" "to retard spoilage" "a mold inhibitor" "to help protect flavor" or "to promote color retention."

  Example - INGREDIENTS: Dried Bananas, Sugar, Salt, and Ascorbic Acid to Promote Color Retention.

- Spices may be declared in ingredient lists by using either specific common or usual names or by using the declarations "spices," "flavor" or "natural flavor," or "artificial flavor."

  Example - INGREDIENTS: Apple Slices, Water, Cane Syrup, Corn Syrup, Modified Corn Starch, Spices, Salt, Natural Flavor and Artificial Flavor

Water as an ingredient

"...Water added in making a food is considered to be an ingredient. The added water must be identified in the list of ingredients and listed in its descending order of predominance by weight. If all water added during processing is subsequently removed by baking or some other means during processing, water need not be declared as an ingredient." Compliance Policy Guide 555.875

Example - Can of beans:

INGREDIENTS: Pinto Beans, Water, Salt.

Example - Cookies:

INGREDIENTS: Flour, Sugar, butter, vanilla extract.

In the "beans" example, water is a part of the ingredient list. However, it is NOT part of the "cookies" example because all water has been removed during the baking process.

Be sure to consult the guide provided on the FDA site for specific information, requirements, and regulations concerning your product.

FALCPA Regulation

FALCPA - Is the Food Allergen Labeling and Consumer Protection Act of 2004.

FALCPA addresses the labeling of all packaged foods regulated by the FDA. In Addition labeling having to do with meat products, poultry products, and egg products are regulated by the U.S. Department of Agriculture (USDA.)

Major food allergen is an ingredient that is one of the following eight foods or food groups or an ingredient that contains protein derived from one of them:

milk	crustacean shellfish
fish	egg
tree nuts	wheat
peanuts	soybeans

Although more than 160 foods have been identified to cause food allergies in sensitive individuals, the "major food allergens" account for 90 percent of all food allergies.

Allergens other than the major food allergens are not subject to FALCPA labeling requirements.

- Tree nuts, Crustacean shellfish and fish must be declared specifically.

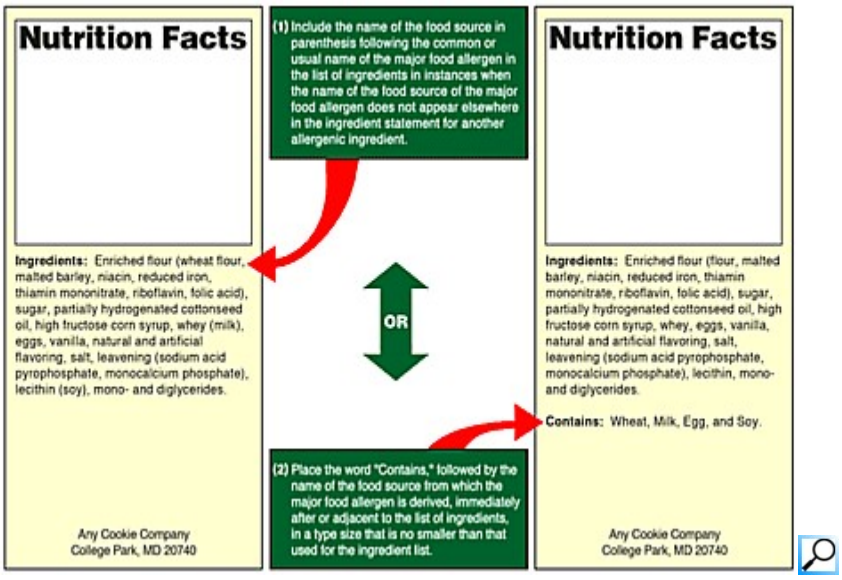
  For Tree Nuts: almonds, pecans, walnuts, etc.

  For fish: bass, flounder, cod, etc.

  For Crustacean shellfish: crab, lobster, shrimp, etc.

- Wheat refers to any species in the genus Triticum: wheat, durum wheat, club wheat, spelt, semolina, Einkorn , emmer, kamut and triticale.

FALCPA requires food manufacturers to label food products that are made with an ingredient that is a major food allergen in one of the following two ways:



What is PDP?

PDP - Principal Display Panel

The FDA defines the PDP in these terms:

> *"...The PDP, is that portion of the package label that is most likely to be seen by the consumer at the time of purchase. Many containers are designed with two or more different surfaces that are suitable for display as the PDP. These are alternate PDPs."*
>
> 21 CFR 101.1

What Should be Displayed on the PDP?

There are two statements that must appear on the PDP:

Statement of Identity = The name of the food.

1. Use common or usual name. If none exists, use a descriptive term. The label may, in addition, bear a fanciful name which is not false or misleading.

2. Name should include description such as: whole, slices, diced, etc., *unless it can be seen through the package*.

Net Quantity of Contents Statement = The weight of the product (in ounces and grams, for beverages in liquid ounces)

Identification of Manufacturer/distributor/packer - This information can either be placed on the PDP or if more than one label is used on a product, it can also be placed on the second label.

The information must include the following:

1. 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").

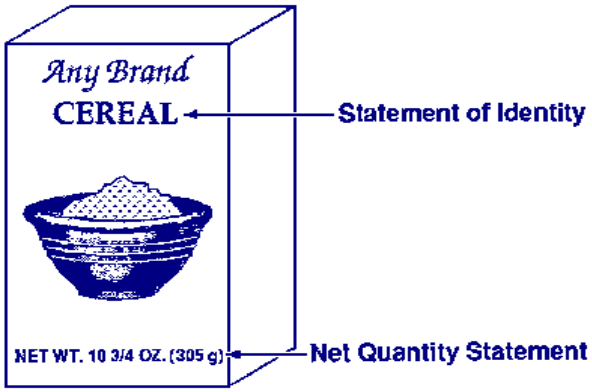
2. Street address *if the firm name and address are not listed in a current city directory or telephone book*;

3. City or town;

4. State (or country, if outside the United States); and

5. ZIP code (or mailing code used in countries other than the United States).

The Layout of the PDP



Print Size - use prominent, conspicuous and easy to read print size.

Use letters that are at least one-sixteenth (1/16) inch in height based on the lower case letter "o". The letters must not be more than three times as high as they are wide, and the lettering must contrast sufficiently with the background so as to be easy to read. *Do not crowd required labeling with artwork or non-required labeling.*

Print Type - statement of identity shall be presented in bold type.

Appendix I

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