Food Consulting COMPANY

Nutrition • Labeling • Regulatory

FDA Food Label Compliance

Ask your questions about FDA food label regulations here.

Food Consulting Company provides FDA-compliant food label development and regulatory support services. The company offers final food label compliance reviews for FDA-regulated products, develops nutrition facts and ingredient statements, and provides ongoing regulatory support for companies both large and small. Food Consulting Company also publishes a popular e-newsletter, *Food Label News*, where readers are invited to submit questions for consideration in an upcoming Reader Q&A Spot (no charge).

Recent questions asked and answered in the Reader Q&A Spot include:

For a product that contains multi-component ingredients (e.g., cherry pie contains fruit filling and crust, both with sub-ingredients), does FDA require that the ingredient statement show each ingredient with sub-ingredients in parentheses, or is it ok to list the subcomponents one time in order by total weight in the whole product?

FDA regulations allow a product that contains multi-component ingredients to use either a "composite" ingredient statement or an "expanded" (parenthetical) statement. Which type to use depends on the goal for final label appearance and on the availability of the formula breakdown for multi-component ingredients.

The "composite" ingredient statement is generally a cleaner, more concise ingredient statement that helps present a product in the best possible light within the law. This type of statement identifies each ingredient one time, in descending order based on each ingredient's total weight in the whole product.

Ingredient suppliers usually do not provide exact formula breakdowns for multi-component ingredients, but may provide a range, e.g., 60% to 70% sugar. The ingredient statement developer must then be able to use the percent range information given to create a truthful ingredient statement. This requires skill in understanding FDA ingredient labeling regulations and in applying the information provided by suppliers of multi-component ingredients.

Unless a client requests otherwise, Food Consulting Company normally prepares a composite ingredient statement. The exception is when a labeling client (or their supplier) is not able to provide adequate information for multi-component ingredients.

Does the nutritional labeling have to be printed in black?

Per the Code of Federal Regulations, the Nutrition Facts panel must be in black or one color type printed on a white or neutral background with the intent that it is very easy to read. However, the other required labels components (ingredient statement, signature line, etc.) can use inverse printing as in light type with dark background. In all cases, the information must be readable and compliant with regulations for minimum type size and specific placement. For compliance checks on your label prototypes select Label Compliance Review service.

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Do nut oils and soybean oil have to be declared as allergens on food labels?

FDA food labeling regulations require that the source of the oil is identified (soybean oil, peanut oil, walnut oil, etc.) in the ingredient statement. Per FDA guidance related to the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), if a "Contains" statement is used after the ingredient statement, then all of the "big eight" allergens contained in the product need to be in this statement - tree nut and legume (soy or peanut) oils are no exception unless the oil is highly refined and therefore free of the allergenic protein.

For background, FALCPA exempts highly refined oils and ingredients derived from highly refined oils from allergen labeling. FDA does not have a regulatory definition for highly refined oil, however the Agency refers to the Senate Report that accompanied FALCPA that describes a highly refined oil as one that is refined, bleached and deodorized.

If a company is using a safe lubricant like beef tallow or lard to lubricate pans for baking, or is using those animal products in the packaging of the product, does FDA require that these additives be listed in the ingredient list?

Pan release agents are generally considered to be processing aids and therefore are typically exempt from ingredient statement labeling for FDA-regulated foods. However when release agents contain an allergen (milk, eggs, wheat, soybeans, peanuts, tree nuts, fish, and shellfish per the Food Allergen Labeling and Consumer Protection Act of 2004) the lubricant should be listed by the common or usual name in the ingredient statement. In addition, if omitting an ingredient would cause the product to be misbranded because its label is misleading or not truthful (e.g., the product is commonly understood to be vegetarian or labeled as such but a release agent from an animal source is used), then the presence of the release agent should be disclosed in the ingredient statement.

What is the legal definition for "trans fat free?" Can a restaurant or product make this claim?

To date, FDA has not established a definition for "trans fat free." Therefore this claim cannot be made on food labels or on menus and menu boards, or in food marketing.

Per FDA regulations the term "free" is a nutrient content descriptor. The regulations regarding the use of nutrient content claims are specific; they are intended to ensure that the descriptive terms that characterize or compare nutrient levels are used consistently for all types of food products and are thus meaningful to consumers. In general, nutrient content claim regulations apply only to nutrients or dietary substances that have an established daily value; no daily value has been established for trans fat.

In addition to "free," the existing regulations disallow trans fat claims using the following terms: Free, Zero, No, Without, Trivial Source of, Negligible Source of, Dietarily Insignificant Source of, Low, Little, Few, Contains a Small Amount of, Low Source of, Reduced/Less, Lower, Fewer, and any synonyms of these words.

FDA regulations do allow the Nutrition Facts to state 0g trans fat when the serving contains less than 0.5 gram (1/2 g) of trans fat, and a separate factual statement "0g trans fat per serving" can be used elsewhere on the label. Menus can also make this statement about a menu item when it is true and factual.

FDA continues to conduct research and consider scientific evidence that may influence the use of nutrient content and other claims for trans fat on food labels and menus and in marketing.

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I want to highlight that my dessert topping with 1.5g fat and less than 0.5g trans fat per serving contains only a small amount of partially hydrogenated oil compared to competing brands that contain almost all partially hydrogenated oil. Can I highlight this with my simplified Nutrition Facts panel?

You are puzzled about the specifics of the trans fat labeling rules, and Food Consulting Company agrees the rules are tricky.

Per the rules for simplified Nutrition Facts [21CFR101.9(f)], you are not allowed to report trans fat as a separate line item under total fat in the Nutrition Facts panel when trans fat is 0 (0.49g or less per serving); however in some cases the rules do require a declaration of trans fat in the "not a significant source" statement.

You also have the option of using a standard Nutrition Facts panel [21CFR101.9(c) rules]. These rules require that when total fat is a reportable amount, saturated fat and trans fat must both be listed as separate line items within the Nutrition Facts panel.

See examples of correct and incorrect Nutrition Facts panels here.

In either case (simplified or standard) you may state "0g trans fat" on the front label panel but be aware, under current rules, your product label may not state "trans fat free" or "no trans fat."

Is FDA approval of food labels required? If yes, does Food Consulting Company include this step in my label order?

FDA does not require or provide a service for the Agency's approval of food labels. However, labelers must comply fully with the labeling regulations on their own or through the help of their choice. Food Consulting Company helps you produce 100% FDA compliant labels with Full Label Compliance and Label Compliance Review.

The requirements for food labeling are detailed in the Federal Food Drug and Cosmetic Act, Code of Federal Regulations, Food Labeling Guide, Food Allergen Labeling and Consumer Protection Act, and in FDA guidance documents all of which can be accessed at www.fda.gov.

The Agency learns of non-compliant labels on foods via random checks and checks during inspections, and through tips from consumer groups, individual consumers and competitors.

FDA issues warning letters to food packagers when violations are discovered; the Agency directs food packagers to correct non-compliant labels or face further FDA action.

Is it a requirement that vitamins and minerals (Vitamins A and C, Calcium, Iron, etc.) in the Nutrition Facts be reported using even numbers? If yes, what is the logic for this, and what is the rule?

FDA regulations specify "rounding rules" for the % Daily Value of vitamins and minerals. When the rules are properly followed the % Daily Value for a nutrient can be an even or odd number. Per FDA regulations for vitamins and minerals (Vitamins A and C, Calcium, Iron, etc.), round the Daily Value to:

- nearest 2% if less than 10%
- nearest 5% if between 10% and 50%
- nearest 10% if greater than 50%

If the Daily Value is between 1 and 2%, the % Daily Value may be stated as 0% or 2%.

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I would like to sell my product in grocery stores/gourmet shops. What service do I order to make sure my label meets FDA label regulations?

To sell an FDA-regulated product by retail in the United States the product label must contain five label components. These are: statement of identity, statement of net content, Nutrition Facts, ingredient statement with allergen labeling compliance, and name and address of manufacturer, packer or distributor. Labeling rules state where each component must be placed, minimum type size requirements, and more.

Food Consulting Company's Label Compliance Review service takes the product information you provide and produces the required components for you. The service includes nutrition analysis, a Nutrition Facts panel, an ingredient statement including allergen labeling compliance, and help with product naming and label claims. The package also includes label layout instructions and a final label review.

You have options to successfully produce FDA-compliant labeling:

- Food Consulting Company can help you from start to finish with Full Label Compliance. With this choice, once you supply the necessary information for a product you will receive ready-to-print label components and a guarantee for accuracy.
- Produce your labels by referring to the FDA website. Use FDA resources (Code of Federal Regulations, FDA Guidance Documents, and FDA's Food Labeling Guide) and contract with Food Consulting Company for Ongoing Regulatory Support to get expert advice as needed.
- Refer to FDA's food labeling resources (Code of Federal Regulations, FDA Guidance Documents, and FDA's Food Labeling Guide) for detailed information on labeling requirements and proceed to produce your product label. Submit your final label work to Food Consulting Company for Label Compliance Review to assure FDA compliance.

Are sample food packages required to include Nutrition Facts or other food label components?

Food samples do not have to be labeled with any of the required label components as long as the product package clearly identifies the product as a sample. For example, the product packaging can include the words "not labeled for retail sale."

It doesn't matter if the samples are distributed by mail, handed out, or offered for taste testing in a retail store or other public place.

A company may voluntarily include some or all of the required label components on a food sample package, but if all five label components are not presented in the manner FDA specifies, the label must state "not labeled for retail sale" or equivalent wording.

Providing retail-ready samples is often a smart choice in achieving the objective of a sample campaign; there is widespread consumer interest in knowing the ingredients and nutritional value of purchased foods.

To have retail sale ready sample packages, the five required label components are: statement of identity, statement of net contents, Nutrition Facts, ingredient statement with allergen labeling compliance, and name and address of manufacturer, packer or distributor. For help with FDA compliant food labels select Full Label Compliance service.

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My product (non perishable grain) was stamped with an incorrect and too early "best before" date. Does FDA allow me to use a sticker to cover the incorrect information with the correct date?

Per FDA's Food Labeling Guide it is permissible to use stickers to make changes in labeling, therefore you can correct the best before date with an over-sticker.

Best before/shelf life labeling is not an FDA requirement. However if used the information must be truthful and not misleading; truthful and not misleading is a minimal requirement for all label statements and information.

Voluntary inclusion of a freshness date on labels encourages retailers to rotate products and lets consumers know when the time is up for highest product quality. Food Consulting Company believes that including best before/shelf life labeling is a wise consumer-friendly business practice.

Food Consulting Company offers Shelf Life Evaluation. A food technologist will test your product sample for parameters that affect the shelf life (pH, water activity, moisture, solids, others); these findings will be used along with specifics about product ingredients, processing methods, and packaging to determine the current shelf life of your product and help you reach your shelf life goal.

Can I use my product label to tell how my food fits into MyPyramid guidelines?

FDA has not issued formal guidance on using MyPyramid on food labels, but in conversations with Food Consulting Company the Agency has referred to USDA's guidance document to explain how MyPyramid can be used on FDA-regulated food labels.

In 2005 USDA published a Statement of Interim Policy Guidance entitled "Use of the USDA MyPyramid Reference on Meat and Poultry Labeling and Whole Grain Claims."

In part, the USDA guidance advises labelers:

- MyPyramid replaced the Food Guide Pyramid in 2005; food labels referencing the old graphic (Food Guide Pyramid) need to be revised to eliminate this outdated reference.
- MyPyramid uses discreet numbers in common household measure, i.e., cups and ounces (not numbers of servings).
- MyPyramid references on food labels should be based on the 2,000 calorie level when stating the amount the product provides toward the recommendation for a major food group.
- MyPyramid references to whole grain that state or imply a high or increased amount (example, excellent source of whole grains) cannot be used on food labels. However, truthful and not-misleading statements of fact that do not characterize the specific level of whole grains can be used.

For more information on FDA food label claims, see the Center for Food Safety and Applied Nutrition webpage at http://www.cfsan.fda.gov/~dms/lab-hlth.html, or contract with Food Consulting Company for One-time or Ongoing Regulatory Support.

To read future answers to Reader Questions, subscribe to *Food Label News* at www.foodlabels.com/subscribe. For individualized help with food labeling requirements for FDA-regulated foods, Contact Us. Thank You!

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LABEL LAYOUT INSTRUCTIONS FOR FDA-REGULATED FOODS

FDA regulations require components of every retail food package with positioning and minimum type size as outlined below. The sidebar picture is provided as a sample representation of a Principal Display Panel and an Information Panel. Note that all Information Panel requirements must be placed together without intervening material, starting at the top left of the panel.

PDP - Principal Display Panel (Front of Package)

1. Product Identity
Must include a descriptive name in addition to any fanciful name you use. Descriptive name must be in bold prominent lettering (at least half the largest type size), generally parallel to the base of the container. Fanciful names may be used but are not required.

2. Net Contents Statement
Must include the net content statement in the lower 30% of the front panel, and generally parallel to the base of the container. Do not crowd with other words or pictures – include space of "N" above and below and "NN" to the right and left. Minimum height of lettering:

1/16" for PDPs with 5 square inches or less
1/8" for PDPs with 5-25 square inches
3/16" for PDPs with 25-100 square inches
1/4" for PDPs with 100-400 square inches
1/2" for PDPs over 400 square inches

Examples of correctly written net contents statements:

NET WT 12 OZ (340g)
NET WT 24 OZ (1 LB 8 OZ) 680g
NET 16 FL OZ (473mL)

IP - Information Panel (Back or Right Side of Package)

3. Nutrition Facts
Choose the appropriate style based on package dimensions (total space available for labeling), and the appropriate format based on number of nutrients that are present in insignificant amounts.

Three styles: (a) Standard/Vertical, (b) Tabular/Horizontal, (c) Linear/Paragraph
Two formats: (a) Full uses 21CFR101.9c rules, (b) Simplified uses 21CFR101.9f rules

4. Ingredient/Allergen Statement
Use lettering at least 1/16th inch in height (by the small "o" unless all upper case letters are used).
If an Allergen (Contains) statement is used, it must be in lettering at least as bold and as prominent as the Ingredient Statement and must contain all "big 8" allergens present.

5. Signature Line
Include name, street address, city, state/province, and postal code of responsible party immediately after the Ingredient/Allergen Statement. (Street address may be omitted if listed in a current city directory or telephone book). Website and telephone number are optional. Minimum height of lettering is 1/16th inch.