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:

I have seen products with a Nutrient Content Claim (NCC) stating "0 grams trans fat." I have not found this claim to be one of the approved NCC claims. Is the claim illegal or allowed? (March 2009)

"0 grams trans fat per serving" is a factual statement, not a defined nutrient content claim. Factual statements have always been allowed on labels provided the information is truthful and not misleading. "0 grams trans fat per serving" is truthful as long as the food contains less than 0.5 gram (1/2 g) of trans fat per serving. "0 grams trans fat" without qualification (i.e., "per serving") is an incomplete factual statement and should not be used on labels.

While "0 grams trans fat per serving" can be used on labels, "trans fat free" cannot be used. 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. Nutrient content claim descriptors 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 claims about trans fat 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.

I've heard that you can't make a low-sodium claim on a product that contains cholesterol. Is this true? (February 2009)

A low-sodium claim can be made on a product that contains cholesterol, but depending on the amount of cholesterol you might have to include a disclosure statement.

A disclosure statement is required for nutrient content claims (e.g., low sodium, fat free, sugar free) if certain other nutrients exceed set thresholds. The nutrients and thresholds are: 13.0g fat, 4.0g sat fat, 60mg cholesterol, 480mg sodium. These values are for Reference Amount Customarily Consumed

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(RACC) per labeled serving. The rules for foods with small serving sizes and main dish/meal products are different.

A disclosure statement calls consumers' 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 identifies the nutrient that is present above the prescribed level, e.g. "See nutrition information for cholesterol content." This statement must be placed immediately adjacent to the claim in boldface type and a type size at least as large as the net quantity of contents declaration.

Is there a regulated definition for high protein, as a percentage of protein in a serving? (January 2009)

Yes. Per the Nutrition Labeling and Education Act of 1990 (NLEA), "high protein" is a regulated nutrient content claim and the word "high" means greater than or equal to 20% Daily Value (DV). The Daily Value for protein is 50 grams. Therefore, a food that contains 10 grams of protein (or more) per serving, can be described as high protein.

If a high protein claim is made, the %DV for protein must be stated within the Nutrition Facts. The %DV must be calculated based on the corrected amount of protein per serving (also known as protein digestibility corrected amino acid score, or PDCAAS). This is the actual amount of protein per serving multiplied by the amino acid score corrected for protein digestibility.

Any time a nutrient content claim is made, a disclosure statement is required if certain other nutrients exceed set thresholds; the nutrients and thresholds are: 13.0g fat, 4.0g sat fat, 60mg cholesterol, 480mg sodium.

I am launching a line of side dishes and some will contain bacon. Are they covered by USDA or FDA labeling rules? (December 2008)

The Food Safety and Inspection Service (FSIS) of USDA has authority over meat and poultry products and processed egg products. FDA has authority over all other foods.

When meat or poultry is part of a mixed dish product (e.g., pepperoni pizza, chicken noodle soup, side dish with bacon), the product might fall under FDA rather than USDA regulations. Where it falls depends on the formulation.

In general, mixed food products with more than 2% cooked meat or poultry (3% raw) are regulated by USDA; products with 2% or less cooked meat or poultry (3% or less raw) are regulated by FDA. To determine which labeling regulations apply to the side dish with bacon, consider the weight of bacon in the formulation.

I would like to know how many new labeling regulations will be in effect on the January 1, 2010, uniform compliance date? (November 2008)

FDA established January 1, 2010, as the uniform compliance date for food labeling regulations that are issued between January 1, 2007, and December 31, 2008. FDA sets uniform compliance dates to minimize the economic impact of labeling regulation changes.

FDA does not publish a summary list of updated/new regulations due on a uniform compliance date. This means labelers are themselves responsible for staying informed on all labeling regulations activity. Food Label News reports on updated and new regulations as they are proposed, opened for comment, and as they are made final. Food Consulting Company offers services to help labelers meet

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compliance dates as economically as possible.

Labelers also have the option of reading the daily Federal Register and making frequent visits to FDA's website since all regulation changes are announced in both locations accessible through the Internet.

Since fish / aquaculture are excluded from National Organic Program standards, is labeling fish and seafood with the term "organic" acceptable in the U.S.? (October 2008)

An official from USDA's Agricultural Marketing Service (AMS) told Food Consulting Company that USDA has no jurisdiction over how organic is used outside of the rules of the National Organic Program (NOP). Current NOP rules say that aquatic animals shall not be included in the program and therefore NOP has no restriction on using the term "organic" on a fish label at the present time as long as the USDA Organic seal is not used.

Fish is an FDA-regulated food product and FDA requires that all labeling is truthful and does not mislead the consumer. Therefore the food labeler needs to decide if the organic claim on a fish product meets consumer expectation for organic.

In the August Q&A you said high fructose corn syrup should be labeled as glucose-fructose syrup in Canada. Can I also label it as glucose-fructose syrup on my U.S. labels for the same product? (September 2008)

No, the required nomenclature for this ingredient for U.S. regulated food labels is high fructose corn syrup. Reference Code of Federal Regulations in Title 21, Section 184.1866.

I've heard that Canada does not allow high fructose corn syrup in food products. Is this true? (August 2008)

Canadian food regulations do not prohibit the use of high fructose corn syrup. However Canadian regulations differ from U.S. regulations regarding nomenclature for this ingredient.

The Canadian Food Inspection Agency "Guide to Labelling and Advertising – Basic Labelling Requirements" specifies that the ingredient equivalent to high fructose corn syrup is to be listed as "glucose-fructose syrup" on Canadian food labels.

Food labelers using high fructose corn syrup/glucose-fructose syrup as an ingredient may find Food Label News archived articles from June 2008 helpful.

I frequently get incomplete nutrition information from ingredient suppliers and my nutrient analysis program only helps part of the time. How can I get complete information? (July 2008)

When complete and accurate nutrition information is not provided by ingredient suppliers or readily available from a particular database, accurate values must be obtained through a process of due diligence.

Food Consulting Company has posted an article on the due diligence process. The content was presented by Karen C. Duester, MS, RD, company president, to the nutrition study group meeting of the National Restaurant Association in May 2007 and included in a 2007 article published in DBC Dimensions. Read due diligence article.

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NOTE: Due diligence article is at www.foodlabels.com/duediligence.htm.

Is St John's wort allowed in a beverage at any level? (June 2008)

No, this botanical is not allowed for use as an ingredient in a beverage; this is explained in a January 30, 2001, "Dear Manufacturer" letter.

In the letter, FDA explains that in order for a substance, such as the botanical St John's wort, to be added to food, the substance must be GRAS (Generally Recognized as Safe) or be an approved food additive. Food additives require pre-market approval by FDA; data demonstrating safety is submitted by the petitioner to the agency in a food additive petition. If the petition is accepted, the agency issues food additive regulations. The regulations specify the conditions under which the additive has been demonstrated to be safe and how it may lawfully be used.

St John's wort is not a GRAS substance or an approved food additive.

I see butter listed on ingredient statements alone sometimes and sometimes followed by a parenthesis around the butter ingredients e.g., (cream, salt). How should I list butter in my ingredient statement? (May 2008)

If the formula includes unsalted butter, it is correct to simply list "butter" (or specify as "unsalted butter") in the ingredient statement in descending order according to total weight compared to other ingredients. However if the formula includes salted butter, the salt in the butter must be factored into the ingredient statement in one of two ways.

The most concise way to accurately list the salt in salted butter is to determine the salt weight vs. cream weight and then add the salt weight to the salt contributed from other ingredients. The "butter" and "salt" from all sources will then be listed in correct order according to their weights compared to other ingredients.

The other option for listing salted butter (a composite ingredient) is to list the butter in descending order by weight followed by a parenthetical listing of the sub-ingredients, e.g., "butter (cream, salt)."

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.