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:

What does FDA require regarding redemption value labeling for beverage containers?

FDA does not regulate this aspect of beverage labeling. Rather, it is regulated by the individual states. The requirements vary depending on type of container (plastic, glass, aluminum, etc.), contents of the container (carbonated, non-carbonated, juice, etc.) and if the container is marketed as single or multi-serving. The Container Recycling Institute maintains a website at bottlebill.org that outlines the various requirements for U.S., Canada and worldwide.

If lecithin is present, does soy need to be claimed as an allergen?

Yes, for FDA regulated foods, if lecithin is derived from soy then soy needs to be listed in plain, common English within the ingredient statement. In addition, soy would also be included if you are using a separate "Contains" allergen statement.

In FDA Guidance Specific to Soy Lecithin, FDA specifies that if lecithin is derived from soy then the plant source of the ingredient (soy) must be included in the ingredient name within the ingredient statement. Additionally, if you are using a separate "Contains" allergen statement, soy must be included with all of the "big eight" allergens (eggs, milk, soy, wheat, peanuts, tree nuts, fish, crustacean shellfish) present in the product.

For additional information read June 2006 *Food Label News* report about allergen labeling for incidental additives.

When we designed our bags for popcorn, we naturally used the label warning from our contract manufacturer "Manufactured in a facility that also processes peanuts, tree nuts and milk ingredients." Our contract manufacturer is no longer using nuts in their products and we are thinking about eliminating the peanut warning. However, to do this economically and not create a whole new printing plate, we would also need to eliminate the warning about milk being processed in the factory. Is it OK to eliminate the milk warning or does that violate a code or present a serious risk to those with milk allergies?

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The use of an allergen advisory statement such as the one you use "Manufactured in a facility that also processes peanuts, tree nuts and milk ingredients" is voluntary so you are free to eliminate the statement or any other allergen advisory statement from your labeling if you choose.

For more information on allergen labeling, see FDA's Guidance for Industry regarding food allergens or a Food Consulting Company article that helped companies prepare for allergen labeling when the Food Allergen Labeling and Consumer Protection Act went into effect on January 1, 2006.

If you sell foodservice products to restaurants by the case, are you required to label each 'package', 'packet' or 'bottle' in the case?

No, you are not required to label the individual units within the case. The required labeling for foodservice items (product identity, net quantity of contents, ingredient statement, and signature line) can be on either the individual units or on the shipping container; it does not have to be in both places.

Foodservice items are exempt from nutrition facts labeling, except when a nutrient content claim is made. If a company elects to label individual units and uses the exemption for Nutrition Facts labeling, then it is wise to include a label statement such as "not labeled for individual retail sale."

Can we label our agave syrup as a natural low glycemic sweetener in the U.S.?

This question has two parts: "natural" and "low glycemic." As outlined in last month's *Food Label News*, FDA does not restrict the term "natural" on food labels provided the product is free of artificial flavors, chemical preservatives, or added colors (from any source). The FDA has not defined the term "glycemic." If you use the word "low" with "glycemic," you must have authoritative basis for the claim and include the reference on your label to ensure that the label is truthful and not misleading.

Rather than labeling a product as "low glycemic," we suggest using a statement such as Agave Syrup: glycemic index = X, compared to Granulated Sugar: glycemic index = Y. This is a statement of fact (provided you have research documentation to substantiate your values) and provides the consumer with comparison data without using the descriptive phrase "low."

Can enzymes used in dough conditioners in a bakery product be declared by a class name "enzymes" or must they be declared by the actual name of the enzymes in the Ingredient List?

The enzymes used in dough conditioners need to be listed in the ingredient statement by "common or usual name" (actual name of the enzyme). This is true for both USA and Canada.

I have a new product and need help with food labels. Do I need to send a sample of my product to you? What information will you need from me?

Food Consulting Company uses database analysis of a product's recipe formulation so a sample is not needed. Database analysis is a lower cost alternative to laboratory analysis and is an excellent predictor of a product's nutritional content.

To produce the nutritional information for your product, Food Consulting Company needs information about your recipe formulation, your processing and your packaging. The regulatory specialist who will be working on your project can help you determine the specific information you will need.

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Will either the LEAN Act or the MEAL Act affect supermarket foodservice operations?

LEAN Act and MEAL Act are separate bills introduced to the U.S. Congress that would require mandatory nutrition disclosure in certain restaurant/retail food service establishments. In June 2009, the bills were subject to compromise in the U.S. Senate and the compromise is to be a component of health reform legislation currently being debated.

Very little detail about the compromise was made public and so the answer to the original question is not known. It might be helpful though to consider how FDA has defined the term "restaurants" per FDA's Restaurant Labeling Guide:

- The term "restaurant" applies broadly to establishments where food is served or sold for immediate, on-site consumption (e.g., institutional food service establishments such as schools, hospitals, and cafeterias; transportation carriers such as trains and airplanes; delicatessens and catering operations with facilities for immediate consumption on the premises).

- The definition of "restaurant" extends to establishments where foods are generally consumed immediately where purchased or while walking away (e.g., lunch wagons, cookie counters in a mall, vending machines, and similar foods sold from convenience stores); and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices for immediate consumption.

See Food Label News archive (April 2009, June 2009, July 2009) for reports on LEAN, MEAL and compromise.

I heard that stevia can now be used in conventional foods (and not just dietary supplements). If true, are there special considerations I need to be aware of for labeling?

Only rebaudioside A (RebA), an isolated component of the stevia plant is allowed by FDA for use in conventional foods. In December 2008, FDA responded to notices from Whole Earth Sweetener Company LLC and Cargill Incorporated requesting GRAS status for rebaudioside A purified from *Stevia rebaudiana* (Bertoni) Bertoni. In both responses (1,2) FDA stated that the agency has no questions at this time regarding the conclusions that rebaudioside A is GRAS under the intended conditions of use.

The ingredient statement needs to indicate the presence of the purified form "RebA" - "stevia" is not appropriate labeling nomenclature for this ingredient.

My products are syrups and fruit toppings; what determines if the label should use 'fluid ounces' or 'net weight' to declare net quantity of contents?

The Code of Federal Regulations says that the 'net quantity of contents' statement is to be expressed in terms of fluid measure, weight, numerical count, or a combination of numerical count and weight or fluid measure. The statement is to be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semisolid or viscous, or a mixture of solid and liquid. If syrups are pourable and do not contain solid pieces of anything the net quantity statement will be in terms of fluid measure as in the U.S. gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions as appropriate for the product container. If the fruit toppings are a mixture of syrup and pieces of fruit the net quantity statement will be by weight in terms of pound and ounce.

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Exception to the above regulations is possible; if there is a firmly established general consumer usage and trade custom of declaring the contents of a liquid by weight, or a solid, semisolid or viscous product by fluid measure, it may be used. In all cases 'net quantity of contents' statement must facilitate value comparisons by consumers and must not cause consumer confusion.

In addition to stating the U.S. Customary System terms (ounces, pounds, and fluid ounces,) food labels must show the net contents in Metric System terms (grams, kilograms, milliliters, liters.)

FDA's Food Labeling Guide (http://www.cfsan.fda.gov/~dms/flg-toc.html) gives more information about net quantity of contents.

What is the 2400 milligram Daily Value for sodium based on?

The Institute of Medicine's most recent (2004) Recommended Dietary Intake for sodium established 1.5g per day as the Adequate Intake (AI) and 2.3g per day as the Upper Limit (UL).

The Recommended Dietary Allowances, Tenth Edition (1989) recommended that daily intakes of sodium chloride be limited to 6g (2.4g of sodium) or less. This 2.4g recommendation correlates with the 2400 mg Daily Value for sodium established for nutrition facts panels that became mandatory on food labels in 1993.

Does your company offer shelf life testing?

Yes, Food Consulting Company offers a Shelf Life Evaluation service. A food technologist determines shelf life by testing a product sample for pH, water activity, moisture, solids, and other components; the findings are used along with specifics about the product ingredients, processing methods, and packaging to determine the product shelf life.

Although labeling regulations do not include a requirement for shelf life, voluntary inclusion of a freshness date (Best Before or Use By) on labels encourages retailers to rotate products and lets consumers know when the time is up for highest product quality.

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?

"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, unless the product is in a single-serve container.

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:

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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.

NOTE: Whenever a quantitative value is provided outside the Nutrition Facts panel, 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.

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.