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:

We have four different flavors of a beverage packaged in a box. Do we need four different nutritional statements on the box or can we just put the nutrition info on each bottle instead?

The regulations specify that labeling must be placed on the retail sales package. This enables the consumer to be informed when they make their purchasing decision. For a multi-pack, the labeling needs to be on the outer package unless there is a transparent wrapper that joins the individual packages together so that the labeling can be seen on the individual packages at the point of purchase.

The labeling can also be on both the outer and individual packages. If the labeling is on the outer package only, then the individual packages must include a phrase to indicate that they are not labeled for individual retail sale. This is true for both USA and Canada.

Can my product (an aseptically shelf stable ready-to-eat pudding) that is made in the U.S. and labeled for sale in Canada state "2% or 1% or less" in the ingredient statement?

Canadian regulations make no mention of an "X% or less" clause for ingredient statements. In the U.S., the clause "2% or less of the following" (or 1.5%, 1%, or 0.5%, as appropriate) can be used at the end of the ingredient statement to list minor ingredients in any order. Canadian regulations specify that ONLY specific classes of ingredients can be shown at the end of the ingredient statement in any order. For these specific classes of ingredients in Canada, the "X% or less of the following" clause could be used, but it is not common practice because it significantly lengthens the ingredient statement given the English-French bilingual labeling requirement.

In Canada, the specific classes of ingredients that can be shown in any order at the end of the ingredient statement include: spices, seasonings and herbs (except salt), natural and artificial flavors, flavor enhancers, food additives, and vitamin and mineral nutrients and their derivatives or salts.

For more information about Canadian ingredient labeling, consult the Canadian Food & Drug Regulations (FDR), Section B.01.008. For information about U.S. ingredient labeling, consult the U.S. Code of Federal Regulations (CFR), Title 21, Part 101.4.

13724 Recuerdo Drive
Del Mar, CA 92014 USA
www.foodlabels.com
info@foodlabels.com
tel 858.793.4658
fax 858.712.3323

Can you reference me to the section of the CFR that deals with synthetic and/or artificial substances that are exempt in trace amounts as food processing aids? Also include information on secondary synthetics (synthetic and/or artificial substances that are exempt due to being ingredients in ingredients)?

Ingredient exemption information can be found in 21 CFR 101.100 - Food; exemptions from labeling. Under this provision of the Code of Federal Regulations, incidental additives present in a food at insignificant levels with no technical or functional effect in that food are not required to be listed in the ingredient statement.

Incidental additives are:

- ingredients that are incorporated in the food as an ingredient of another food
- processing aids which are added during processing but removed, converted to a normal constituent of the food at normal levels or are present at insignificant levels
- substances migrating from equipment or packaging

Insignificant level means there is no technical or functional effect at the level used.

Incidental additives should always be listed in the ingredient statement when they are allergens (i.e. soy lecithin as a lubricant on equipment), when they are sulphiting agents at detectable levels (greater than 10ppm), or when the manufacturer is uncertain if the additive is functional in the finished product (for example, a preservative could be functional when incorporated as an ingredient of another food).

Which is better for getting the most accurate results: lab or database analysis?

FDA does not require a specific method of analysis for Nutrition Facts, but the Agency does require label values to be accurate within the tolerances specified in the Code of Federal Regulations.

When performed correctly, the database method is typically a better predictor of the nutritional analysis from multiple production runs than a single laboratory analysis. This is because the database method uses the statistical average for commodity products that can vary with growing conditions and other factors. FDA actually encourages the use of nutrient databases as a low-cost alternative to laboratory analysis. In fact nearly all Food Consulting Company clients choose this approach; exceptions are for products that contain ingredients for which nutrient data is not available or for foods that undergo processing where the nutrient changes cannot be confidently predicted.

When you select database analysis you will provide your product formulations, raw material specifications, and processing information to us under strict confidentiality. We will analyze your product to determine the 100-gram data.

With laboratory analysis you will provide us with the 100-gram data lab report. Contact Us if you need a referral for a new lab analysis.

In both cases we use the findings of the analysis to develop the Nutrition Facts panel for your product. As part of this work we determine the FDA-regulated serving size and servings per container, then calculate the nutrient profile per serving, apply the rounding rules, and determine percent daily values for the required Nutrition Facts panel components. Finally we produce a camera-ready Nutrition Facts panel formatted according to your package dimensions and FDA specifications. This is what you provide to your printer, artist, or package designer.

13724 Recuerdo Drive
Del Mar, CA 92014 USA
www.foodlabels.com
info@foodlabels.com
tel 858.793.4658
fax 858.712.3323

Our ingredient supplier insists that insoluble fiber does not need to be included in total calories, however this would not make sense in context of the 4-4-9 formula. Is it allowable to have insoluble fiber listed as part of carbohydrates on the Nutritional Facts Panel but not included in the calorie consideration?

In the U.S., your ingredient supplier's approach is allowed according to FDA regulations. In Canada however, this approach is not allowed.

For the U.S., FDA allows several different methods for calorie determination [21 CFR101.9(c)(1)(i)]] such as general factors or specific Atwater factors. Most companies use the general factors 4-4-9 (4 calories per gram for carbohydrates and protein and 9 calories per gram for fat). It is allowable but not required to subtract insoluble fiber from the total carbohydrate value for the purpose of calculating calories. Insoluble fiber must be included in the Nutrition Facts Panel if any claims about insoluble fiber are made -- otherwise it is a voluntary nutrient. If insoluble fiber is shown, companies can choose whether or not they subtract the calories from this type of carbohydrate. To list the fewest number of calories and to avoid confusing consumers, you can subtract the insoluble fiber from the carbohydrates before applying the 4-4-9 formula but then you would not want to include the optional 4-4-9 footnote on the Nutrition Facts Panel.

For Canada, it is unacceptable to subtract the weight of dietary fiber from the weight of carbohydrate prior to applying the 4-4-9 formula when calories for the specific fiber source have not been determined. To date, Health Canada has only approved reduced calorie levels for wheat bran (0.6 calories per gram) and specific inulin sources (2.2 calories per gram).

Could you give me the current status on labeling for gluten-free products. What are the rules?

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) mandated that FDA establish a definition for the term "gluten-free" and uniform conditions for its use in the labeling of foods. FDA has published a proposed rule for "gluten-free".

In this proposed rule, the use of the term "gluten-free" is voluntary. However, it will not be allowed for foods that contain any species of the following prohibited grains: wheat, rye, barley or a crossbred hybrid of these grains. Furthermore, a "gluten-free" claim will not be allowed if the food contains 20ppm or more gluten. If the food is inherently free of gluten, the claim must acknowledge that all foods of that same type are gluten-free (i.e., "all milk is gluten-free" or "milk, a gluten-free food").

How many milligrams of Vitamin C can I add to my beverage without having to declare "ascorbic acid (Vitamin C)" under the beverage's ingredient listing?

If ascorbic acid is added to the beverage, it must be listed in the ingredient statement. Furthermore, if the function of the ascorbic acid is as a preservative, this must also be disclosed in the ingredient statement (i.e. "ascorbic acid to preserve freshness" or something equally descriptive).

According to the Code of Federal Regulations at 21 CFR 101.4, all food ingredients (except incidental additives as defined in 21 CFR 101.100) must be listed in descending order of predominance by weight. Rules for declaring spices, flavorings, colors and preservatives can be found in 21 CFR 101.22.

13724 Recuerdo Drive
Del Mar, CA 92014 USA
www.foodlabels.com
info@foodlabels.com
tel 858.793.4658
fax 858.712.3323

When a product like Fruitabu or V8 vegetable juice says "contains a serving of fruit" or "contains a serving of vegetables" what does that mean? What methodology are they using, because when you look at the NLEA serving sizes or the USDA serving size for a fruit or vegetable, the calories, total sugar and fiber are inconsistent with how the product is labeled?

FDA does not define serving sizes for food groups (i.e., fruits, vegetables, grains). FDA's Reference Amounts (the NLEA serving sizes) are the amounts customarily consumed; they are defined for 135 product categories (i.e., breads, crackers, puffed cereals, high fiber cereals). These Reference Amounts do not necessarily correlate with serving sizes for food groups. Serving sizes for food groups vary depending upon which food group system you use: diet exchanges, Child Nutrition program information, USDA's *MyPyramid* information for a 2,000 calorie diet, or the NLEA serving sizes.

The number of servings for a particular food group can be listed on the label as long as it is truthful and not misleading. The method used to calculate or determine the number of food group servings needs to be listed or referenced by a symbol near the statement of the number of servings.
For example:

> A FULL SERVING OF FRUIT IN EACH 8 FL OZ GLASS†
>
> †Each 8 fl oz glass provides ½ cup of fruit. USDA's *MyPyramid* recommends a daily intake of 2 cups of fruit for a 2000, calorie diet.

Our sales team wants to create a food package that would be equally acceptable in Mexico and the U.S. Is this do-able?

We consulted with Mexican colleagues who confirmed that yes, it is possible to have a single food label that satisfies the requirements of both U.S. and Mexico. Of course, the label must be bilingual.

Mexico has new food labeling regulations, known as NOM-051, that went into effect on January 1, 2011. There are several new requirements including a calculation for the Mexican Recommended Dietary Intake (RDI) when different from the U.S. Daily Value (DV) and a quantitative ingredient declaration for any ingredients that are highlighted on the label. A U.S. bilingual label can be used as long as the additional mandatory information for Mexico is also included.

I am working on a Canadian label with a sugar-free claim. The product has less than 0.4g sugar and 2g carbohydrate. Does this product qualify for the claim?

In Canada, only products that are both sugar-free (less than 0.5g sugar per serving) and calorie-free (less than 5 calories per serving) qualify for a "sugar-free" claim. Though the calorie content of the product wasn't included with your question, using the standard factor of 4 calories per gram of carbohydrate, your product likely contains at least 8 calories per serving. Therefore, a sugar-free claim would not be permitted on this product in Canada.

In the U.S., a product qualifies as sugar-free *if* it has less than 0.5g sugar per serving *and* per reference amount for the product category. The claim can be made on the product label providing two conditions are met: (1) the calorie profile is also disclosed on the label (either low calorie, reduced calorie or not a low calorie food), and (2) the product does not include an ingredient that is a sugar or is generally understood by consumers to contain sugars unless that ingredient appears with an asterisk linked to a statement such as "adds a trivial amount of sugar" below the ingredient statement.

13724 Recuerdo Drive
Del Mar, CA 92014 USA
www.foodlabels.com
info@foodlabels.com
tel 858.793.4658
fax 858.712.3323

Food Consulting COMPANY

Nutrition • Labeling • Regulatory

I work for the Anchorage school district for student nutrition and we have students that have an allergy to MSG. I need to know if it is used in CN-labeled foods?

Whenever MSG (monosodium glutamate) is added to a food, it must be declared in the ingredient statement. This is true for foods labeled for the Child Nutrition (CN) program or any other foods. There are some ingredients, however, that contain naturally occurring monosodium glutamate. This naturally occurring substance is the result of a free glutamate that combines with sodium in processing to create monosodium glutamate. Some ingredients that contain free glutamate are: yeast extract, autolyzed yeast extract, disodium inosinate, disodium guanylate, and hydrolyzed vegetable proteins.

I am using all natural ingredients in a package. It says it has vanillin in it. I think vanillin is a compound, so does that mean I cannot say "all natural ingredients"?

Vanillin is typically a synthetically-derived compound (artificial flavor). FDA does not allow a "natural" claim for products that contain artificial flavors, added colors (from any source), or chemical preservatives. See June 2008 *Food Label News* for further discussion about "natural" claims on FDA, USDA and CFIA-regulated products.

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, please Contact Us. Thank You!

13724 Recuerdo Drive
Del Mar, CA 92014 USA
www.foodlabels.com
info@foodlabels.com
tel 858.793.4658
fax 858.712.3323