Food Consulting COMPANY

Nutrition • Labeling • Regulatory

# FDA Food Label Compliance

As part of the e-monthly newsletter, *Food Label News*, Food Consulting Company answers questions from subscribers. Here are recent questions and answers:

**I am in a start-up candy business and plan to cut the candy bar into pieces on a tray. How exact does the weight need to be per piece given that I may cut the bar inaccurately and the nuts or chocolate may be unevenly distributed?**

For products with a variable weight per piece such as your candy bar, pickles, shrimp, or scallops, the Serving Size used for Nutrition Facts labeling is the amount in ounces rounded to the nearest half-ounce that most closely approximates FDA's Reference Amount Customarily Consumed (RACC), along with a visual unit of measure.

The RACC for chocolate and most other candies is 40 grams. We translate this to serving size by selecting the ounces that is the closest to 40 grams. In this case 1.5 ounces (at about 42.52 grams) is closer to the 40 gram RACC than 1 ounce (at about 28.35 grams). Putting it all together, if the Net Weight of the entire package is 6 oz (170g) and there are typically 7 to 9 pieces in the tray, then the Serving Size line on the Nutrition Facts would be written as: Serving Size 1.5 oz (43g/about 2 pcs)

Note: Gram weights for Serving Size are expressed as whole numbers for weights over 5 grams.

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**I plan on distributing a jarred tomato sauce to my friends, family and through a farmer's market. I want to label it as "All Natural." However, the bulk tomato sauce I buy has some preservatives added to extend the shelf life. Must I include the preservatives on my label even though I cook it for hours?**

Yes, if preservatives are used in a product or as a sub-ingredient of another ingredient, they must be declared on the label. Therefore, if you want to have an all natural product, you will need to source a bulk tomato product that does not contain preservatives.

FDA's policy for "natural" indicates that this claim can only be used when a product contains no added colors from any source, no artificial flavors, and no preservatives. Read about the difference between natural on U.S. and Canadian regulations in the *Food Label News* archives.

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**Regarding FDA and nutrient content claims, is it true that FDA sees any restatement of the Nutrition Facts on the front-of-pack as a nutrient content claim? If so, can you direct me to the ruling?**

Yes, that is correct. If you make a statement of fact such as "0g trans fat per serving" on the front-of-pack, this is enforced as a nutrient content claim and you are required to include the disclosure statement when your product exceeds threshold levels of total fat, saturated fat, cholesterol and sodium.

Regulations specific to your question are outlined in 21 CFR 101.13(b) and 21 CFR 101.65(a). Also of interest, FDA issued several warning letters related to this issue in February, 2010. See a previous *Food Label News* article and our March 2009 Reader Q&A for earlier reports on this topic.

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**If a single flavor compound is added to a product for flavor, do you list it as flavor or by its common name in the ingredient statement?**

The ingredient statement of the food to which the flavor is added may declare the flavor as "natural flavor" or "artificial flavor" as long as the flavor additive meets the applicable definition in 21 CFR 101.22.

Note that ingredients such as salt, monosodium glutamate, and protein hydrolysates must be declared by their common or usual name. Also note that, per FDA regulations, an ingredient such as dehydrated onion, dehydrated garlic, onion powder, garlic powder, or celery powder must be declared by its common or usual name (not as a "natural flavor.") USDA, however, has guidance that allows the powdered form of onion, garlic, and celery to be labeled as a "natural flavor."

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**Is there a standard to call an FDA or USDA product a "meal replacement"?**

Although there is no standard definition for "meal replacement", there are four references in Title 21 of the Code of Federal Regulations for this term:

- 21 CFR 101.12(b), Table 2: relating to reference amounts customarily consumed for milk and milk-based drinks (meal replacement is one example given)
- 21 CFR 105.66(e): relating to label terms suggesting usefulness of meal replacements as low calorie or reduced calorie foods
- 21 CFR 122.345(h): relating to folic acid fortification
- 21 CFR 172.380(c): relating to Vitamin D fortification

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**I'm creating a gift set to be sold wholesale. All items in the gift set are pre-packaged and labeled with the nutritional information. I need to know regulations on labeling the outer box with contents included.**

The outer label for a gift pack sold at retail must contain all five of the required label components with one exception: the nutrition information may be included either on the outer label, inside the package, or attached to the outer package. See 21 CFR 101.9(h)(3).

Even when the nutrition information is placed inside the gift pack, the outer gift package must bear the following, which some companies choose to do via a hang tag:

- product identity (contents of the gift package using allowable product names for each component)
- a net contents declaration (contents of each component, as well as contents of the entire package)
- a listing of all ingredients contained in the package
- the signature line (name and address of the responsible party)

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**According to my reading and understanding of the FDA guidelines, Vitamin E does not need to be included in the Nutrition Facts Panel unless a claim is made about it on packaging or when it is added as a supplement. Is this correct? The FDA guidelines are so detailed! Just wanted to make sure I get it right.**

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You are correct. Vitamin E is a voluntary nutrient for U.S. Nutrition Facts labeling unless it is the basis for a claim on the label, in labeling or advertising, or is used to fortify the food.

The mandatory nutrients required to be shown within the Nutrition Facts Panel are: Calories, Calories from Fat, Total Fat, Saturated Fat, Trans Fat, Cholesterol, Sodium, Total Carbohydrate, Dietary Fiber, Total Sugars, Protein, Vitamin A, Vitamin C, Calcium and Iron.

The voluntary nutrients are Polyunsaturated Fat*, Monounsaturated Fat*, Potassium, Soluble Fiber, Insoluble Fiber, Sugar Alcohol**, Other Carbohydrate, Vitamin D, Vitamin E, Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Biotin, Pantothenic Acid, Phosphorus, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Chloride. When a voluntary nutrient is the basis for a claim or is used to fortify a food, then the nutrient becomes mandatory and must be included within the Nutrition Facts Panel.

* Polyunsaturated Fat and Monounsaturated Fat must both be included in the Nutrition Facts when one is included, and must also be included when a fatty acid or cholesterol claim is made.

** Sugar Alcohols is a required listing within the Nutrition Facts when sugar alcohols are present in a food and a sugar claim is made.

Note that nutrients or food components excluded from the mandatory and voluntary lists cannot be declared within the Nutrition Facts Panel. For example, it is not permissible to include Omega-3 Fatty Acids or Bioflavonoids within the Nutrition Facts box on a food label.

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**For an already printed box, we'd like to add a stamp that says Contains Milk as the box is supposed to say Contains Milk and Wheat but currently only says Contains Wheat. We would like to put the stamp under the statement that says "made on shared equipment with products containing milk, soy, tree nuts, etc." Can we do that?**

It is not acceptable to separate the allergen information into multiple Contains statements. However, it is permissible to use stickers to make changes in labeling as long as the sticker is firmly affixed and will adhere to the packaging under the intended storage conditions.

Please be advised that incorrect allergen labeling is a major reason for FDA warning letters and recalls so you will want to ensure that your allergen labeling is 100% compliant. One solution is to over-sticker the current allergen statement and allergen advisory statement with the corrected version: "Contains Wheat and Milk. May Contain Soy, Tree Nuts, etc."

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) requires that each of the "Big 8" allergens are clearly identified in plain English in one of two ways: 1) within the Ingredient Statement, or 2) in a separate Allergen (Contains) Statement at the end of the Ingredient Statement.

Per FDA guidance, the Allergen (Contains) Statement must contain all "Big 8" allergens present and needs to be placed immediately after or adjacent to the Ingredient Statement; it cannot be preceded or interceded by an allergen advisory statement. See questions 13, 14 and others in the guidance.

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**If you use the USDA organic symbol on your food labels, are you required to also have a statement indicating the certifying agent? Assuming you follow the USDA National Organic Program rules, have the appropriate certification and show the organic symbol but do not have the name of the agent on the label, what are the possible consequences (i.e. penalties, not being able to import, not being able to sell, etc.)?**

Foods labeled as "Organic" including those with the USDA Organic symbol on the package must list the name of the certifying agency with the phrase "Certified organic by (certifying agency)" on the

Information Panel, immediately below the Signature Line. If you have failed to list the certifying agency on the package, you will need to work with the agency to correct that. Be aware that ignoring compliance issues could result in discontinued organic certification by your certifying agency, among other possible consequences.

Some operations are exempt from USDA organic certification, including organic farmers who sell $5,000 or less. All other operations that handle or process organic products, including blending, packaging, or labeling **must** be certified.

In the event a product certified as organic is missing the name of certifying agent, the agency will likely issue a non-compliance warning and the company must work out an action plan to correct the labeling error. This could include a temporary re-stickering of the information until future label reprinting can occur.

If the product is not certified organic and not exempt from certification, but is labeled as organic, the fines can be up to $11,000 per violation.

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**We have 54 single serving pouches each weighing 0.9 OZ that go into a carton. The nutrition facts serving size on the carton is labeled 1 pouch (26g). Which is correct for the net weight statement?**

**54 – 0.9 OZ (25.5g) Pouches, 48.6 OZ (3LB 0.6 OZ) 1.37kg**
**or**
**54 – 0.9 OZ (26g) Pouches, 49.5 OZ (3LB 1.5 OZ) 1.40kg**

The net weight statement must be the true product net weight and not a rounded value. Therefore, the first option is correct.

Regulations for serving size in nutrition labeling and regulations for net weight labeling are different and in some cases produce different values for the same package. When the serving size in the Nutrition Facts panel is greater than 5g, the regulations require that the gram weight be rounded to the nearest whole number. However, regulations for net weight labeling require that the product weight not be overstated, and therefore cannot automatically be rounded to the nearest whole number.

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**What is the best way to disclose sugar alcohol on the ingredient statement? Can we just mention "low calorie sweeteners"?**

Sugar alcohols, like all other low and reduced calorie sweeteners, must be declared in the ingredient statement by common or usual name (e.g., sorbitol, maltitol); it is not allowable to identify these ingredients as "low calorie sweeteners" within the ingredient statement.

Note also that two of the sugar alcohols - mannitol and sorbitol - along with polydextrose (which contains small amounts of bound sorbitol) require a label statement such as “Excess consumption may have a laxative effect” when certain threshold amounts are exceeded. See 21 CFR 172.841 regarding polydextrose, 21 CFR 180.25 for mannitol, and 21 CFR 184.1835 for sorbitol.

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**I know the following statement needs to be on an imported FDA food product - Product of "X" - but does it need to be on the Principal Display Panel or can it be anywhere on the package?**

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When a U.S. company distributes or imports a product and declares its name and address within the signature line of the product, FDA guidance says that the country of origin must appear in close proximity to the signature line in at least comparable size lettering. If, however, a foreign manufacturer is listed within the signature line, then the country of origin is part of the address and the words "Product of" can be shown after the signature line or any other conspicuous place on the label.

Please note that the country of origin statement is not a requirement of the Federal Food, Drug & Cosmetic Act, therefore there is no official FDA regulation concerning its placement and use. However, the Tariff Act of 1930 does require the country of origin statement and it is codified into the U.S. Customs and Border Protection regulations under 19 CFR 134.

Contrary to FDA-regulated foods, USDA-regulated foods must show the country of origin statement directly under the product name as specified in 9 CFR 327.14.

References:
FDA Food Labeling Guide (Sec. 4, No. 11)
FDA Compliance Policy Guide (Sec. 560.200)

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There are a number of ways to get your questions answered:

- ***Subscribe*** to *Food Label News* – www.foodlabelnews.com/subscribe
- ***Search*** the Reader Q&A Archive – www.foodlabels.com/q&a.htm
- ***Join*** the discussion about topics of interest to food labelers on LinkedIn's Food Label Community - www.foodlabels.com/linkedin/community
- ***Contact us*** for individualized help at www.foodlabels.com

**About Food Consulting Company**
Food Consulting Company, founded in 1993, delivers nutrition analysis and food label guidance to ensure 100% regulatory compliance. The largest contract provider of food labeling services with well over 1,500 clients worldwide, the company's services are ideal for start-ups, established food manufacturers and distributors, food importers and brokers, and restaurateurs.

Our experienced team of registered dietitians, regulatory specialists and food technologists work side-by-side with your team, like your virtual food label department. Our goal is to make food label compliance easy.

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