

## 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:

**My supplier changed one of the ingredients we use in our product, resulting in small changes to our ingredient statement and nutrition facts. Is there any phase-in period so that we don't have to discard the packaging we have in stock?**

There is no phase-in period for new labels, as they must accurately reflect the contents of the package. However, under certain circumstances FDA will agree to enforcement discretion on a case-by-case basis.

Very minor changes to the nutrition facts and/or ingredient statement (with no affect on allergens) may qualify for FDA enforcement discretion where the agency could allow a phase-in period for labels. You must request and get approval to this special circumstance.

To request enforcement discretion from FDA, submit name of product(s), current labels and proposed label changes, number of current labels, dollar amount of inventory, estimated time to use current inventory, and an explanation about why enforcement discretion is requested. Submit requests to Felicia Billingslea (HFS-820) at 5100 Paint Branch Parkway, College Park, MD 20740 or email to felicia.billingslea@fda.gov.

For another alternative, see a previous [Reader Q&A](#) about over-stickering.

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### When is lab nutrition analysis recommended?

FDA requires Nutrition Facts label values to be accurate within the tolerances specified in the Code of Federal Regulations, but does not require a specific method of analysis to determine the values. When performed correctly, database analysis is typically a better predictor for nutrient values as it uses the statistical average for commodity ingredients. There are, however, certain situations that may warrant lab testing.

Lab analysis is a snapshot of nutrient values for a single sample, representing a single point in time. As a result, be cautious when using lab testing to determine Nutrition Facts label values and consider multiple testing points throughout the year to capture variability in your ingredients and process.

In some instances, lab analysis is recommended:

- Unique ingredients for which nutrition data is not available
- Special processing that affects nutrient composition when the changes cannot be confidently predicted
- Tool for validation of extensive nutrient content claims
- Tool for assessing effect of shelf life on product claims (e.g., vitamin loss)

The lab analysis can then be analyzed against and incorporated into database results, creating a robust analysis of Nutrition Facts label values.

**Are there any regulations governing the use of the term "fresh" as part of a brand name, e.g., "Fresh Expressions"?**

FDA defines the terms fresh, freshly frozen, fresh frozen and frozen fresh in the Code of Federal Regulations. "Fresh" conveys that the food is unprocessed - this means that the food is in its raw state and has not been frozen, subject to thermal processing or any other form of preservation. This applies to all label claims including the brand name.

The regulation specifically allows for the term fresh to be used on foods that contain added waxes or coatings, use approved pesticides post-harvest, are washed with a mild chlorine or acid solution, are raw foods treated with ionizing radiation, require refrigeration, or are widely recognized by consumers to be pasteurized (for example, milk).

Reference: [21 CFR 101.95](#).

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**Are words like "approximately" or "about" allowed in the serving size for Nutrition Facts labeling? For example, "approx. 3 cookies" or "about 3 cookies"?**

The term "about" or "approximately" should not be used for serving size declaration when there are discrete units in a multi-serving package. For packages with discrete units such as cookies, the weight of one cookie and the Reference Amount Customarily Consumed (RACC) is used to determine the correct serving size.

The RACC for cookies is 30g. When the weight of one cookie is 50% or less of the 30g RACC, then the serving size is the whole number of cookies closest to 30g. For example, if one cookie weighs 11g the serving size would be "3 cookies (33g)." Reference: [21 CFR 101.9\(b\)\(2\)\(i\)](#).

For information about determining serving size when products naturally vary in size, see a previous [Reader Q&A](#).

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**I want to use the new Nutrition Facts format now but cannot get all the required values from my ingredient suppliers. Do ingredient suppliers have the same compliance dates for new label regulations (7/26/18)? In the interim, can I note on the label that Potassium and Vitamin D are unavailable?**

The new nutrition label regulations pertain to manufacturers and distributors that sell food at retail. Ingredient suppliers who do not sell food at retail are not obligated to provide this information. Because partial values are not allowed within a Nutrition Facts (either original or new), you can only adopt the new format once you have values for Potassium, Vitamin D and all other required nutrients.

The reality is that ingredient suppliers will begin making this nutrition information available earlier than the compliance dates recognizing that it is necessary to satisfy their customer requirements. Compliance dates are July 26, 2018, for manufacturers with \$10 million or more in annual food sales and one year later for manufacturers with less than \$10 million in sales. You will want to request this information from your ingredient suppliers now if you wish to phase into the new Nutrition Facts format ahead of schedule.

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**Can I attach a tag to a jar of fruit spread since I do not have room for a conforming Nutrition Facts label?**

Yes, this is possible. If a manufacturer chooses to add label space for any purpose with a hangtag then this additional space is included in the total available space for labeling. This combined space determines the minimum type size requirements for all label components including the specific Nutrition Facts format to be used. In addition, the tag must adhere to the package throughout storage and shelf life conditions.

Manufacturers are not required to include a Nutrition Facts label on a package that has less than 12 square inches of available label space (jar sides and lid) provided: 1) no nutrition claims are made on the label or in advertising and 2) no extra label space was added via hang tag or any other means. In this case, an address or phone number must be provided (e.g., "For nutrition information call 1-800-123-4567") so that consumers can obtain the nutrition information upon request.

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**Two of my frozen bread formulas include baking powder although my ingredient list does not include the sub-components of the baking powder (sodium bicarbonate, potassium tartrate, cornstarch). Do the sub-ingredients need to be included within the ingredient statement in the U.S.?**

Yes, the sub-ingredients for baking powder must be included within the ingredient statement of foods sold in the U.S. Specifically, 21 CFR 101.4 requires that all ingredients be listed in descending order of predominance in the ingredient statement. You may include the sub-ingredients parenthetically after baking powder, or as separate ingredients by weight within the finished product ingredient statement.

Interestingly, Canada does not require the inclusion of sub-ingredient components for baking powder. See a previous [one-pager](#) on this topic.

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## **What are the allowable recycling claims that can be put on my label for a composite can made of paperboard with steel ends?**

According to the Federal Trade Commission (FTC), a recycling claim for a food package containing multiple components is acceptable provided the package has clear instructions for consumers about which pieces are recyclable. If a package requires disassembly before recycling, it is necessary for specific directions to also appear on the label.

FTC has issued documentation called "Green Guides" to assist marketers with claims about the environmental attributes of their products that are truthful and non-deceptive. See FTC's website for the most recent version of the "[Green Guides](#)".

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## **Our Supplement Facts Label shows Sodium 180 mg/serving and Potassium 420 mg/serving. The actual test results are Sodium 147 mg/serving and Potassium 399 mg/serving. Do we have an issue?**

It depends if these nutrients are naturally-occurring or added by fortification. FDA has different regulatory requirements for Class I (fortified) and Class II (naturally-occurring) nutrients.

For Class I nutrients (nutrients added for fortification), the analyzed value must be at least equal to the label value. Using your example above, if Potassium was added for fortification, your label would be non-compliant because the actual value is lower than the label value. Very likely, Sodium was not added for fortification but even if it were your actual value exceeds the label value and is therefore acceptable.

For Class II nutrients that are naturally-occurring, the analyzed value for Potassium (a positive nutrient) must be at least 80% of the label value and the analyzed value for Sodium (a negative nutrient) must not be greater than 120% of the label value. Your lab results fall into this range and would therefore be acceptable. See a related [Reader Q&A](#) for additional allowable variance information.

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## **What are the rules about declaring net contents in Canada?**

Canadian food labels must express net quantity declarations in metric units of measure. Non-metric units may also be used as long as the metric is placed first and there is no intervening information between the two including marks, punctuation, parentheses or brackets.

When declaring volume it is permissible to use U.S. fl oz as long as they are clearly indicated on the packaging. Note: when calculating metric volume from U.S. fl oz, 1 U.S. fl oz = 1.041 Canadian fl oz and 1 Canadian fl oz = 29.574 mL.

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## **I have a product that is made with hand-peeled green chiles. Is it allowable to list it as "Hand-Peeled Green Chiles" in the ingredient statement, or is only "Green Chiles" acceptable?**

21 CFR 101.4 states that the common or usual name must be used in ingredient labeling. In this case, the common or usual name is "green chiles." Descriptions such as hand-peeled, pure, extra premium, and Grade A, are not acceptable for use in ingredient statements.

You may, however, add a starburst or other graphic call out on the principle display panel that states "made with hand-peeled green chiles." This allows you to include important marketing messages and product features and still maintain a compliant ingredient statement.

## Is there regulation against using the phrase "hand-crafted" for an FDA packaged product?

"Hand-crafted" can appear on the principle display panel for an FDA-regulated food provided it accurately reflects the facts and does not mislead consumers. You will want to be sure that your processes are consistent with what hand-crafted is generally understood to mean. Note that misuse of this type of label statement is more likely to garner FTC attention because it is related to advertising and product promotion.

## I have heard that you always need to have a U.S. address on your food label but I can't find the regulation that requires this. Can you clear this up for me?

21 CFR 101.5 states that the manufacturer, packer or distributor name and place of business must be displayed prominently on every food label. If a product is manufactured outside the U.S., it is acceptable to label the address of its origin including the country name. However, there is also a mandate specific to dietary supplements in Section 403(y) of the FD&C Act [21 U.S.C. 343(y)] referenced in [FDA guidance](#) that requires a U.S. domestic address or phone number for the purpose of adverse event reporting.

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

- **Subscribe** to *Food Label News* – [www.foodlabelnews.com/subscribe](http://www.foodlabelnews.com/subscribe)
- **Search** the Reader Q&A Archive – [www.foodlabels.com/q&a.htm](http://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](http://www.foodlabels.com/linkedin/community)
- **Contact us** for individualized help at [www.foodlabels.com](http://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, fortune 500s, manufacturers and distributors, retailers, ingredient suppliers, importers and brokers, restaurateurs and others in the food industry.

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.