



# **Silliker Nutrient and Health Claims U.S. and Canadian Regulatory Guide**

*Technical Content by  
Food Consulting Company*

**2013 Edition**



With over 40 years of experience and part of the Mérieux Alliance group of companies, Silliker, Inc. provides consulting, testing, auditing, research and education services that help assure food safety and nutrition worldwide. Log on to **[www.silliker.com](http://www.silliker.com)** to learn more about our safety and quality solutions.

# Silliker Nutrient and Health Claims U.S. and Canadian Regulatory Guide

Label claims and statements can draw attention to products and increase product sales, but developing compliant claims can be tricky. This guidebook was developed to help product developers become familiar with the various types of label claims and statements available, and aid in recognizing which is best suited to a product's nutritional attributes and marketing objectives.

**Nutrient Content Claims** describe directly or by implication the level of a nutrient or dietary substance in a serving.

**Statements of Fact** can be made on labels as long as they do not make a nutrient content claim, health claim or other claim that requires specific FDA authorization.

**Health Claims** characterize the ability of a nutrient or functional component to reduce the risk of disease or a health-related condition.

**Structure/Function Claims** describe the role of a nutrient or functional component in affecting or maintaining normal body structure or function, or general well-being.

**Dietary Guidance Statements** typically explain the relationship between a group of foods (such as fruits and vegetables or whole grains) and health.

Regardless of the type of label claim or statement chosen, all labeling must be truthful and not misleading.



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## Conventional Food vs. Dietary Supplement

Early in the product development process, manufacturers will want to determine if the product will be regulated as a conventional food or as a dietary supplement. This determination carries many ramifications for formulation, labeling and marketing (i.e., allowable/restricted ingredients, possible label claims, etc.).

**Conventional foods** are labeled with Nutrition Facts; dietary supplements are labeled with Supplement Facts. Though there is not a regulated FDA definition for conventional food, it is a term that FDA uses. Conventional foods are commonly understood to be all foods, beverages and chewing gums for human consumption that do not qualify as dietary supplements.

A **dietary supplement** is a product taken by mouth that contains a *dietary* ingredient intended to *supplement* the diet. Dietary ingredients include vitamins, minerals, herbs/botanicals, amino acids, enzymes, organ tissues, glandulars, metabolites, extracts or concentrates. Dietary supplements have many forms that include tablets, capsules, softgels, gelscaps, liquids and powders. They can also come in the form of a bar. Regardless of the form, the information on the label must not represent the product as a conventional food or a sole item of a meal or diet.

At this time, FDA has not established a regulatory definition for functional foods or nutraceuticals. All products must comply with regulatory requirements for conventional foods or dietary supplements.

### Label Claims and Statements for Conventional Foods and Dietary Supplements

| Type of Label Claim or Statement | Allowed on Conventional Foods?  | Allowed on Dietary Supplements?   |
|----------------------------------|---|---|
| Nutrient Content Claims          | Yes, as pre-approved by FDA except on labels for products intended for infants and children less than two years of age. | Yes, as pre-approved by FDA except on labels for products intended for infants and toddlers. Certain claims can be made only on products with over 40 calories per serving. |
| Statements of Fact               | Yes   | Yes   |
| Health Claims                    |   |   |
| SSA* Health Claims               | Yes, as pre-approved by FDA.  | Yes, as pre-approved by FDA. Requires specific FDA notification.  |
| FDAMA† Health Claims             | Yes. Requires FDA authorization via notification from a stakeholder.  | No  |
| Qualified Health Claims          | Yes. Requires a petition to FDA.  | Yes. Requires a petition to FDA.  |
| Structure/Function Claims        | Yes, except on USDA-regulated foods.  | Yes. Requires specific FDA notification and label "disclaimer."   |
| Dietary Guidance Statements      | Yes   | No  |

\* SSA – Significant Scientific Agreement

† FDAMA – FDA Modernization Act



## Disclosure Statement Requirements

Specific regulations have been established to help ensure that label claims and statements are not misleading to consumers.

When claims are made about a product's nutrition or health benefits on FDA-regulated products, a **disclosure statement** is required if one or more of the four nutrients shown in the chart below exceed threshold levels for the product's reference amount<sup>1</sup> or labeled serving size if larger, or per 50 grams for small servings<sup>2</sup>. The disclosure statement must be placed adjacent to the claim without intervening material, and generally must be presented in a type size at least as large as the Net Contents statement, but never less than half of the size of the claim. (See example in shaded box below which calls the consumer's attention to the Nutrition Facts.)

### Disclosure Statement Threshold Levels

| Nutrient      | Individual Foods <sup>3</sup><br>(includes small servings) | Main Dishes <sup>4</sup> | Meals <sup>5</sup> |
|---------------|--|--------------------------|--------------------|
| Total Fat     | 13.0 g   | 19.5 g                   | 26.0 g             |
| Saturated Fat | 4.0 g  | 6.0 g                    | 8.0 g              |
| Cholesterol   | 60 mg  | 90 mg                    | 120 mg             |
| Sodium        | 480 mg   | 720 mg                   | 960 mg             |

### Definitions

<sup>1</sup> **Reference Amounts** are Reference Amounts Customarily Consumed per eating occasion (RACC).

<sup>2</sup> **Small Servings** are those with reference amounts of 30 grams or less, or 2 Tbsp or less.

<sup>3</sup> **Individual Foods** are those with reference amounts of more than 30 grams, or more than 2 Tbsp.

<sup>4</sup> **Main Dishes** are products that weigh at least 6 oz per serving, contain not less than 40 grams each of at least two different foods from at least two specified food groups, and are represented as main dishes.

<sup>5</sup> **Meals** are products that weigh at least 10 oz per serving, contain not less than 40 grams each of at least three different foods from at least two specified food groups, and are represented as meals.

### Example of a disclosure statement for a product low in sodium and high in fat:

**LOW SODIUM**  
**SEE NUTRITION PANEL**  
**FOR FAT CONTENT**

Use of disclosure statements is discussed further in the Nutrient Content Claims and Statements of Fact sections.

