

## U.S. Health Claim Regulations

Supplement and food product marketers want to use the most attractive claims to garner new consumers. Bold claims such as “reduced fat,” “natural,” “gluten free” and “high in fiber” can draw health-conscious consumers to products and increase sales. However, it is critical that companies familiarize themselves with regulations that pertain to claims made on their product labeling.



### FDA and FTC

- Share jurisdiction over ensuring supplement claims are truthful and not misleading
- Typically apply the standard of “competent and reliable scientific evidence” to claim substantiation

### Disease Claims

- Not to be used for foods or supplements
- An express or implied claim to diagnose, mitigate, treat, cure or prevent a disease
- Center on a negative disease condition



#### EXAMPLES

- ⦿ “Zinc cures colds”
- ⦿ “Relieves crushing chest pain”
- ⦿ “Hangover relief”
- ⦿ “Dissolving fibrin and scar tissues in the lungs”



### Structure/Function Claims



- Focus on positive health
- Not pre-approved by FDA
- Describe a nutrient’s or dietary ingredient’s effect on or maintenance of the structure or function of the body



#### LEGAL REQUIREMENTS:

- Marketers must notify FDA of the text of the claim no later than 30 days after first marketing the product
- The label must bear the disclaimer that FDA has not evaluated the claim, and the product is not intended to diagnose, treat, cure or prevent any disease
- The marketer must possess substantiation that the claim is truthful and not misleading

#### EXAMPLES:

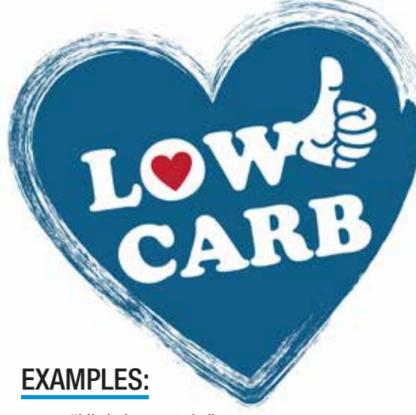
- ⦿ “Calcium builds strong bones”
- ⦿ “Antioxidants maintain cell integrity”
- ⦿ “Helps maintain cardiovascular function and a healthy circulatory system”

### Nutrient Content Claims

- Explicit or implied claims that characterize the level of a nutrient in a food or dietary supplement

#### LEGAL REQUIREMENTS:

- Based upon a nutrient’s percentage of the recommended daily intake (RDI) as established by FDA.
- For omega-3s, brands can use “high,” “good source” and “more” claims in reference to alpha-linolenic acid (ALA) based on specific nutrient levels. Nutrient-content claims in reference to eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) remain prohibited.



#### EXAMPLES:

- ⦿ “High in protein”
- ⦿ “Good source of calcium”

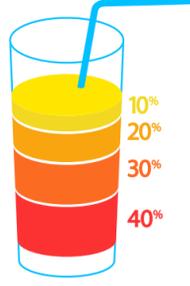
### Relative Claims

- A claim about the level of a nutrient compared to an amount of nutrient in a reference food



#### LEGAL REQUIREMENTS:

- Must include the percentage or fraction by which the food has been modified, the reference food, and the amount of nutrient in the labeled food and in the reference food
- Foods that have relatively high amounts of nutrients, such as calories and fat, may require additional disclosure statements adjacent to the claim



#### EXAMPLES:

- ⦿ “Reduced fat sour cream”
- ⦿ “Light potato chips”

### Health Claims

- Describes a relationship between a food, food component or dietary supplement ingredient, and the risk reduction of a disease or health-related condition

#### LEGAL REQUIREMENTS:

- Must be specifically authorized by FDA. Usually, FDA will authorize the exact claim and the nutrient requirements to make it
- Approved based upon the standard of significant scientific agreement (SSA)
- Foods that make this claim must also qualify for the nutrient content claim relating to the health claim

#### EXAMPLE:

- ⦿ “Diets low in saturated fat and cholesterol, and as low as possible in *trans* fat, may reduce the risk of heart disease”

### Qualified Health Claims

- Based on evidence that is not well enough established to meet the standard required for an FDA-approved health claim

#### LEGAL REQUIREMENTS:

- Must clarify the evidence supporting the claim is limited.

#### EXAMPLE:

- ⦿ “FDA has determined that, although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive”



**ALL  
NATURAL  
PRODUCT**

### Natural Claims

- FDA stated it would not object to use of the term “natural” on products that contained no artificial flavors, color additives or chemical preservatives.
- As use of the term has grown, FDA has come under fire to issue more substantive policies regarding its appropriateness.
- In November 2015, FDA issued a Federal Register soliciting comments regarding the use of the term “natural” in food labeling; the comment period closed May 10, 2016

### Gluten-Free Claims

- Final rule that went into effect in 2014
- For products that are inherently free of gluten, do not contain an ingredient derived from wheat/barley/rye, contain less than 20 ppm of gluten, or have an ingredient derived from wheat/barley/rye that has been processed to remove gluten, resulting in a level of gluten below 20 ppm

