

Understanding Dietary Supplement Claims

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Dietary supplement claims are a consumer's primary source of information about the product and its function. With a growing number of consumers new to the dietary supplements category, it is more important than ever for manufacturers to ensure the credibility of their claims in order to establish consumer trust.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) defined structure/function claims, which describe how a nutrient or dietary ingredient affects or maintains the normal structure or function of the human body or general wellbeing. Structure or function claims are different from disease claims – claims that a product can treat, mitigate, or cure disease. Disease claims are limited to drugs and certain devices.

While the Food and Drug Administration (FDA) is primarily responsible for claims on product labeling, the Federal Trade Commission (FTC) has primary responsibility for claims in advertising and direct marketing materials. And in this digital age, it's not just the label that matters. Supplements that are sold on the internet are subject to both FDA and FTC regulations.

Product claims may be directly expressed or implied. Implied claims include statements, symbols, images, or other forms of communication that indirectly suggest that a relationship exists between an ingredient and a disease or health condition. Other less obvious forms of regulated claims include testimonials, product names, research citations, endorsements, and even the meta-tags that describe a website's content.

The FDA defines three different categories of claims that dietary supplement manufacturers are permitted to use on their product's packaging: structure/function claims, nutrient content claims, and health claims. All claims must be truthful, substantiated with scientific evidence, and compliant with placement and type size requirements, however each category has its own specific set of regulations.

Permissible Claims:

1. Structure/function claims are the most common, permissible claim used for dietary supplements. DSHEA established special requirements for structure/function claims, including claims that are related to general well-being and nutrient deficiencies. Structure function claims can be easily confused with disease claims, which refer to a specific disease or class of diseases. Using a disease claim or including a S/F claim implying disease management on a dietary supplement product would be considered misleading and out of compliance.

To help distinguish the difference between structure/function claims and disease claims, FDA provides 10 criteria in their [Small Entity Compliance Guide on Structure/Function Claims](#), including:

- Manufacturers must collect and maintain "[competent and reliable scientific evidence](#)" to substantiate the relationship of evidence to the claim
- FDA notification is required within 30 days of marketing the product
- The disclaimer, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease" must either be linked to each claim with a symbol (e.g., an asterisk) or placed adjacent to the claim without intervening material
- Product names may not suggest that the dietary supplement has an effect on a disease.
- The claim's overall context must not imply that the product treats or prevents disease or can substitute or augment medical treatments or prescription drugs.

Examples of compliant/permissible structure/function claims when supported by evidence:

- "Supports urinary tract health"
- "Helps maintain cardiovascular function"
- "Helps to maintain cholesterol levels that are already within the normal range"

- “Promotes joint health”
- “Helps maintain a healthy blood sugar level as part of a healthy diet”
- “Supports a healthy weight loss plan”
- “Supports immune health”
- “Mood support”

Examples of non-compliant/impermissible structure/function claims:

- “For chronic indigestion”
- “Relieves chronic constipation”
- “Helps ease depression”
- “Prevents hangovers”
- “Helps maintain a healthy blood sugar level for people with diabetes”
- “Prevents cold and flu”
- “Relieves headache pain”
- “Appetite suppressant treatment for obesity”
- “Lowers cholesterol”
- “Reduces joint inflammation and pain”

FDA references:

2. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using defined terms such as “high,” or “good source.” The majority of nutrient content claims apply to ingredients with an established Daily Value (DV), such as Vitamin C or calcium, which can be found on the [National Institutes of Health \(NIH\)](#) website. Nutrients without an established DV are only allowed to specify the amount of the nutrient per serving and may not describe the level of the nutrient using defined terms. Percentage claims are a type of nutrient content claim that is used on dietary supplements to either describe the quantity of a dietary ingredient or to make a comparison between two products.

- FDA notification is not required prior to use.
- All nutrients that are referenced in the claim, including those without an established DV, must be listed in the Supplement Facts panel
- “High,” “rich in,” or “excellent source of” may only be used to describe a product that contains 20 percent or more of a nutrient’s daily value
- “Good source,” “contains,” or “provides” may be used to describe a product that contains 10 to 19 percent of a nutrient’s daily value

Examples of compliant/permissible nutrient content claims:

- A supplement that provides at least 20% DV of Vitamin C per serving may use the claim “Excellent source of vitamin C” or other related descriptors.
- A supplement that provides at least 10% DV of Calcium per serving may use the claim “Good source of calcium” or other related descriptors.

- Contains 300 milligrams (mg) of phosphatidylserine per serving
- Simple percentage claim: “40% omega-3 fatty acids, 10 mg per capsule”
- Comparative percentage claim: “Twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg).”

Examples of nutrient content claims:

Impermissible Claim: “High in Iron” on a supplement that provides 10% DV of iron per serving.	Permissible Claim: “Contains Iron,” or, “Good Source of Iron.”
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Reason: “High in” is a regulated term that describes a nutrient present in a product at 20% or more of its DV. Since the product in this example provides 10% of the DV of iron, it may claim “Contains” or “Good source.”

Impermissible Claim: “Provides Calcium” on a supplement with 8% DV of Calcium per serving.	Permissible Claim: 100 mg of calcium per serving.
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Reason: The claim “Provides” is a regulated term that applies to products with 10% to 19% DV of a nutrient.

Impermissible Claim: “Packed with omega-3 fatty acids.”	Permissible Claim: “Contains 400 mg of omega-3 fatty acids”
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Reason: There is no established DV for omega-3 fatty acids, and the term “packed” implies that the product provides 20% or more of the DV.

FDA References for Nutrient Content Claims:

3. Health claims suggest that a dietary ingredient may reduce the risk of a disease or health-related condition. Unlike other permissible claims, health claims require FDA review prior to use. There are two types of health claims, authorized health claims and qualified health claims. Authorized health claims require Significant Scientific Agreement (SSA) among qualified experts that the claim is supported by scientific evidence or an authoritative statement from a scientific body of the U.S. Government or the National Academy of Sciences. Once approved, the FDA will issue a regulation that specifies how a health claim may be used.

However, very few claims are able to meet the SSA standard. In fact, the FDA has authorized only 12 health claims since 1990. To allow more health-related information on product labels, FDA established rules for the use of qualified health claims (QHC), which require less scientific evidence than authorized health claims. Unlike authorized health claims, FDA does not “approve” qualified health claims. Instead, FDA issues a Letter of Enforcement Discretion that outlines how these claims may be used.

- Manufacturers must submit a petition to the FDA for all new health claims
- Existing health claims that are approved for use on dietary supplements do not require additional review as long as the claim meets specific requirements defined by FDA
- Approved claims must be used verbatim
- Claims may not imply that a dietary supplement can cure, mitigate, or treat a disease
- Qualified Health Claims require a disclaimer to communicate the strength of scientific evidence that supports the claim and must be used verbatim

Examples of Authorized Health Claims:

- “A healthful diet with adequate folate may reduce a woman’s risk of having a child with a brain or spinal cord defect”
- “Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis”

Examples of Qualified Health Claims:

- “Consuming eicosapentaenoic acid (EPA) and docosahexaenoic (DHA) combined may help lower blood pressure in the general population and reduce the risk of hypertension. However, the FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [___] gram(s) of EPA and DHA.”
- “Consuming 500 mg each day of cranberry dietary supplement may help reduce the risk of recurrent urinary tract infection (UTI) in healthy women. FDA has concluded that there is limited scientific evidence supporting this claim.”

Examples of non-compliant/impermissible health claims:

- “Protects against the development of cancer”
- “Reduces the pain and stiffness associated with arthritis”
- “Treats diabetes”
- Any claim that has not been reviewed and/or approved by FDA
- A claim that deviates from approved language
- A QHC disclaimer that deviates from FDA-defined language

FDA references:

This guide is not intended to serve as a sole source of information on claims; the FDA guidelines should be the primary source for every company. Regulations are frequently updated or changed, so manufacturers must be aware of any changes to remain current with the legal requirements for food labeling.

For more information on how to read a dietary supplement facts label, please visit the **[CHPA Educational Foundation's interactive label](#)**.

Other Useful resources: