

## 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). Conventional foods are labeled with Nutrition Facts while dietary supplements are labeled with Supplement Facts.

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: tablets, capsules, softgels, gelpcaps, liquids, and powders. They can also be in the form of a bar, and in this case information on the label must not represent the product as a conventional food or a sole item of a meal or diet. Regardless of the form, every supplement must be labeled as a dietary supplement.

### 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 toddlers.	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. Use 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. Use requires specific FDA notification and label “disclaimer.”
Dietary Guidance Statements	Yes	No

\* SSA – Significant Scientific Agreement

\*\* FDAMA – FDA Modernization Act

