Dietary Supplement Definition: A product taken by mouth that is intended to supplement the diet and that contain a dietary ingredient. Can include vitamins, minerals, herbs, and other botanicals, or amino acids. Includes concentrates, metabolites, constituents, extracts, or combinations of the above ingredients.

Drug Definition:
“articles intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease or other condition...” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”

Health claims are limited to claims about disease risk reduction, and cannot be claims about the diagnosis, cure, mitigation, or treatment of disease. Health claims are required to be reviewed and evaluated by FDA prior to use. An example of an authorized health claim, is: “Three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams per serving.”

Nutrient content claims describe the level of a nutrient in the product, using terms such as free, high, and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced, and lite. An accurate quantitative statement (e.g., 200 mg of sodium) that does not otherwise “characterize” the nutrient level may be used to describe the amount of a nutrient present. However, a statement such as “only 200 mg of sodium” characterizes the level of sodium by implying that it is low. Therefore, the food would have to meet the nutritional criteria for a “low” nutrient content claim or carry a disclosure statement that it does not qualify for the claim (e.g., “not a low sodium food”). Most nutrient content claim regulations apply only to those nutrients that have an established Daily Value.

Permitted structure/function statements. Dietary supplement labels or labeling may bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function of humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims.... Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, for example, “calcium builds strong bones.” In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, “fiber maintains bowel regularity,” or “antioxidants maintain cell integrity.” Structure/function claims for dietary supplements may focus on non-nutritive as well as nutritive effects.

Manufacturer requirements for structure/function claims: First, the law says you can make these claims if you have substantiation that the claims are truthful and not misleading. You must have this substantiation before you make the claims. Second, you must notify FDA that you are using the claim within 30 days of first marketing your product. Third, the claim must include a mandatory disclaimer statement that is provided for in the law.

Disease claim definition: ...if it mentions a specific disease or class of diseases. For example, a claim that a product is “protective against the development of cancer” or “reduces the pain and stiffness associated with arthritis” would be a disease claim. A statement also is a disease claim if it implies that it has an effect on a specific disease or class of diseases by using descriptions of the disease state. Examples of implied disease claims are “relieves crushing chest pain (angina),” “improves joint mobility and reduces inflammation (rheumatoid arthritis),” or “relief of bronchospasm (asthma).”

References:

Disease Claim Criteria:
Criterion 1: Claims an effect on a disease or class of diseases
Criterion 2: Claims an effect on characteristic signs or symptoms of disease using scientific or lay terminology
Criterion 3: Claims an effect on a condition associated with a natural state or process
Criterion 4: It is an implied disease claim because of the product name, formulation, use of pictures, or other factors
Criterion 5: Claims that a product belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease
Criterion 6: Claims to be a substitute for a product that is a therapy for a disease
Criterion 7: Claims to augment a therapy or drug intended to diagnose, mitigate, treat, cure, or prevent a disease
Criterion 8: Has a role in the body’s response to a disease or to a vector of disease
Criterion 9: Claims to treat, prevent, or mitigate adverse events associated with a therapy for a disease
Criterion 10: Otherwise suggests an effect on a disease or diseases