

Follow up links to approved health claims and more on FDA web site:

Link for Approved Claims – link to web site:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064919.htm>

use

<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm064919.htm>

Link to more on types of Health Claims:

<http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm111447.htm>

Approved

Health Claims

A "health claim" by definition has two essential components:

- (1) a substance (whether a food, food component, or dietary ingredient)
- (2) a disease or health-related condition.

A statement lacking either one of these components does not meet the regulatory definition of a health claim. For example, statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in health are considered to be dietary guidance rather than health claims, provided that the context of the statement does not suggest that a specific substance is the subject.

Statements that address a role of a specific substance in maintaining normal healthy structures or functions of the body are considered to be structure/function claims. Structure/function claims may not explicitly or implicitly link the relationship to a disease or health related condition.

Structure Function claims:

Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, 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," or they may describe general well-being from consumption of a nutrient or dietary ingredient. Structure/function claims may also describe a benefit

related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the United States.

A. What is the definition of a disease?

Section 101.93(g) defines disease as:

...damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

There are 10 criteria in the rule that are useful in determining if a statement is a disease claim. Follow link:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm103340.htm>

Disclaimer Wording:

"This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease"?

This statement or "disclaimer" is required by law (DSHEA) when a manufacturer makes a structure/function claim on a dietary supplement label. In general, these claims describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not approved by FDA. For this reason, the law says that if a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated this claim. The disclaimer must also state that this product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim.