

STRUCTURE/FUNCTION CLAIMS ...

- ... describe the role of a nutrient or functional component in affecting or maintaining normal body structure or function, or general well-being
- ... cannot describe or imply that a nutrient or functional component affects a disease or health-related condition via diagnosis, cure, mitigation, treatment or prevention (a claim doing this is an unauthorized drug claim)
- ... can be used on FDA-regulated conventional foods and dietary supplements
- ... cannot be used on USDA-regulated products because USDA does not recognize these claims
- ... are not pre-approved by FDA; the manufacturer must have substantiation on file (clinical trials* or other research) to show that the claim is truthful and not misleading
- ... require that the manufacturer of a dietary supplement submit a notification to FDA no later than 30 days after the product goes to market; the notification must include the text of the claim (conventional foods do not require this notification)
- ... require that the label of a dietary supplement includes the following disclaimer placed adjacent to the statement with no intervening material, or enclosed in a box and linked to the statement with an asterisk or other symbol (labels for conventional foods do not require this 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.

12



EXAMPLES AND EXPLANATIONS:

ALLOWED: Antioxidants help maintain cell integrity (no mention of disease)

NOT ALLOWED: Antioxidants prevent the onset of cancer (this is an unapproved drug claim)

ALLOWED: Echinacea supports the body's immune system (no mention of disease)

NOT ALLOWED: Echinacea is useful in preventing colds (this is an unapproved drug claim)

**Clinical trials are human studies designed to provide definitive answers to substantiate claims made for foods and dietary supplements, and ingredients used in these products. The amount and nature of the evidence needed to support a claim depends on the type of claim. FDA oversees labeling claims and FTC oversees advertising claims to ensure truthfulness for consumers.*

The first step in determining the study protocol is to understand the expressed and implied meaning of the claim being substantiated. This helps formulate the study hypotheses and measurable endpoints. For example, trials to support SSA or qualified health claims (which describe the relationship between a substance and a disease or health-related condition) are designed to support that relationship.

A well-designed clinical trial provides the credible scientific evidence that FDA and FTC need for evaluating claims. Animal studies, in-vitro studies, meta-analysis and anecdotal evidence provide useful background information but these alone may not be adequate to substantiate a claim. When determining whether there is adequate evidence to substantiate a claim, the marketer should consider the totality of the evidence, i.e., all relevant research (both favorable and unfavorable). This is the same standard used by FDA and FTC for determining appropriate use of a claim.

Additional information about substantiating claims is available at www.fda.gov and www.ftc.gov.



Examples of Allowable Structure/Function Claims*

Component Category	Component Sub-category	Structure or Function
Vitamins (Water-Soluble)	Vitamin B1 (Thiamin)	may contribute to maintenance of mental function helps regulate metabolism
	Vitamin B2 (Riboflavin)	helps regulate metabolism helps support cell growth
	Vitamin B3 (Niacin)	helps regulate metabolism helps support cell growth
	Vitamin B5 (Pantothenic Acid)	helps regulate metabolism helps regulate hormone synthesis
	Vitamin B6 (Pyridoxine)	may contribute to maintenance of healthy immune function helps regulate metabolism
	Vitamin B9 (Folate/Folic Acid)	supports healthy brain and spinal cord development may contribute to maintenance of heart health
	Vitamin B12 (Cyanocobalamin)	helps regulate metabolism supports blood cell formation may contribute to maintenance of mental function
	Biotin	helps regulate metabolism helps regulate hormone synthesis
	Vitamin C	functions as an antioxidant to neutralize free radicals may contribute to healthy immune function may contribute to maintenance of bone health
Vitamins (Fat-Soluble)	Vitamin A	may contribute to maintenance of healthy vision may contribute to maintenance of healthy immune function may contribute to bone health may contribute to cell integrity
	Vitamin D	helps regulate calcium and phosphorus helps contribute to bone health may contribute to healthy immune function helps support cell growth
	Vitamin E	functions as an antioxidant to neutralize free radicals may contribute to healthy immune function may contribute to maintenance of heart health
	Vitamin K	helps support normal blood clotting
Minerals	Calcium	builds strong bones
	Magnesium	contributes to bone health and healthy immune function
	Potassium	helps maintain a healthy blood pressure level, in combination with a low-sodium diet
	Selenium	neutralizes free radicals supports a healthy immune system



Component Category	Component Sub-category	Structure or Function
Carotenoids	Beta carotene	may neutralize free radicals may increase cellular antioxidant defense
	Lutein, Zeaxanthin	may help maintain healthy vision
	Lycopene	may help maintain prostate health
Fatty Acids	ALA, DHA/EPA (Omega-3 fatty acids)	may contribute to maintenance of heart health may contribute to maintenance of mental and visual function
	Conjugated linoleic acid	may contribute to maintenance of desirable body composition may contribute to maintenance of healthy immune function
Flavonoids	Anthocyanins (Cyanidin, Delphinidin, Malvidin)	supports antioxidant defenses may contribute to maintenance of brain function
	Flavanols (Catechins, Epicatechins, Epigallocatechin, Procyanidins)	may contribute to heart health
	Flavanones (Hesperetin, Naringenin)	neutralizes free radicals supports cellular antioxidant defenses
	Flavonols (Quercetin, Kaempferol, Isorhamnetin, Myricetin)	neutralizes free radicals supports cellular antioxidant defenses
	Proanthocyanidins	may contribute to urinary tract health and heart health
Isothiocyanates	Sulforaphane	bolsters cellular antioxidant defenses
Phenolic Acids	Caffeic acid, Ferulic acid	may contribute to maintenance of healthy vision may contribute to maintenance of a healthy heart may bolster cellular antioxidant defenses
Prebiotics	Inulin, Fructo-oligosaccharides (FOS), Polydextrose	may improve gastrointestinal health may improve calcium absorption
Probiotics	Yeast, Lactobacilli, Bifidobacteria, and other specific strains of beneficial bacteria	may improve gastrointestinal health and systemic immunity (benefits are strain-specific)
Phytoestrogens	Isoflavones (Daidzein, Genistein)	may contribute to maintenance of bone health may contribute to a healthy brain may contribute to healthy immune function may contribute to maintenance of menopausal health for women
	Lignans	may contribute to maintenance of heart health may contribute to healthy immune function
Sulfides/Thiols	Diallyl sulfide, Allyl methyl trisulfide	may enhance the body's detoxification process may contribute to maintenance of heart health may contribute to a healthy immune function
	Dithiolthiones	may enhance the body's detoxification process may contribute to maintenance of healthy immune function



* Adapted from "Functional Foods" by International Food Information Council Foundation (www.ific.org)

