

The OK and Not OK List of Structure/Function Claims

These are merely some examples. Most (but not all) of these examples are directly from the FDA.

This not an all-inclusive list. Not each “OK” or “Not OK” claim has a counterpart.

OK	NOT OK
Antioxidants help neutralize free radicals, which in turn, reduce the incidence of cellular degeneration.	Protective against the development of cancer.
Helps support cartilage and joint function.	Reduces the pain and stiffness associated with arthritis.
Helps reduce muscle pain following exercise or over-exertion.	Improves joint mobility and reduces joint inflammation and pain” (rheumatoid arthritis).
	Decreases the effects of alcohol intoxication (Alcohol intoxication, like all poisonings (mushroom, digitalis, or any drug overdose), meets the definition of disease.)
Helps promote regularity, or relief of occasional constipation. NOTE – The labeling of a product that claimed to treat occasional constipation should make clear, however, that the product is not intended to be used to treat chronic constipation, which may be a symptom of a serious disease.	Alleviates chronic constipation.

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Helps maintain cardiovascular function and a healthy circulatory system.	Relieves crushing chest pain (angina or heart attack).
Promotes relaxation.	Prevents depression.
Helps maintain healthy intestinal flora.	Help maintain the intestinal flora in people on antibiotics.
Helps promote urinary tract health.	Prevents benign prostatic hypertrophy.
	Improves urine flow in men over 50 years old.
Maintains bone health.	Prevents bone fragility in post-menopausal women" (osteoporosis).
Promotes health digestive function.	Heals stomach or duodenal lesions and bleeding (ulcers)
Helps maintain/promote healthy blood pressure levels.	Lowers blood pressure.
Helps to maintain cholesterol levels that are already within the normal range, or helps maintain a healthy cholesterol level. NOTE – FDA will review all cholesterol claims to determine whether the labeling as a whole implies that the product is intended to lower elevated cholesterol levels. In such cases, FDA would consider the labeling to create an implied disease claim.	Lowers or reduces cholesterol.
	Anticonvulsant (epilepsy).

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Helps maintain/promote health collagen and cellular connectivity.	Prevents the spread of neoplastic cells (prevention of cancer metastases).
Promotes healthy respiratory function.	Relief of bronchospasm (asthma).
Helps promote or maintain healthy immune function.	Prevents wasting in persons with weakened immune systems (AIDS) (acquired immune deficiency syndrome).
Promotes/maintains normal heart functions.	Prevents irregular heartbeat (arrhythmias).
Use as part of your diet to help maintain a healthy blood sugar level.	Controls blood sugar in persons with insufficient insulin (diabetes).
Promotes/maintains healthy blood sugar levels.	Use as part of your diet when taking insulin to help maintain a healthy blood sugar level.
	Antibiotic (infections).
Promotes/maintains normal or stable mood.	Herbal Prozac (depression).
Maintains healthy lung function.	Maintains healthy lungs in smokers (prevention of lung cancer and chronic lung disease).
Promotes optimal cellular health and functionality.	Helps maintain a tumor-free state (cancer prevention).
Promotes normal bone density.	Promotes normal bone density in post-menopausal women (osteoporosis).

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Supports a normal, healthy attitude during PMS.	
Supportive for menopausal women.	
Maintains/promotes urinary tract health.	Helps to maintain normal urine flow in men over 50 years old.
	Inhibits platelet aggregation (stroke).
	Reduces cholesterol (cardiovascular disease).
Helps alleviate morning sickness associated with pregnancy.	Prevents toxemia of pregnancy. Prevents hyperemesis gravidarum.
Prevents leg edema associated with pregnancy.	
Helps with mild mood changes.	Helps sooth the acute psychosis of pregnancy.
Helps with cramps and edema associated with the menstrual cycle.	Prevents severe depression associated with the menstrual cycle.
Helps moderate hot flashes.	
Promotes skin elasticity that delays the onset of wrinkles.	
Helps to prevent other signs of aging on the skin (e.g., liver spots, spider veins).	Prevents or cures arteriosclerotic diseases of coronary, cerebral or peripheral blood vessels.
Helps to prevent presbyopia (inability to change focus from near to far and vice versa) associated with aging.	Supports your general well-being while you're getting glaucoma (I just put that in here to see if you were asleep).
Helps to ameliorate mild memory problems associated with aging.	Prevents Alzheimer's disease or other senile dementias.

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Helps prevent hair loss associated with aging.	Helps prevent male/female pattern baldness.
Helps prevent noncystic acne.	Prevents acne; or Prevents cystic acne
“Laxative” (as long as the remainder of the labeling makes clear that the product is not intended to treat chronic constipation.).	
“Anti-inflammatory” (as long as the labeling makes clear that the product is not intended to treat chronic inflammation).	
“Tonic” is commonly understood as a general term for anything that refreshes, and, by itself, would not be considered to constitute a disease claim.	
"Diuretic that relieves temporary water-weight gain."	
Claims that the product was an “energizer,” a “rejuvenative,” a “revitalizer,” or an “adaptogen.”	
“Appetite suppressant.”	
For the relief of occasional sleeplessness.	“Helps you fall asleep if you have difficulty falling asleep,” and “helps to reduce difficulty falling asleep.”
Supports the body’s immune system.	Supports the body's antiviral capabilities.

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<p>“Smoking alternative,” “temporarily reduces your desire to smoke” and “mimics the oral sensations of cigarette smoke” (for products that otherwise meet the definition of a dietary supplement) (if the context does not imply treatment of nicotine addiction).</p>	<p>To be used as a dietary adjunct in conjunction with your smoking cessation plan. (Suggesting that the product can be used in smoking cessation, or prevention or mitigation of tobacco-related diseases is a no-no).</p>
<p>“Occasional simple nervous tension,” “nervousness due to common every day overwork and fatigue,” “a relaxed feeling,” “calming down and relaxing,” “gently soothe away the tension,” “calmative,” “resolving that irritability that ruins your day,” “helps you relax,” “restlessness,” “nervous irritability,” and “when you're under occasional stress, helps you work relaxed.”</p>	<p>Helps relief nervous tension headache. Helps with anxiety disorders.</p>
<p>Arouses or increases sexual desire and improves sexual performance.</p>	<p>“Helps restore sexual vigor, potency, and performance,” “improves performance, staying power, and sexual potency,” and “builds virility and sexual potency” are disease claims because they use the term “potency,” which implies treatment of impotence, a disease.</p>
<p>Improves absentmindedness (as long as the overall context does not imply treatment of Alzheimer’s Disease).</p>	<p>Improves the symptoms of Alzheimer’s Disease.</p>
<p>Reduces stress and frustration (as long as the overall context does not imply treatment of anxiety disorders).</p>	<p>Reduces the affects of anxiety disorders.</p>

Common conditions associated with natural states or processes (e.g., menopause, aging, adolescence, and pregnancy) that do not cause significant or permanent harm will not be treated as diseases. For example, hot flashes, common symptoms associated with the menstrual cycle, ordinary morning sickness associated with pregnancy, mild memory problems associated with aging, hair loss associated with aging, and noncystic acne will not be treated as diseases.

1. Verbs to Use

- a. Maintains
- b. Regulates
- c. Stimulates
- d. Promotes – Whether a claim for “promoting” structure or function is a disease claim will depend on the context and nature of the claim. For example, a claim that a product “helps promote digestion” would be a structure/function claim because it does not refer explicitly or implicitly to an effect on a disease state. A claim that a product promotes low blood pressure would be considered a disease claim. Statements using the word “promote” can be appropriate when the statements do not suggest disease prevention or treatment or use for a serious health condition.
- e. Improves – **Be careful with this one.** “Improves” often suggests some abnormality or deficiency that can be treated, so a claim to “improve” a structure or function of the body would be more likely to be a disease claim. On the other hand, a claim to improve memory or strength would be a permitted structure/function claim, unless disease treatment were implied.

2. More Verbs to Use

- a. No specific verbs constitute a disease claim. Therefore, words such as "restore," "support," "maintain," "raise," "lower," "promote," "regulate," or "stimulate" might create an implied disease claim if, in the context they are used, they imply an effect on disease.
- b. Words like "prevent," "mitigate," "diagnose," "cure," or "treat" would be disease claims if the context of their use implied an effect on a disease.
- c. Words such as "augment," such as "strengthen," "reduce," "improve," "modify," "inhibit," "protect," or "defend" may be appropriate in some contexts, i.e., when the statements do not suggest disease prevention or treatment use. If, however, the use of these terms implies that the dietary supplement augments a particular therapy or drug action or otherwise suggests an effect on disease, the agency will consider the statement a disease claim.