

Suntheanine®

Evaluation of Acceptable Structure Function Claims

Federal Register - January 6, 2000 (page 1000 to 1050)

Food and Drug Administration Final Rule under Food Labeling – 21 CFR Part 101.93
Statements Made for Dietary Supplements Concerning the Effect of the Product on the
Structure or Function of the Body

Acceptable structure/function claims for relaxation:

All of the following are acceptable structure/function claims for relaxation, as all suggest occasional rather than long-term or chronic mood changes. Although occasional or acute symptoms can be characteristic of diseases in other settings, none of the occasional symptoms referred to here is characteristic of a specific disease:

- promotes relaxation
- helps promote relaxation
- promotes relaxation without drowsiness
- helps promote a restful, relaxed state
- promotes a sense of relaxation
- promotes a relaxed feeling
- reduces stress
- helps to reduce stress
- eases occasional simple nervous tension
- eases nervousness due to common every day overwork and fatigue
- calming down and relaxing
- gently soothe away the tension
- calmative
- resolving that irritability that ruins your day
- reduces restlessness
- reduces nervous irritability
- when you're under occasional stress, helps you work relaxed

Acceptable structure/function claims for sleep aids:

- for the relief of occasional sleeplessness (not a characteristic symptom of a disease)
- improves the quality of sleep

Acceptable structure/function claims for alertness aids:

- helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness (should not imply treatment of chronic fatigue or daytime drowsiness as these are symptoms of chronic fatigue syndrome and narcolepsy, respectively).

Acceptable structure/function claims for PMS:

- supports a normal, healthy attitude during PMS (PMS is generally a common, mild condition associated with a normal physiologic process.
- diminishes normal symptoms of premenstrual syndrome