

FDA LABELING GUIDANCE: MAKING STRUCTURE/FUNCTION CLAIMS FOR DIETARY SUPPLEMENTS

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Dietary supplement manufacturers seeking to explain and market their products must carefully craft statements on supplement labels to ensure compliance with the Food and Drug Administration's ("FDA's") regulations regarding supplements.

The FDA permits supplements to so-called "structure-function claims," which are claims that describe the role of a nutrient or dietary supplement "intended to affect the structure or function in humans" or characterize the "documented mechanism" by which the nutrient acts to maintain such structure or function, but do not claim to "diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C.A. § 343. Structure/function claims are permissible without pre-approval by the FDA if the statement satisfies three criteria:

- (a) the manufacturer possesses "substantiation" that such statement is truthful and not misleading;
- (b) the product label "prominently displays" the following statement: "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."; and
- (c) the manufacturer notifies the FDA within 30 days after the product is first marketed with the claim.

In contrast, "disease claims" are not permissible without FDA pre-market review and authorization under the rules for health claims or drugs, as appropriate. It is thus important to distinguish permissible structure/function claims from impermissible disease claims. A "disease" means "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." 21 C.F.R. § 101.93(g). The FDA has provided guidance as to when statements constitute "disease claims." *Id.* Generally, a statement is a disease claim if it states that the product:

- has an effect on a disease, a characteristic sign or symptom of a disease, or an abnormal condition that is either uncommon or can cause significant harm;
- has an effect on a disease by implication through, for example, the product name, an ingredient in the product, citation to literature referencing a disease or other product label details implying connection to a disease;
- is a substitute for, is similar to, or augments a product that does diagnose, treat, or prevent a disease;
- has a role in the body's response to a disease; or
- treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events themselves constitute diseases.

Practical Tips:

1. Remember that context matters. Evaluate the entirety of the label in addition to the specific statement to determine if there is an inference that the supplement is related to a specific disease.
2. Avoid reference to a specific disease or condition.
 - "Promotes joint health" instead of "reduces the pain and stiffness associated with arthritis."
 - "Calcium builds strong bones" instead of "protects against osteoporosis."
 - "Fiber maintains bowel regularity" instead of "alleviates constipation."
3. Avoid references to a symptom that is commonly associated with a specific disease or, if referencing a specific symptom, use statements related to normal function or status.
 - "Supports cartilage and joint function" instead of "reduces joint pain."
 - "Helps maintain a healthy cholesterol level" instead of "lowers cholesterol."
 - "Use to help maintain balanced blood sugar levels" instead of "reduces blood sugar levels."
4. Refer to states that exist absent a specific disease.
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- Use "Reduces stress."
- Use "Improves absentmindedness."
- Use "Improves mood."5. Refer to natural states or processes that occur absent a specific disease.
- "Helps prevent mild memory loss associated with aging" instead of "helps prevent Alzheimer's disease."
- "Helps with mild mood changes associated with the menstrual cycle" instead of "helps prevent severe depression associated with the menstrual cycle."

6. Avoid even inferring or implying a relationship to a specific disease.

- - Avoid using a disease name in any manner on label, including in the product name (e.g., "AlzheiMed").
 - Avoid referring to a substitute or ingredient that treats, addresses, or prevents disease (e.g., "Use instead of Omeprazole.").
 - Avoid use of images referencing a disease (e.g., an EKG tracing).
 - Avoid citation to literature whose title indicates treatment of a disease (e.g., "Benefits identified in *"Use of Proton pump inhibitors in the treatment of GERD."*").
 - Avoid grouping with drugs that are known to prevent or treat disease (e.g., antibiotic, antidepressant).

7. Use more general statements that do not indicate that the product treats a specific disease.

- - "Supports the immune system" instead of "supports the body's ability to resist infection."
 - "A good diet promotes good health and prevents the onset of disease" instead of "promotes good health and prevents the onset of disease."

For questions or more information, please contact the author.

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