

Ohio Revised Code

Section 3715.84 Requirements for labeling - misbranding.

Effective: March 22, 2001

Legislation: House Bill 381 - 123rd General Assembly

- (A) A dietary supplement is not misbranded under section 3715.60 of the Revised Code solely because the label or labeling contains a statement that characterizes the relationship of a nutrient or dietary ingredient to a disease or health-related condition if all of the following conditions are met:
- (1) The statement does one of the following:
- (a) Claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of the disease in the United States;
- (b) Describes the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body;
- (c) Characterizes a documented mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function of the human body;
- (d) Describes general well-being from consumption of a nutrient or dietary ingredient.
- (2) The manufacturer of the dietary supplement has substantiation that the statement is not false or misleading.
- (3) The label contains, prominently displayed and in boldface type, one of the following statements:
- (a) In the case of a product manufactured or sold in Ohio and in other states, "This statement has not been evaluated by the United States food and drug administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- (b) In the case of a product manufactured and sold only within the state of Ohio, "This statement has not been evaluated by the Ohio department of agriculture. This product is not intended to diagnose,



treat, cure, or prevent any disease."

- (4) The manufacturer of the dietary supplement complies with the requirements of the federal "Food, Drug, and Cosmetic Act," 108 Stat. 4327 (1994), 21 U.S.C.A. 343(r)(6), as amended.
- (B) The statement described in division (A)(1) of this section shall not claim that the supplement is to be used to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.
- (C) If the director of agriculture finds or has cause to believe that a dietary supplement is misbranded under this section, the director shall proceed under the provisions of this chapter applicable to misbranded food. In any action taken under this section, the burden of proof to establish misbranding is on the director.
- (D) A dietary supplement is not a drug within the meaning of section 3715.01 or 4729.01 of the Revised Code solely because the label or labeling contains a statement authorized by this section or because a warning appears on the supplement's label.