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Bill Analysis
Legislative Service Commission

Sub. H.B. 381

123rd General Assembly
(As Reported by H. Commerce & Labor)

Reps. Perz, Gardner, Ford, Olman, Bateman, Britton, Corbin, Flannery, Hollister, Opfer, Padgett, Taylor, Winkler, Young, D. Miller

BILL SUMMARY

- Codifies in Ohio law portions of the federal Food, Drug, and Cosmetic Act concerning dietary supplements.
- Specifies that a dietary supplement is treated the same as a food under Ohio law.
- Specifies that the Director of Agriculture has exclusive authority to administer and enforce the bill's provisions.

CONTENT AND OPERATION

Intent

The bill states that the intent of the statutes it enacts is to codify in Ohio law portions of the federal "Dietary Supplements Health and Education Act of 1994," 21 U.S.C.A. 301 et seq., as amended (Section 3).

Dietary supplements as food

The bill specifies that a dietary supplement is to be treated as a food under Ohio's pure food and drug law and the term "dietary supplement" has the same meaning as in the federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. 301, et seq., as amended (R.C. 3715.80 and 3715.81).¹

¹ Under federal law, "dietary supplement" means a product, other than tobacco, intended to supplement the diet and includes any of the following: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance used by humans to increase total dietary intake, a concentrate, a metabolite, a constituent, an extract, or any combination of the previous ingredients.

Existing Ohio law specifies what constitutes a drug for the purposes of the pure food and drug law and the pharmacy law (R.C. 3715.01 and 4729.01, not in the bill).² The bill specifies that a dietary supplement is not to be considered a drug solely because the label or labeling of the dietary supplement contains a statement describing the supplement, as authorized by the bill, or because the label contains a warning (R.C. 3715.84(D)). The bill also specifies that a dietary supplement is not a "food additive" within the meaning used in the federal Food, Drug, and Cosmetic Act (R.C. 3715.86).

Administration

The bill requires the Director of Agriculture to administer and enforce its provisions and any rules adopted under it (R.C. 3715.81). The bill authorizes the Director to adopt rules regulating dietary supplements, but specifies that the rules may be no more restrictive than federal food, drug, and cosmetic regulations (R.C. 3715.82).

Adulterated products

Existing law sets forth conditions under which a food is considered "adulterated" (R.C. 3715.59, not in the bill). In addition to those conditions, the bill adds that a dietary supplement is adulterated if it presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in its labeling or, if there are no recommended or suggested conditions of use, under the ordinary conditions of use. If the Director finds or has cause to believe that a dietary supplement is adulterated, the Director must proceed under the existing laws for dealing with adulterated food. The Director of Agriculture bears the burden of proving that a dietary supplement is adulterated. (R.C. 3715.83.)

Labeling of dietary supplements

Misbranding

Existing law provides that food is misbranded if its labeling is false or misleading in any particular or if the label fails to comply with other standards set forth in existing law (R.C. 3715.60, not in the bill). The bill provides that a dietary supplement is not misbranded solely because the label or labeling contains a warning or a statement that characterizes the relationship of a nutrient or dietary

² "Drug" means any article intended for the diagnosis, cure, mitigation, treatment or prevention of disease in humans or in animals and any article, other than food, intended to affect the structure or any function of a human or animal body.

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 one of the following statements, prominently displayed and in boldface type:
 - (a) In the case of a product manufacturer or sold in interstate commerce, "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 or sold only in 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.

The bill also prohibits a dietary supplement label from claiming that the supplement is to be used to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

If the Director of Agriculture finds or has cause to believe that a dietary supplement is misbranded, the bill requires the Director to proceed under the provisions of the Ohio Pure Food and Drug Law that prohibit misbranding. (R.C. 3715.60, not in this bill). Under the bill, the burden of proof to establish misbranding is on the Director. (R.C. 3715.84.)

Statements made related to dietary supplements

Under the bill, a person who offers dietary supplements for sale at retail, wholesale, or distribution may make the following statements without being subject to the laws that govern licensing of dietitians if the statements are consistent with the dietary supplement's label:

- (1) Claim a benefit related to a classical nutrient deficiency disease and disclose the prevalence of the disease in the United States;
- (2) Describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body;
- (3) Characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain the structure or function of the human body;
- (4) Describe general well-being from the consumption of a nutrient or dietary ingredient. (R.C. 4759.10.)

Publications

Under the bill, a publication, including a book chapter, article, or official abstract of a peer-reviewed scientific article prepared by the article's author or the editors of the publication in which the article is published, used in connection with the sale of dietary supplements to consumers, is not considered to be a part of the label of the dietary supplement if the publication meets all of the following criteria:

- (1) The publication is reprinted in its entirety;
- (2) The publication is not false or misleading;
- (3) The publication does not promote a particular manufacturer or brand of dietary supplement;
- (4) The publication is displayed or presented, alone or with other publications on the same subject matter, presenting a balanced view of the available scientific information on a dietary supplement;
- (5) If the publication is displayed in a location where dietary supplements are offered for sale, the publication is physically separate from the dietary supplements;
- (6) The publication does not have any other information affixed to it.

The bill specifies that these rules on publications do not apply to or restrict the actions of a person who offers dietary supplements for sale at retail or wholesale in the sale of books or publications as part of the person's business.

Under the bill, if the Director of Agriculture finds or has cause to believe that a publication used in the connection of the sale of a dietary supplement is actually a label and that label is false or misleading, the Director is required to proceed under the laws that prohibit misbranding food. Again the burden of proof under the bill to establish misbranding is on the Director. *See above, "Misbranding."* (R.C. 3715.85.)

HISTORY

ACTION	DATE	JOURNAL ENTRY
Introduced	06-08-99	p. 785
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