

AN ACT

To amend section 4759.10 and to enact sections 3715.80, 3715.81, 3715.82, 3715.83, 3715.84, 3715.85, and 3715.86 of the Revised Code regarding the regulation of dietary supplements.

Be it enacted by the General Assembly of the State of Ohio:

SECTION 1. That section 4759.10 be amended and sections 3715.80, 3715.81, 3715.82, 3715.83, 3715.84, 3715.85, and 3715.86 of the Revised Code be enacted to read as follows:

Sec. 3715.80. As used in sections 3715.80 to 3715.86 of the Revised Code, "dietary supplement" has the meaning given in the federal "Food, Drug, and Cosmetic Act," 108 Stat. 4327 (1994), 21 U.S.C.A. 321(ff), as amended.

Sec. 3715.81. For purposes of this chapter, a dietary supplement shall be treated as a food. The director of agriculture shall administer and enforce sections 3715.80 to 3715.86 of the Revised Code and any rules adopted under those sections in accordance with Chapter 3717. of the Revised Code.

Sec. 3715.82. The director of agriculture may adopt rules, in accordance with Chapter 119. of the Revised Code, to administer and enforce sections 3715.80 to 3715.86 of the Revised Code. If rules are adopted, the rules shall be no more restrictive than the regulations promulgated under the federal "Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, et seq., as amended.

Sec. 3715.83. In addition to the conditions specified in section 3715.59 of the Revised Code, 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 of agriculture finds or has cause to believe that a dietary supplement is adulterated under this section, the director shall proceed under the provisions of this chapter applicable to adulterated food. In any action taken under this section, the burden of proof shall be on the director.

Sec. 3715.84. (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.

Sec. 3715.85. (A) As used in this section, "publication" includes 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.

(B) A publication used in connection with a sale to consumers of a dietary supplement is not considered 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, so as to present 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.

(C) Division (B) of this section does 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.

(D) If the director of agriculture finds or has cause to believe that a publication under division (B) of this section is a label and that label is false or misleading under division (B) of 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 shall be on the director.

Sec. 3715.86. A dietary supplement is not considered a "food additive" within the meaning given in the federal "Food, Drug, and Cosmetic Act," 21 U.S.C.A. 321(s), as amended.

Sec. 4759.10. Sections 4759.01 to 4759.09 of the Revised Code do not apply to any of the following:

(A) A person licensed under Chapters 4701. to 4755. of the Revised Code who is acting within the scope of ~~his~~ the person's profession, provided that ~~he~~ the person complies with division (B) of section 4759.02 of the Revised Code;

(B) A person who is a graduate of an associate degree program approved by the American dietetic association or the Ohio board of dietetics

who is working as a dietetic technician under the supervision of a dietitian licensed under section 4759.06 of the Revised Code or registered by the commission on dietetic registration, except that the person is subject to division (B) of section 4759.02 of the Revised Code if ~~he~~ the person uses a title other than "dietetic technician";

(C) A person who practices dietetics related to employment in the armed forces, veteran's administration, or the public health service of the United States;

(D) Persons employed by a nonprofit agency approved by the board or by a federal, state, municipal or county government, or by any other political subdivision, elementary or secondary school, or an institution of higher education approved by the board or by a regional agency recognized by the council on postsecondary accreditation, who performs only nutritional education activities and such other nutritional activities as the board of dietetics, by rule, permits, provided the person does not violate division (B) of section 4759.02 of the Revised Code;

(E) A person who has completed a program meeting the academic standards set by the American dietetic association for dietitians, received a baccalaureate or higher degree from a school, college, or university approved by a regional accreditation agency recognized by the council on postsecondary accreditation, works under the supervision of a licensed dietitian or registered dietitian, and does not violate division (B) of section 4759.02 of the Revised Code;

(F) A person when acting, under the direction and supervision of a person licensed under Chapters 4701. to 4755. of the Revised Code, in the execution of a plan of treatment authorized by the licensed person, provided the person complies with division (B) of section 4759.02 of the Revised Code;

(G) The free dissemination of literature in the state;

(H) Provided that the persons involved in the sale, promotion, or explanation of the sale of food, food materials, or dietary supplements do not violate division (B) of section 4759.02 of the Revised Code, the sale of food, food materials, or dietary supplements and the marketing and distribution of food, food materials, or dietary supplements and the promotion or explanation of the use of food, food materials, or dietary supplements provided that the promotion or explanation does not violate Chapter 1345. of the Revised Code;

(I) A person who offers dietary supplements for sale and who makes the following statements about the product if the statements are consistent with the dietary supplement's label or labeling:

(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.

(J) Provided that the persons involved in presenting a general program of instruction for weight control do not violate division (B) of section 4759.02 of the Revised Code, a general program of instruction for weight control approved in writing by a licensed dietitian, a physician licensed under Chapter 4731. of the Revised Code to practice medicine or surgery or osteopathic medicine or surgery, a person licensed in another state that the board considers to have substantially equivalent licensure requirements as this state, or a registered dietitian;

~~(J)~~(K) The continued practice of dietetics at a hospital by a person employed at that same hospital to practice dietetics for the twenty years immediately prior to July 1, 1987, so long as the person works under the supervision of a dietitian licensed under section 4759.06 of the Revised Code and does not violate division (B) of section 4759.02 of the Revised Code. This division does not apply to any person who has held a license issued under this chapter to practice dietetics. As used in this division, "hospital" has the same meaning as in section 3727.01 of the Revised Code.

SECTION 2. That existing section 4759.10 of the Revised Code is hereby repealed.

SECTION 3. Sections 3715.80 to 3715.86 of the Revised Code, as enacted by this act, are intended to codify in Ohio law portions of the federal "Dietary Supplement Health and Education Act of 1994," 108 Stat. 4325 (1994), 21 U.S.C.A. 301, et seq., as amended.

Speaker _____ of the House of Representatives.

President _____ of the Senate.

Passed _____, 20____

Approved _____, 20____

Governor.

Sub. H. B. No. 381

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The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

Director, Legislative Service Commission.

Filed in the office of the Secretary of State at Columbus, Ohio, on the ___ day of _____, A. D. 20____.

Secretary of State.

File No. _____ Effective Date _____