By Senator Gruters

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A bill to be entitled

An act relating to dosage form animal health products; creating s. 585.012, F.S.; defining terms; requiring a manufacturer or distributor of dosage form animal health products to register with the Department of Agriculture and Consumer Services; authorizing the department to waive the registration requirement under certain conditions and to require specified information for registration applications; providing requirements for product labels; providing conditions under which dosage form animal health products are considered misbranded or adulterated; providing construction; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 585.012, Florida Statutes, is created to read:

585.012 Dosage form animal health products.—

(1) As used in this section, the term:

(a) "Brand name" means any distinguishing word, name, symbol, or device, or combination thereof, identifying the dosage form animal health product of a manufacturer or distributor.

(b) "Distribute" means to offer for sale, sell, barter, or exchange a dosage form animal health product or to supply, furnish, or otherwise provide such a product for use by any consumer or customer in the state.

(c) "Distributor" means a person or entity that distributes

dosage form animal health products.

(d) "Dosage form animal health product" means any product, including oils, tinctures, capsules, tablets, liquids, soft chews, and chewable limited dose products, intended to affect the structure or function of an animal's body other than by providing nutrition to the animal. The term does not include animal feed supplements, products represented as a primary meal for the intended animal species, products intended as a snack treat or behavioral reward treat, or dental products providing mechanical or abrasive action.

(e) "Label" means a display of written, printed, or graphic matter upon or affixed to the container in which a dosage form animal health product is distributed, or on the invoice or delivery slip with which the product is distributed.

(f) "Labeling" means all labels and other written, printed, or graphic matter upon a dosage form animal health product or any of its containers; all wrappers accompanying the product; and all advertisements, brochures, posters, or television or radio announcements used in promoting the sale of the product.

(g) "Manufacture" means the grinding, mixing, blending, or further processing of a dosage form animal health product for distribution.

(h) "Manufacturer" means a person or entity that manufactures dosage form animal health products.

(i) "Product name" means the name of a dosage form animal health product which identifies the kind, class, or specific use of the product.

(2)(a) A manufacturer or distributor that manufactures or distributes the finished form of a dosage form animal health

product in the state must submit a registration application to the department every 2 years as prescribed by department rule. The department may waive the registration requirement if a manufacturer or distributor is registered under another federal or state law in compliance with department rule.

(b) The department may require a registration application to include a copy of the label and labeling for each dosage form animal health product.

(3) A dosage form animal health product label must contain, at a minimum, all of the following information:

(a) The net weight or count of the product.

(b) The product name and brand name, if any, under which the product is manufactured or distributed.

(c) The established name of each active ingredient in the product and the amount of each active ingredient per serving in descending order by predominance of the ingredient in the product.

(d) The established name of each inactive ingredient in the product and the amount of each inactive ingredient per serving in alphabetical order.

(e) Adequate directions and precautionary statements and warnings necessary to ensure safe and effective use of the product.

(f) The name and principal mailing address of the manufacturer or distributor. Only the name, city, state, and zip code are required for a manufacturer or distributor listed in a local telephone directory.

(g) A structure-function claim stating the intended non-nutritional benefit of the product.

(h) The expiration date.

(4) A dosage form animal health product is considered misbranded if the product label or labeling:

(a) Does not provide the information required in subsection (3) in a prominent and conspicuous manner which can be easily identified and understood under customary conditions of purchase and use.

(b) Includes the term "guaranteed analysis."

(c) Is false or misleading.

(5) A dosage form animal health product is considered adulterated if:

(a) The product contains any poisonous or deleterious substance that may be injurious to animal health.

(b) Any valuable ingredient of the product has been in whole or in part omitted or removed.

(c) Any valuable ingredient of the product has been in whole or in part substituted by any less valuable ingredient.

(d) The composition or quality of the product falls below or differs from what the label or labeling purports or represents.

(e) The methods or controls used to manufacture or package the product do not conform to current good manufacturing practice.

(6) Dosage form animal health products may not be considered commercial feed, a drug, or feedstuff as those terms are defined in s. 580.031.

Section 2. This act shall take effect July 1, 2023.