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S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2013

A N A C T

RELATING TO ANIMALS AND ANIMAL HUSBANDRY -- BIOLOGICAL PRODUCTS

Introduced By: Senators Sosnowski, Ruggerio, Walaska, Kettle, and Cool Rumsey

Date Introduced: February 28, 2013

Referred To: Senate Environment & Agriculture

(Environmental Management)

It is enacted by the General Assembly as follows:

SECTION 1. Sections 4-9-1, 4-9-2, 4-9-3, 4-9-8, 4-9-9 and 4-9-11 of the General Laws in Chapter 4-9 entitled "Biological Products" are hereby amended to read as follows:

4-9-1. Products to be labeled. -- All ~~tuberculin, mallein, brucellosis vaccine, hog cholera serum, hog cholera virus, haemorrhagic, septicemiae aggressin, canine distemper vaccine or other~~ biological products as defined under the Virus-Serum-Toxin Act 21 USC 151-159 et. seq., used for the testing or immunizing of animals sold, given away, or used within the state shall bear a label, stating the name, and address of the person, firm, or institution making it, and the date of its preparation and comply with all other provisions of the Virus-Serum-Toxin Act 21 USC 151-159 et. seq.

4-9-2. ~~Monthly report of products sold or given away~~ Authorization for distribution of products sold or given away. – (a) Only products listed in section 4-9-1 and that are either conditionally or unconditionally licensed by the Center for Veterinary Biologics of the United States Department of Agriculture are eligible for distribution in the state. All persons other than duly licensed veterinarians ~~selling or giving away~~ intending to sell or give away any of the products listed in section 4-9-1 shall ~~report monthly to the director of environmental management the amount of each product sold or given away, the degree of strength of the product, the name and address of the person to whom sold or given, and the date of delivery. The report shall also include the address of and be signed by the person making the report.~~ notify, in writing, the director of the department of environmental management of their intent to sell or give away

products enumerated in section 4-9-1. No later than ten (10) business days after receipt of the notification, the director of the department of environmental management shall provide a written response either authorizing or denying the sale or give away of the products identified in the notification. No person other than duly licensed veterinarians may sell or give away any of the products listed in section 4-9-1 until obtaining written authorization, which may include conditions or restrictions on the distribution, sale or use of said products, from the director of the department of environmental management.

(b) Failure to obtain written authorization from the director of the department of environmental management prior to selling or giving away a product enumerated in section 4-9-1 shall constitute a violation of this section. Failure to comply with the restrictions or conditions included in said authorization shall constitute a violation of this section.

4-9-3. Use and disposition of products -- Records and reports. -- ~~Persons buying or procuring any of the products listed in section4-9-1 shall not use or dispose of those products until assured, in writing, by the person from whom the tuberculin or biologics is received that its delivery to that person has been reported to the director of environmental management or unless they have themselves reported its receipt to the director, with information required to be furnished to those who distribute those products. Those persons buying or procuring those products shall keep a correct record of the amount used and the amount on hand, and shall report these facts whenever any of these products left on hand are not deemed fit for use, or are not to be used. Those persons shall forward the record and report to the director of environmental management, with a statement of where and when procured, the amount procured at the time, the amount used and his or her name and address. If the amount forwarded to the director of environmental management, and the amount used, do not equal the amount procured or purchased, a satisfactory statement shall be made as to what became of the remainder.~~

(a) The director of the department of environmental management may, as a condition of the authorization provided in subsection 4-9-2(a), require records to be kept by persons that sell or give away any of the products enumerated in section 4-9-1. The director may, at his or her discretion, require records to be kept by any person using or administering any of the products enumerated in section 4-9-1. Such records may include, but not be limited to, the product trade name, the product generic name, the name and address of the company that produced the product, the U.S. Department of Agriculture product code, the strength of the product, the dates the product was produced, delivered, or administered, the product serial number or lot number, the name and address of the person who received the product, the name and address of the owner of the animal(s) that the product was administered to or used on, and the individual identification of

the animal(s) that the product was administered to or used on. The records may be subject to review by the director of the department of environmental management for a period of five (5) years from the date that the record was established.

(b) Failure to keep records required by the director of the department of environmental management under this section shall constitute a violation of this section.

4-9-8. Treatment of animals to prevent normal reaction to tests -- Sale or removal of reactors. -- No person shall treat any animal with any material or substance nor in any manner for the purpose of preventing normal reaction on the part of the animal to ~~the tuberculin mallein or other~~ any diagnostic test. No person shall knowingly sell or offer for sale any animal that has reacted positively to ~~the tuberculin mallein~~ any U.S. Department of Agriculture approved official tuberculosis test or the blood test for brucellosis. No animal that has reacted to ~~the tuberculin mallein~~ any U.S. Department of Agriculture approved official tuberculosis test or other test shall be sold or removed from the premises where the test was made without permission, in writing, from the director of environmental management.

4-9-9. ~~Penalty for violations of section 4-9-8~~ Penalty for violations. – (a) Any person, firm or corporation willfully and knowingly violating subsections 4-9-2(b) or 4-9-3(b) shall be subject to a fine not to exceed one hundred dollars ($100).

(b) Any person, firm or corporation willfully and knowingly violating section 4-9-8 is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not less than ~~twenty-five dollars ($25.00)~~ one hundred dollars ($100) nor more than ~~one hundred dollars ($100)~~ two hundred fifty dollars ($250), or by imprisonment ~~for not less than one week nor more than~~ not exceeding six (6) months, or by both ~~the fine and imprisonment, in the discretion of the court~~, for the first offense; and not less than two hundred fifty dollars ($250), nor more than five hundred dollars ($500), or by imprisonment not exceeding six (6) months, or both, for each subsequent offense.

4-9-11. Federal approval of vaccines required. -- No vaccine or other biological product prepared for the purpose of immunizing animals shall be used in the state unless that product has been approved for that use by the ~~biological division~~ Center of Veterinary Biologics of the U.S. Department of Agriculture.

SECTION 2. Sections 4-9-4, 4-9-5, 4-9-6 and 4-9-7 of the General Laws in Chapter 4-9 entitled "Biological Products" are hereby repealed.

~~**4-9-4. Orders for products containing living organisms. --** The selling, giving, or distribution of vaccines, or biological products containing living organisms to be used for the immunization of cattle against tuberculosis, glanders or other diseases is prohibited, except as~~

~~provided. An order of a doctor of medicine or graduate veterinarian, who has been admitted by the representative state board to practice in Rhode Island, shall accompany the order for the material, with a statement containing the name and address of the owner of the animals it is proposed to treat and the object of the treatment and the doctor or veterinarian shall state over his or her signature that he or she will be personally responsible for the proper use of the vaccinating material or other biological products. The original of the order shall be kept on file by the vendor or distributor, and a copy of the order shall be filed by him or her with the director of environmental management.~~

~~**4-9-5. Reports of receipt of products containing living organisms. --** The person, firm, or corporation shall report the receipt of the material to the director of environmental management along with a list of the animals it is proposed to treat, giving their ages and a description of each as will enable the director, or his or her representatives, to identify the animals.~~

~~**4-9-6. Use of products containing live organisms. --** Further use of all vaccines and other biological products containing live organisms for the purpose of immunizing animals is restricted to approved veterinarians under strict supervision of the director of environmental management.~~

~~**4-9-7. Penalty for inoculations without consent of director. --** It is unlawful for any person, without the consent, in writing, of the director of environmental management, to inoculate any animal in this state with the virus of any infectious or contagious disease incident to animals. Any person convicted of this offense shall be fined a sum not less than one hundred dollars ($100) nor more than five hundred dollars ($500), in the discretion of the court.~~

SECTION 3. This act shall take effect upon passage.

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EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

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RELATING TO ANIMALS AND ANIMAL HUSBANDRY -- BIOLOGICAL PRODUCTS

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This act would make a number of technical and definitional changes regarding the provisions of the general laws governing veterinary biologics, and increase the penalty for violations of said laws.

This act would take effect upon passage.

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