Nevada Department of Agriculture
Board of Ag Meeting
June 1, 2016

Proposed Biological products regulation

(a) No biological product, including antigens, used to immunize, test, or treat livestock or any other species of animals shall be manufactured, produced, transported, distributed, sold, or offered for sale, or possessed in Nevada unless the biological product has been licensed or permitted by and produced in an establishment licensed by the United States Veterinary Biologics Division of the United States Department of Agriculture, and approved by the Nevada Department of Agriculture. *Exemption: Autogenous vaccines and/or bacterins when prepared for use on individual premises or animals may be prepared in laboratories approved by the Department.*

(b) Johne's (Paratuberculosis) vaccine is expressly prohibited in Nevada without prior approval of the Department. This approval may be obtained only after a written agreement is developed between the producer, attending veterinarian, and state regulatory officials. A plan of herd management, vaccination and any restrictions shall be a part of this agreement.

(c) Each biological product distributed, sold, offered for sale or used in Nevada or delivered for transportation or transported in intrastate or interstate commerce shall be registered with the Department on an annual basis.

(d) Each person registering biological products shall pay an annual registration fee of Two Hundred Dollars ($200.00) for each biological product registered.

(1) The Department may require the submission of the complete formula of any biological product.

(2) Trade secrets and formulations submitted with the registration shall be kept confidential.

(e) If it appears to the Department that the composition of the biological product is adequate to warrant the proposed claims and if the biological product, its labeling, and other material required to be submitted comply with the requirements of this section, then the biological product shall be registered.

(f) Additional registration of a biological product shall not be required in the case of a biological product shipped from one location within Nevada to another location within Nevada so long as the location is operated by the same person.

(g) All biological product registrations shall expire on July 1 of each year but may be renewed by the Department. Any person who fails to renew a biological product by July 1 of each year shall pay a penalty of an additional Two Hundred Dollars ($200.00).

(h) No person shall sell or offer for sale an unregistered biological product or an expired biological product.

(i) The term "Biological Product" shall mean all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, including antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. The term biological products includes but is not limited to vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies. The term shall not include any product identified and regulated as a pesticide by the Department.

(1) A product's intended use shall be determined through an objective standard and not a subjective one, and would be dependent on factors such as representations, claims (either oral or written), packaging, labeling, or appearance.

(2) The term analogous products shall include the following:

(A) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which are similar in function to biological products in that they act, or are intended to act, through the stimulation, supplementation, enhancement, or modulation of the immune system or immune response;

(B) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity; or

(C) Substances, at any stage of production, shipment, distribution, or sale, which resemble or are represented as biological products intended for use in the treatment of animals through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means.

(j) The term "unregistered biological product" shall mean a biological product that has not been registered with the Department or a biological product that has been previously registered with the Department but the registration has lapsed.

(k) The term "expired biological product" shall mean a biological product which exceeds the expiration date established by the manufacturer.

SB 488 language

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Title 50 of NRS is hereby amended by adding thereto a new chapter to consist of the provisions set forth as sections 2 to 13, inclusive, of this act.

Sec. 2. ***As used in this chapter, unless the context otherwise requires, the words and terms defined in sections 3 to 7, inclusive, of this act have the meanings ascribed to them in those sections.***

Sec. 3. (Deleted by amendment.)

Sec. 4. ***"Department" means the State Department of Agriculture.***

Sec. 5. ***"Director" means the Director of the Department.***

Secs. 6 and 7. (Deleted by amendment.)

Sec. 8. ***1. The Department may establish, by regulation, a program to implement the requirements of federal regulations concerning veterinary feed directives, as defined in 21 U.S.C. § 354, including, without limitation, requirements for the registration of any animal remedy, veterinary biologic or pharmaceutical, as those terms are defined in those federal regulations.***

2. The regulations adopted by the Department pursuant to subsection 1 must provide that:

(a) Except as otherwise provided in this paragraph, no person shall sell, offer or expose for sale, or deliver to a user, an animal remedy, veterinary biologic or pharmaceutical, in package or in bulk, which has not been registered with the Department pursuant to this chapter and the regulations adopted pursuant thereto. Any product registered pursuant to NRS 586.010 to 586.450, inclusive, or under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 et seq., is not subject to the provisions of this chapter and the regulations adopted pursuant thereto.

(b) Except as otherwise provided by law, the manufacturer of each brand of animal remedy, veterinary biologic and pharmaceutical to be sold in this State, whether in package or in bulk, shall register such products with the Department annually

pursuant to this chapter and the regulations adopted pursuant thereto. The regulations may authorize a manufacturer who sells more than one animal remedy, veterinary biologic or pharmaceutical in this State to register all such products with one application.

(c) An application for registration of an animal remedy, veterinary biologic or pharmaceutical must be made on forms provided by the Department and must be accompanied by a reasonable annual registration fee established by the Department by regulation for each animal remedy, veterinary biologic and pharmaceutical.

(d) An application pursuant to paragraph (c) must:

(1) Be filed on or before July 1 of each year; and

(2) Include a list of all animal remedies, veterinary biologics and pharmaceuticals that the applicant intends to market in this State during the following fiscal year.

Sec. 9. (Deleted by amendment.)

Sec. 10. *The Department shall deposit all fees collected pursuant to this chapter in the Livestock Inspection Account created by NRS 561.344.*

Sec. 11. *1. Any person violating the provisions of this chapter is subject to a civil penalty not to exceed:*

(a) For a first offense, $250.

(b) For a second offense, $500.

(c) For a third or subsequent offense, $1,000.

2. Of the money collected by the Department from a civil penalty pursuant to subsection 1:

(a) Fifty percent of the money must be used to fund a program selected by the Director that provides loans to persons who are engaged in agriculture and who are 21 years of age or less; and

(b) The remaining 50 percent must be deposited in the Account for the Control of Weeds created by NRS 555.035.

Sec. 12. *The Director may apply for and accept any gift, donation, bequest, grant or other source of money to carry out the provisions of this chapter and the regulations adopted pursuant thereto.*

Sec.