Senate Bill No. 112-Senator Hansen

CHAPTER.....

AN ACT relating to pharmacy; exempting certain veterinary biologic products for the treatment of certain animals from regulation under state law; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing federal law regulates viruses, serums, toxins and analogous products for use in the treatment of domestic animals. (21 U.S.C. § 154) That federal law preempts any state law that regulates viruses, serums, toxins and analogous products for use in the treatment of domestic animals. (57 Fed. Reg. 38,758, 38,759 (August 27, 1992); *Lynnbrook Farms v. Smithkline Beecham Corp.*, 79 F.3d 620, 624-30 (7th Cir. 1996)) In accordance with federal law, this bill excludes certain veterinary biologic products for administration to certain livestock from regulation under Nevada law governing drugs and medicines.

EXPLANATION - Matter in bolded italics is new; matter between brackets [omitted material] is material to be omitted.

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

Sections 1 and 2. (Deleted by amendment.)

- **Sec. 2.5.** Chapter 639 of NRS is hereby amended by adding thereto a new section to read as follows:
- 1. The provisions of this chapter and any regulations adopted pursuant thereto do not apply to a veterinary biologic product that is:
 - (a) Licensed for production under a product license; and
- (b) Directly marketed by a manufacturing facility holding an establishment license for administration to livestock.
 - 2. As used in this section:
- (a) "Establishment license" means a U. S. Veterinary Biologics Establishment License issued by the Administrator of the Animal and Plant Health Inspection Service of the United States Department of Agriculture pursuant to the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151 to 159, inclusive, and any amendments to or replacements of the Act, and any regulations adopted pursuant to the Act.
- (b) "Livestock" has the meaning ascribed to it in subsections 1 and 3 to 6, inclusive, of NRS 571.022.
- (c) "Product license" means a U. S. Veterinary Biological Product License issued by the Administrator of the Animal and Plant Health Inspection Service of the United States Department of Agriculture pursuant to the Virus-Serum-Toxin



- Act, 21 U.S.C. §§ 151 to 159, inclusive, and any amendments to or replacements of the Act, and any regulations adopted pursuant to the Act.
- (d) "Veterinary biologic product" has the meaning ascribed to "biological product" in 9 C.F.R. § 101.2.
 - **Sec. 3.** (Deleted by amendment.)
- **Sec. 3.5.** Chapter 453 of NRS is hereby amended by adding thereto a new section to read as follows:
- 1. The provisions of this chapter and any regulations adopted pursuant thereto do not apply to a veterinary biologic product that is:
 - (a) Licensed for production under a product license; and
- (b) Directly marketed by a manufacturing facility holding an establishment license for administration to livestock.
 - 2. As used in this section:
- (a) "Establishment license" means a U. S. Veterinary Biologics Establishment License issued by the Administrator of the Animal and Plant Health Inspection Service of the United States Department of Agriculture pursuant to the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151 to 159, inclusive, and any amendments to or replacements of the Act, and any regulations adopted pursuant to the Act.
- (b) "Livestock" has the meaning ascribed to it in subsections 1 and 3 to 6, inclusive, of NRS 571.022.
- (c) "Product license" means a U. S. Veterinary Biological Product License issued by the Administrator of the Animal and Plant Health Inspection Service of the United States Department of Agriculture pursuant to the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151 to 159, inclusive, and any amendments to or replacements of the Act, and any regulations adopted pursuant to the Act.
- (d) "Veterinary biologic product" has the meaning ascribed to "biological product" in 9 C.F.R. § 101.2.
 - **Sec. 4.** (Deleted by amendment.)
- **Sec. 4.5.** Chapter 454 of NRS is hereby amended by adding thereto a new section to read as follows:
- 1. The provisions of this chapter and any regulations adopted pursuant thereto do not apply to a veterinary biologic product that is:
 - (a) Licensed for production under a product license; and
- (b) Directly marketed by a manufacturing facility holding an establishment license for administration to livestock.
 - 2. As used in this section:



- (a) "Establishment license" means a U. S. Veterinary Biologics Establishment License issued by the Administrator of the Animal and Plant Health Inspection Service of the United States Department of Agriculture pursuant to the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151 to 159, inclusive, and any amendments to or replacements of the Act, and any regulations adopted pursuant to the Act.
- (b) "Livestock" has the meaning ascribed to it in subsections 1 and 3 to 6, inclusive, of NRS 571.022.
- (c) "Product license" means a U. S. Veterinary Biological Product License issued by the Administrator of the Animal and Plant Health Inspection Service of the United States Department of Agriculture pursuant to the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151 to 159, inclusive, and any amendments to or replacements of the Act, and any regulations adopted pursuant to the Act.

(d) "Veterinary biologic product" has the meaning ascribed to "biological product" in 9 C.F.R. § 101.2.

Sec. 5. (Deleted by amendment.)

- **Sec. 5.5.** Chapter 585 of NRS is hereby amended by adding thereto a new section to read as follows:
- 1. The provisions of this chapter and any regulations adopted pursuant thereto do not apply to a veterinary biologic product that is:
 - (a) Licensed for production under a product license; and
- (b) Directly marketed by a manufacturing facility holding an establishment license for administration to livestock.
 - 2. As used in this section:
- (a) "Establishment license" means a U. S. Veterinary Biologics Establishment License issued by the Administrator of the Animal and Plant Health Inspection Service of the United States Department of Agriculture pursuant to the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151 to 159, inclusive, and any amendments to or replacements of the Act, and any regulations adopted pursuant to the Act.
- (b) "Livestock" has the meaning ascribed to it in subsections 1 and 3 to 6, inclusive, of NRS 571.022.
- (c) "Product license" means a U. S. Veterinary Biological Product License issued by the Administrator of the Animal and Plant Health Inspection Service of the United States Department of Agriculture pursuant to the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151 to 159, inclusive, and any amendments to or replacements of the Act, and any regulations adopted pursuant to the Act.



(d) "Veterinary biologic product" has the meaning ascribed to "biological product" in 9 C.F.R. § 101.2.

Sec. 6. This act becomes effective upon passage and approval.

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