



Oklahoma

Secretary of State

The following is an excerpt from the Oklahoma Administrative Code. The Biological products rule became effective July 1, 2009. See below:

35:15-5-1. Biological products

(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 Oklahoma 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 Oklahoma Department of Agriculture, Food, and Forestry. Exemption: Autogenous vaccines and/or bacterins when prepared for use on individual premises or animals may be prepared in laboratories approved by the Board of Agriculture.

(b) Johne's (Paratuberculosis) vaccine is expressly prohibited in Oklahoma 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 Oklahoma 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 Board 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) Registration shall not be required in the case of a biological product shipped from one location within Oklahoma to another location within Oklahoma so long as the location is operated by the same person.

(g) All biological product registrations shall expire on March 20 of each year.

(h) It shall be a violation of these rules if the renewal application is not received by March 20.

(i) The term "Biological Product" shall mean any substance or mixture of substances, including but not limited to vaccines, autogenous bacterins, and antigens, used to immunize, test or treat livestock, poultry or any other species of animals, but shall not include any product identified and regulated as a pesticide by the Department.

[Source: Amended at 26 Ok Reg 1381, eff 7-1-09]

