Common Questions About Veterinary Biologics

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What are veterinary biologics?

Veterinary biologics are vaccines, bacterins, diagnostics, etc. which are used to prevent, treat, or diagnose animal diseases. These products generally work through some immunological method or process.

How are veterinary biologics regulated?

The U.S. Department of Agriculture (USDA) is authorized, under the 1913 Virus-Serum-Toxin Act as amended by the 1985 Food Security Act, to ensure that all veterinary biologics produced in, or imported into, the United States are not worthless, contaminated, dangerous, or harmful. Federal law prohibits the shipment of veterinary biologics unless these are manufactured in compliance with regulations contained in Title 9 of the Code of Federal Regulations, Parts 101 to 118. Veterinary biologics for commercial use must be produced at a USDA-approved establishment, and be demonstrated to be pure, safe, potent, and efficacious.

Who regulates veterinary biologics?

The Veterinary Biologics Program of the USDA's Animal and Plant Health Inspection Service (APHIS) oversees the veterinary biologics industry in the United States. This Program consists of the Center for Veterinary Biologics and allied services:

- Center for Veterinary Biologics-Policy, Evaluation and Licensing unit establishes licensing standards; reviews all prelicense documentation; reviews test methods and labels; and issues, suspends, or revokes licenses and permits. They also perform prelicense and surveillance testing; test product associated with field problems; and develop references, reagents, and test methods.
- Center for Veterinary Biologics-Inspection & Compliance unit inspects production facilities, methods, and records; and investigates suspected legal violations and consumer complaints.
- APHIS's Investigative & Enforcement Services investigates violations of Federal law.

What licenses or permits are required to manufacture and sell veterinary biologics?

Domestic manufacturers of veterinary biologics, for domestic use or for export, are required to possess a valid U.S. Veterinary Biologics Establishment License and an individual U.S. Veterinary Biologics Product License for each product produced for sale.

Foreign manufacturers of veterinary biologics may export veterinary biologics to the United States, provided that the manufacturer's legal representative (permittee) residing in the United States possesses a valid U.S. Veterinary Biological Product Permit to import these products for general distribution and sale. The U.S. Department of Agriculture may also issue veterinary biologics permits for research and evaluation or for transit shipment.

How do I report an adverse event that occurs after use of a veterinary biologic?

The Veterinary Biologics Pharmacovigilance Program is for the ongoing surveillance of adverse events associated with animal vaccines and other biologics, in cooperation with the veterinary profession and the veterinary biologics industry.

An adverse event is any undesirable occurrence after the use of an biological product, including illness or reaction, whether or not the event was caused by the product.

Reporting instructions are found on the Adverse Event web page.

What documentation must be submitted to USDA for a biologics establishment and/or product license?

Establishment and product license requirements are discussed in Veterinary Services Memorandum 800.50

What documentation must a permittee submit to USDA to obtain a permit to distribute and sell in the United States a veterinary biologic manufactured abroad?

The requirements for a permit to distribute and sell imported product are largely the same as those for domestically produced product (i.e., Veterinary Services Memorandum 800.50) .

For additional details on permit requirements, see Veterinary Services Memorandum 800.101

Are some veterinary biologics exempt from Federal regulation?

A veterinary biologic may be exempt from Federal regulation in any of the following cases:

- The product was manufactured by veterinarians and intended solely for use with their clients' animals under a veterinarian-client-patient relationship.
- The product was manufactured by individuals or companies for use only in their own animals.
- The product was manufactured in States with USDA-approved veterinary biologics regulatory programs, for sale only in those States.

What is required to conduct research with non-exempted experimental veterinary biologics?

An individual or firm must receive USDA authorization prior to conducting research in animals with non-exempted experimental veterinary biologics.

The items that must be submitted to the CVB to request such an authorization are discussed in Veterinary Services Memorandum 800.67.

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