Licensed Veterinary Biological Product Information

Last Modified:

Currently Licensed Veterinary Biological Products

(includes imported under permit)

Current Veterinary Biologics Product Catalog (January 10, 2024)
Currently Licensed Biologics for Aquatic Animals (November 2021)

Product Licensing Data

This web page provides the public with summaries of safety and effectiveness (efficacy) studies used to license a particular USDA-regulated veterinary biological product. Product summaries are published for vaccines, bacterins, and immunomodulators, but not diagnostic test kits, antibody products, or allergenic extracts.

Typically a Product Summary will contain an efficacy study summary for each microbial agent/disease against which the product is claimed to be effective. Additional studies may be included to support administration to multiple animal species, multiple routes of administration, or other product features; some of these studies are conducted after initial licensure of the product. Typically there is also one field safety study, but there may be additional studies for specialized safety claims, such as safety in pregnant animals.

Limited product licensing efficacy or safety data are currently available on this website due to the phased implementation of **the supporting regulation**. Implementation will continue through 2021. Product licensing efficacy and safety data will be available on the website within 30 days of licensure for veterinary biologics licensed after December 15, 2016.

Precautionary Statements and Disclaimers

- **Do not attempt to compare studies of similar products.** Differences in study design, animal sources, environmental conditions, and the number of animals tested can affect study outcomes and preclude meaningful comparisons. These data summaries are not to be used by manufacturers for the purposes of comparative marketing. Please consult with a veterinarian for interpretation of data.
- Products are typically shown to be effective in healthy animals. A protective immune response may not be elicited if animals are incubating an infectious disease, are malnourished or parasitized, are stressed due to shipment or environmental conditions, are otherwise immunocompromised, or the vaccine is not administered in accordance with label directions.
- Products may be considered effective without producing 100% protection against disease. Many products instead reduce the severity of disease. All products must provide a significant, clinically meaningful effect.
- Efficacy studies are conducted with a product batch formulated to the minimum approved potency (strength).
- The studies on this site were conducted over a wide time period. USDA policy has evolved over the years to address increasing scientific knowledge and demands for product quality. The data for an individual study were generated in accordance with applicable regulations and guidelines at the time the study was conducted.
- USDA-APHIS requires published summaries only for studies submitted on, or after, January 2007. Some older studies may be published voluntarily. Also, efficacy and safety data for some products licensed many years ago may no longer be available for various legitimate reasons. The lack of data for those products does not mean those products are any less efficacious or less safe than those products for which efficacy and safety data are available.

Search for Product Summaries

More Information

- History of the single-tier label claim (14.07 KB)
- Common questions about veterinary biologics
- USDA regulatory authority for veterinary biological products (16.44 KB)
- Federal Regulations regarding veterinary biologics

USDA expectations for:

- Efficacy studies (Veterinary Services Memorandum 800.202)
- Safety studies (Veterinary Services Memorandum 800.204)

Contact Us

Please email questions about product licensing data or the supporting regulation to CVB.Single.Tier@usda.gov.

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