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Licensed Veterinary Biological Product Information

Last Modified:

Currently Licensed Veterinary Biological Products

(includes imported under permit)

<u>Current Veterinary Biologics Product Catalog (April 3, 2025)</u>

Currently Licensed Biologics for Aquatic Animals (November 2021)

- A U.S. Veterinary Biologics Establishment License number is granted to companies manufacturing domestically at least one CVB licensed product. CVB assigns a three or four alphanumeric series and usually abbreviated Veterinary License Number "VLN" on labels. Each manufacturer has a unique number assigned.
- A Veterinary Biologics Permittee License number is granted to companies manufacturing outside the U.S. to import at least one CVB licensed product. CVB assigns a three or four alphanumeric series and usually abbreviated Veterinary Permittee Number "VPN" on labels. Each permittee has a unique number assigned.
- A U.S. Veterinary Biologics Product License is assigned by CVB for each licensed product based on the fractions/antigens in the final product. The Product Code Number or "PCN" is a CVB assigned alphanumeric series (4 followed by a "." then 2) that is stated on the license along with a Product True Name (True

Name). PCN may also be referred to as product code, code. The Product True Name is CVB assigned and based on the fractions/antigens in the final product. A Product True Name is not the firm assigned Trade name/trademark. Since the PCN and True Name are based on what is in the final product, multiple manufacturers or permittees can have the same PCN and True Name. A new product license with True Name and PCN is granted for each veterinary biologic that meets all the criteria for licensure for that manufacturer or permittee.

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 (159.85 KB) (Veterinary Services Memorandum 800.202)
- <u>Safety studies</u> (167.18 KB) (Veterinary Services Memorandum 800.204)

Contact Us

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

<u>Print</u>