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Imports: Veterinary Biological Products

Last Modified:

APHIS regulates the import of veterinary biological products, including vaccines, bacterins, antisera, and diagnostic kits. Our import requirements help ensure that these products—used to diagnose, prevent, and treat animal diseases in the United States—are pure, safe, potent, and effective.

You can import international biological products into the United States if you have a permit for distribution and sale, research and evaluation, or transit shipment. The regulation guiding this authority is <u>Title 9</u>, <u>Code of Federal Regulations</u>, <u>Part 104</u>.

To apply for an import permit online, follow these steps:

- 1. Create a Login.gov account, which you'll need to submit APHIS Form 2005 online.
- 2. Submit APHIS Form 2005 through the <u>National Centers for Animal Health</u> (NCAH) Portal.

For more information about NCAH, visit the <u>NCAH Portal Guidance page</u>, where you can find user guides and training videos.

Permits for Distribution and Sale

Products imported under a Permit for Distribution and Sale must meet the same requirements as domestically produced products. This permit can only be held by U.S. permittees, which are at least one of the following:

- 1. A U.S. business
- 2. An individual residing in the United States
- 3. An individual operating a business in the United States

With a Permit for Distribution and Sale, you assume legal responsibility for the imported products. See <u>Veterinary Services Memorandum 800.101</u> (145.55 KB) for more guidance.

Submit Permits for Distribution and Sale applications via the <u>NCAH Portal</u> or complete <u>APHIS Form 2005</u> (210.7 KB) and mail it to: Center for Veterinary Biologics, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010.

Submitters will need a "verified identity" <u>Login.gov account</u> to submit an application via the NCAH Portal.

Permits for Research and Evaluation or Transit Shipment

Permits for Research and Evaluation and Permits for Transit Shipment can **only** be submitted via the <u>NCAH Portal</u>.

A Permit for Research and Evaluation is valid for 1 year and cannot be renewed. You need to reapply annually to receive a new permit.

Need Help?

For CVB-related questions, including policy, evaluation, and licensing as well as inspection and compliance:

Center for Veterinary Biologics

Email: <u>cvb@usda.gov</u>

Phone: 515-337-6100

To report an adverse event:

• USDA Adverse Event Reporting

Mailing Address:

1920 Dayton Ave.

P.O. Box 844

Ames, IA 50010

To report an adverse event:

USDA Adverse Event Reporting

<u>Print</u>