Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

Import Permits for Distribution and Sale

Document Number: CVB-SOP-0084 **Revision:** 02

Previous Number: PEL Reviewer Manual Ch. 4.17

Vault: CVB-Released

Section/Area: CVB-SOP-PEL-REV

Effective Date: 20 Jul 2020

Notes:

Import Permits for Distribution and Sale

Mention of trademark or proprietary product does not constitute a guarantee or warranty of the product by USDA and does not imply its approval to the exclusion of other products that may be suitable.

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1. Purpose and Scope

This chapter covers requirements and activities for the issuance of the U.S. import permits for Distribution and Sale that are relevant to the licensure and regulation of veterinary biologics. Several of the Center for Veterinary Biologics (CVB) Inspection and Compliance requirements are mentioned, as a Reviewer may be asked about these by a prospective permittee. However, the focus of this chapter is Policy, Evaluation, and Licensing (PEL) responsibilities. This chapter discusses the submissions needed and the regulatory considerations.

The CVB issues three kinds of import permits for veterinary biologics. Only permits for Distribution and Sale are discussed in this document. Permits for Research and Evaluation or for Transit Shipment are covered CVB-SOP-5109.

Please note that the National Import and Export Service (NIES) issues import or transport permits for controlled material or organisms (agents) and vectors. Such permits may be needed by firms to import materials not covered under a CVB Research and Evaluation permit. Permit jurisdiction is discussed in CVB-SOP-5109. In general, all animal pathogens require an import permit from NIES; policy regarding the need for a permit for a specific material or isolate may change periodically or be updated: NIES should be contacted regarding current policy before applying for a permit. Contact information for Organisms and Vectors is: OV@usda.gov. Current NIES points of contact include [redacted]

2. Related Documents

Regulations:
Title 9, *Code of Federal Regulations*, part 104 (9 CFR 104.1-104.3, 104.5)

Policy:
Veterinary Services Memoranda Nos. 800.101 (primary reference), 800.50, 800.53, and 800.109
CVB Notice 13-03, CVB Notice 19-10

3. Procedures

3.1 Permits for Distribution and Sale

3.1.1 Application:

This permit is applied for using an APHIS Form 2005. As shown in the figure below, the applicant selects the middle checkbox, “General Sale and Distribution” in Box 2 of the Form 2005. When using the APHIS Form 2005 to apply for a permit for distribution and sale, the application is sent directly to the CVB in Ames, Iowa, either by hard copy in the mail, or electronically. Ideally, applications will be submitted via the NCAH portal as announced in CVB Notice 19-10. A User Guide is available for this submission type.

This application must be submitted for issuance of a U.S. Veterinary Biological Product Permit. This information will be used to determine if the product may be brought into the U.S., or for approval of transit shipment of biological products move through the U.S. (9 CFR 104). **INSTRUCTIONS:** Submit an application for each product. If more space is needed, attach additional sheets and refer to item number. Enclose supporting documents.

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES, CENTER FOR VETERINARY BIOLOGICS

APPLICATION FOR
UNITED STATES VETERINARY BIOLOGICAL PRODUCT PERMIT

☐ INITIAL ☐ RENEWAL

USDA PERMITTEE NUMBER (LEAVE BLANK FOR INITIAL APPLICATIONS)

1. DATE SUBMITTED

2. TYPE OF APPLICATION

☐ RESEARCH AND EVALUATION *(Complete all items except 10 through 15)*
☐ GENERAL SALE AND DISTRIBUTION *(Complete all items except 6, 7, 8, 9, and 15)*
☐ TRANSIT SHIPMENT ONLY *(Complete all items except 9 through 14)*

3. NAME AND ADDRESS OF APPLICANT *(Include Number, Street or RFD Number, City, State, and ZIP Code)*

4. NAME AND ADDRESS OF PRODUCER

5. NAME OF PRODUCT (one only)

FOR EACH SHIPMENT OF SAME PRODUCT GIVE:

6. ESTIMATED ARRIVAL DATE | 7. ESTIMATED QUANTITY | 8. U.S. PORT OF ENTRY

3.1.2 The Permit for Distribution and Sale

An Example Permit for Distribution and Sale is shown in Appendix I. Note that the Permit title varies from the designation on the Form 2005, being "Distribution and Sale". This permit does not have an expiration date.

3.1.3 Eligibility for a Permit, and Important Restrictions

Each person making application to import veterinary biologics shall reside in or operate a business establishment in the United States. Under U.S. law, only domestically produced products may be issued a license; therefore, foreign produced product must be imported under a permit. The holder of the permit is a U.S. entity importing the foreign produced biologic for distribution and sale, and is legally responsible for compliance. In short, there are no foreign permittees, only foreign manufacturers.

There must be a "quarantine" facility in the United States where the serials of the permitted product are received and held until release by CVB Inspection and Compliance (IC); there must be a site contact there to let an inspector in with no notice.

Permits for Distribution and Sale are not issued from countries known to have exotic diseases. There have been rare exemptions.

Ingredients of animal origin must not be derived from Bovine Spongiform Encephalopathy (BSE) countries; the permittee must show this to be true.

If CVB IC is not able to inspect the site due to a U.S. State Department travel restriction and this is expected to be a long term situation, we can't issue the permit.

There may be a trade embargo: If there is a trade embargo the product cannot be imported and we will not issue a permit.

We do not allow conditional permits.

We do allow For Further Manufacture (FFM) as well as Final Use Product (FUP) permits.

3.1.4 General Requirements

Following is a very brief comparison of notable features of a license and a sale and distribution permit:

Domestically Produced Biologic	**Foreign Produced Biologic**
The Establishment or a person holds the license	U.S. entity or person holds the permit.
Each product gets an individual license.	Each product gets an individual permit (see CVB Notice 13-03).
Product is held on licensed premises until CVB release.	Product is held at approved U.S. location in "quarantine" until CVB release.
Manufacturing sites must be inspected prior to licensure and after licensure.	Foreign manufacturing site and U.S. quarantine site must be inspected prior to issuing the permit. After the permit is issued inspections are announced (foreign) and unannounced (U.S. site).
Apply with APHIS Forms 2001 and 2003	Apply with Form 2005
One Establishment Number covering all sites on the Establishment License	One or more Permit Numbers based on the foreign manufacturing site location; Permit Numbers include a letter, e.g., 1000A
Establishments hold establishment and product licenses.	The manufacturer does not have a license or a permit.
Risk Assessments are required for biotechnology products, new agents (live), and as required by the situation.	Same as for a license; and a SIF for the Importation of Veterinary Biological Products into the United States and Risk Assessment are needed based on the risk of introducing unwanted agents into the U.S.
Master Seeds and Cells must be approved.	Master Seeds and Cells must be approved.
Key studies and activities (e.g., efficacy, field safety, inactivation validation, potency test validation, prelicense serials); Outline, Labels, Plots, Blueprints, Legends, etc.	Same as for licenses with the exception of efficacy, field safety are conducted in the U.S.

Upon receipt of an application for a sale and distribution permit, the Reviewer obtains a Permittee Number and a Product Code and proceeds as for a license.

3.1.4.1 Summary Information Format (SIF) and Risk Assessment (RA)

As noted above, a SIF for the Importation of Veterinary Biological Products into the United States specific to imported biologicals is required:

This SIF identifies the information regarding the facilities, reagents, production procedures, and testing procedures that should be evaluated when United States officials must prepare risk analyses for proposals to import veterinary biological products into the United States. The purpose of this SIF is to provide Veterinary Services with the information needed to conduct risk analyses for proposals to import veterinary biological products from countries that represent a risk for the introduction of foreign animal disease into the United States.

Note 1: This SIF is also required for…

A U.S. Veterinary Biological Product License Application for a product being produced from a Master Seed or Master Cell imported under a U.S. Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors (see 9 CFR 122.2).

3.1.4.2 Master Seed (MS) and Cell (MCS) Approval:

To import MS and MCS, the firm must have the necessary NIES permits for entry into the United States for confirmatory testing. For application, the firm uses Forms 16-3 and 16-7, respectively. Recombinant MS requires Forms 16-3 and 16-7. The NIES may require testing at FADDL for entry into the United States. This would be expected to occur only rarely due to the issues outlined in 3.1.3. There will be fees for any testing done at FADDL.

Note 1: The NIES may inspect the recipient before it issues an import permit for an agent or vector.

Note 2: Even with the NIES permit issued, these items may not be moved into a non-separate and apart research and development area (i.e., a biologics production area) without CVB approval. The CVB may require additional information and testing for such movement.

Note 3: If the item is a biologic as well as a live agent or vector, the importer may only need a CVB permit for importation in to the United States.
Otherwise, the requirements for MS and MCS approval are as for a license.

3.1.4.3 Efficacy: Same as for licenses; with CVB approval, these may, with justification and documentation as necessary, be conducted outside the United States. This decision will vary according to product and situation. The Reviewer should consult with the applicable Section Leader.

3.1.4.4 Field Safety: Generally, field safety studies are conducted as for licenses and must be done in the United States. There have been exceptions in special cases. The Reviewer should consult with the applicable Section Leader.

3.1.4.5 Withdrawal Time (Adjuvant Safety) Studies: Any required studies must be conducted in the U.S.

3.1.4.6 Diagnostic Kit Field Evaluation must be done in the United States.

3.1.4.7 The Outline of Production: Same as for licensed products.

3.1.4.8 Labeling: Same as for Licensed Products, and…

The use of labeling approved by the CVB is limited to the biological product imported by the Permittee (i.e., limited to use in the U. S.). When submitting labels for approval, Permittees must add to the Exceptions section of the APHIS Form 2015, "This label is to be used only on containers and packaging imported into the United States. Use of this label on serials (or portions thereof) not imported into the United States is prohibited." (VSM 800.101, Section IV.B.8, and Reviewers' Manual Chapter 4.2). This statement is intended to remind foreign manufacturers they are not to use labels identifying the product as licensed by the USDA on any containers of product distributed in countries other than the U. S. The Veterinary Permit Number implies not only that the product is licensed (permitted) in the United States, but also that the individual serial (or portion thereof) has undergone serial release by APHIS. Only those containers that have been imported into the United States may bear this assurance.

3.1.4.9 Inspections: Same as for licenses, and…

Both the U.S. and foreign sites must be inspected.

A minimum of 3 months' notice (subject to change) is needed for the pre-permit inspection; more than one inspection may be required.

All foreign site inspections are requested by the CVB.

Unannounced quarantine site inspections occur only after the permit is issued.

All expenses are paid by the permittee in advance (foreign site only); cost includes salary and travel expenses: U.S. law does not permit us to allocate funds for non-domestic inspections.

Frequencies of post-permit inspections are determined by risk: Usually 1 year after permitting, then every 2-3 years. If the manufacturer refuses, the CVB can stop sale of the product.

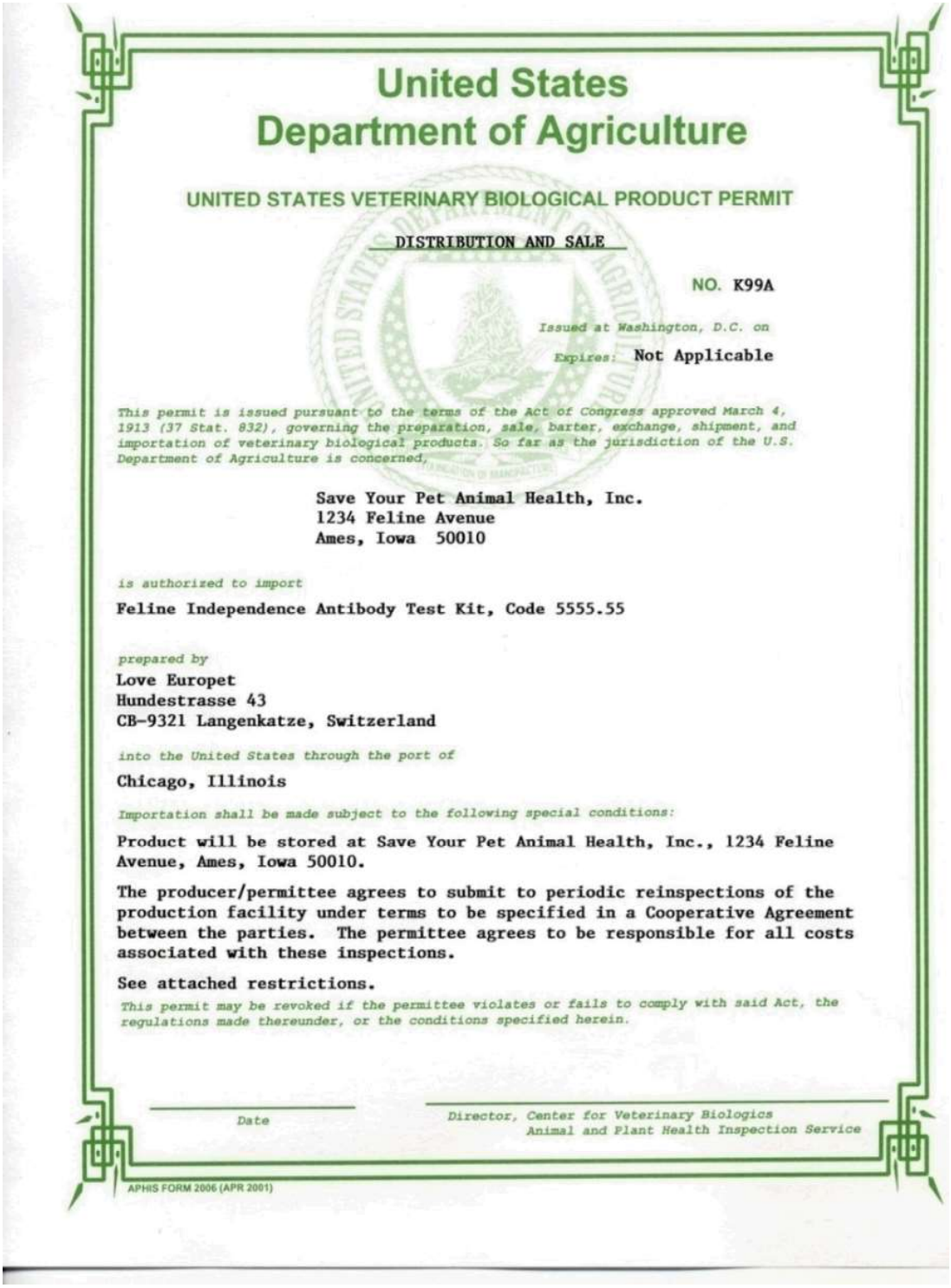
3.1.4.10 Restrictions

Each shipment of biological product distributed and sold under the permit must be accompanied by an original certificate endorsed by a veterinarian of the government agency responsible for animal health (a "competent regulatory authority"), of the country of manufacture. If this is not possible, there must be other assurances acceptable to APHIS certifying that all ingredients of animal origin used to produce this product were obtained from ruminants from the United States or countries acceptable to the CVB.

Ingredients of animal origin are sourced from the United States or countries considered free, low risk, or not affected with foreign animal diseases of concern and with negligible or controlled risk of bovine spongiform encephalopathy (BSE), according to APHIS' Animal Disease Status designations. Similarly, during the manufacturing process, the manufacturing facility does not receive, store, or process any ingredients of ruminant origin from countries not deemed acceptable to the CVB, and complies with all other provisions of 9 CFR 113.53.

See also 9 CFR 113.53 and Reviewers' Manual Chapter 2.2.1, License Restrictions.

APPENDIX I: Example Permit for Distribution and Sale



United States
Department of Agriculture

UNITED STATES VETERINARY BIOLOGICAL PRODUCT PERMIT

DISTRIBUTION AND SALE

NO. K99A

Issued at Washington, D.C. on

Expires: Not Applicable

This permit is issued pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of veterinary biological products. So far as the jurisdiction of the U.S. Department of Agriculture is concerned,

Save Your Pet Animal Health, Inc.
1234 Feline Avenue
Ames, Iowa 50010

is authorized to import

Feline Independence Antibody Test Kit, Code 5555.55

prepared by

Love Europet
Hundestrasse 43
CB-9321 Langenkatze, Switzerland

into the United States through the port of

Chicago, Illinois

Importation shall be made subject to the following special conditions:

Product will be stored at Save Your Pet Animal Health, Inc., 1234 Feline Avenue, Ames, Iowa 50010.

The producer/permittee agrees to submit to periodic reinspections of the production facility under terms to be specified in a Cooperative Agreement between the parties. The permittee agrees to be responsible for all costs associated with these inspections.

See attached restrictions.

This permit may be revoked if the permittee violates or fails to comply with said Act, the regulations made thereunder, or the conditions specified herein.

Date

Director, Center for Veterinary Biologics
Animal and Plant Health Inspection Service

APHIS FORM 2006 (APR 2001)