ROSEMARY SIFFORD
Digitally signed by ROSEMARY SIFFORD
Date: 2021.12.12 06:51:29 -05'00'

VS Memorandum (VSM) 800.52

Export Certificates and Certificates of Licensing and Inspection for Animal Biological Products

1. Purpose and Background

The Center for Veterinary Biologics (CVB) may furnish export certificates for products prepared in accordance with the Virus-Serum-Toxin Act and regulations pursuant to the Act. This memorandum describes the procedures for processing two types of export certifications: Official Export Certificate for Animal Biologics Products, APHIS Form 2017, (based on individual batches); and Certificates of Licensing and Inspection, APHIS Forms 2046, 2046S, 2047, and 2047S (based on the product licensed).

2. Document Status

A. Issue Date: 12/09/2021.

B. This document replaces Veterinary Services Memorandum 800.52, dated June 27, 2018.

3. Reason for Reissuance

VS is updating this memorandum to clarify the process used for hard copy submissions and electronic submissions via the National Centers for Animal Health (NCAH) Portal for export documents.

4. Authority and References

A. Authorities

- Virus-Serum-Toxin Act (21 U.S.C. 151-159)
- 7 CFR 371.4
- 9 CFR 112.2(e)
- 9 CFR 113.53

B. References

- CVB Biologics Forms: Links to current APHIS forms are provided on the CVB Biologics Forms site for ease of access.
- Office of Management and Budget (OMB) Form Disclosure
- All CVB's forms are part of the OMB information collection package 0579-0013. All information collections are required to go through periodic renewals

under the Paperwork Reduction Act, 44 U.S.C. 3501 et. seq. During this renewal cycle, OMB reviews the forms to ensure they meet the Act's standards and are within the bounds of the information collection description. The form's expiration date is based on the renewal cycle and is unrelated to the information in the certificate.

C. Definitions

1) Export Certificate for Animal Biologics (APHIS Form 2017)- A serial or serials (batches)-specific certificate intended for shipment of APHIS-released serials. It certifies that products have been manufactured under a U.S. veterinary biologics license as prescribed under the Virus-Serum-Toxin Act and regulations prescribed under this Act. Further, it indicates that at the time of the certificate issuance, the product or products are suitable and freely marketed under the conditions stipulated in the license.

2) **Certificate of Licensing and Inspection** (APHIS Forms 2046, 2047, 2046-S, and 2047-S - A product license-specific certificate intended for the registration of U.S. veterinary licensed products. It certifies that products are manufactured under a U.S. veterinary biologics license as prescribed under the Virus-Serum-Toxin Act and additional regulations prescribed under this Act. Further, it indicates that at the time of the certificate issuance, the product or products are suitable and freely marketed under the conditions stipulated in the license.

3) **Attestations of good manufacturing practices** - A certification that the U.S. Veterinary Licensed product complies with the good manufacturing practices under a U.S. veterinary biologics license and prescribed under the Virus-Serum-Toxin Act.

4) **Ingredients of Animal Origin Certificate** - A certification that indicates the products comply with the requirements of 9 CFR 113.53 and that by meeting all USDA requirements for the use of ingredients of animal origin, the establishment will produce licensed veterinary biological products that present negligible risk for the transmission of transmissible spongiform encephalopathy (TSEs), specifically bovine spongiform encephalopathy, and other animal diseases foreign to the United States.

5. Audience

VS employees and members of the biologics industry.

6. Guidance

A. Procedures for APHIS Form 2017, Official Export Certificate for Animal Biological Products

1) Portal Submissions

a. NCAH Portal users that meet the following criteria have the opportunity to submit APHIS Form 2017 through the NCAH Portal. Users must:

1. Have an USDA eAuthentication Verified Identity account.

2. Have an APHIS 2007 form on file with CVB.

3. Have their eAuthentication username entered into CVB's Licensing, Serial Release, and Testing Information Service (LSRTIS).

4. Be assigned to an active Establishment site in LSRTIS.

5. Have a role of Export Contact, Liaison, and/or Alternate Liaison assigned to them in LSRTIS.

b. The NCAH Portal can be found here. There are also links available on the CVB NCAH Portal Guidance webpage. Please follow the NCAH Portal User guidelines and training videos for the submission of certificates.

2) Hard Copy Submissions

The licensee can also submit an original paper copy of the completed APHIS Form 2017, Official Export Certificate for Animal Biological Products, to:

Center for Veterinary Biologics
Inspection and Compliance
1920 Dayton Ave
Ames, IA 50010-8197

a. *Block 1.* Enter the recipient (consignee)'s name and address.

b. *Block 2.* Enter the shipper (consignor)'s name and address.

c. *Block 3.* Enter the USDA product code. If more than one product is listed, list in numerical order based on product code.

d. *Block 4.* Enter the True Name of the product that corresponds to the product code; do not abbreviate or add additional details to the True Name. If the destination country requires trade names, list them here, after the True Name. The trade name option is available in hard copy submissions and upon request in Portal Submissions.

e. *Block 5.* Enter the serial number that corresponds to the product code and product name.

f. *Block 6.* Enter the number of containers being exported.

g. *Block 7.* Enter the size of the containers being exported that is most applicable (doses or milliliter). In the case of diagnostic test kits, choose unit as the container size.

h. *Block 8.* Enter the expiration date that corresponds to the serial number listed in block 5.

i. *Block 9.* Enter the Veterinary Biologics Establishment License number for the product listed in block 3.

You may list more than one biological product from the same establishment number on each form but can only designate one destination. Fill out Blocks 3 through 9 for each product/serial number listed. Draw a diagonal line through unused space in blocks 3 through 9.

This information must correspond to the information submitted to CVB on an APHIS Form 2008, Veterinary Biologics Production and Test Report.

Blocks 10 and 11 are optional fields. These fields detail the number of shipping boxes and shipping marks (storage temperature or details specific to the shipment).

Do not include or append additional information to this form and do not submit handwritten forms.

3) CVB Processing. Compare the completed APHIS Form 2017 with the APHIS Form 2008 submitted for the serials listed on the export certificate.

a. Satisfactory submissions. If there are no discrepancies, CVB numbers, dates, signs, and embosses the form with the official veterinary biologics seal.

b. Unsatisfactory submissions. If CVB finds discrepancies, it returns the form for correction. Common reasons for returned submissions are serials not released

by CVB for sale and distribution, or incorrect information.

c. Disposition. After completion, CVB retains copies and returns the original to the licensee.

B. Procedures for APHIS Forms 2046, 2046s, 2047, And 2047s, Certificates of Licensing and Inspection

1) Types - The submission of Certificates of Licensing and Inspection (CLI) can be conducted through the NCAH Portal or through hard copy submissions.

2) NCAH Portal Submissions - English and Spanish language variations of the CLIs for restricted or non-restricted product are available via the NCAH Portal. NCAH Portal users must meet the same criteria listed in Section 6.A.1)a.

Follow the NCAH Portal User Guides and training videos to submit electronic certificates. Using the table below, select the appropriate form to comply with requirements of the country of destination. If you need a Spanish-language certificate, also submit an accurate, complete English translation for reference.

APHIS Form	Product License	Language
2046	Unrestricted	English
2046S	Unrestricted	Spanish
2047	Restricted	English
2047S	Restricted	Spanish

3) Hard Copy CLI submissions - Required Information. Typically, certificates reflect the most current establishment and product license information. If you prefer original licensing information, request this preference in a cover letter accompanying the hard copy certificates. Only paper copy submissions can list the original licensing information in the CLI (block 3 and block 7).

a. *Block 1.* Enter the manufacturer's name and address. You may include additional descriptions such as "Formerly Known As", "Manufacturing Plant", or "Doing Business as Firm X."

b. *Block 2.* Enter the U.S. Veterinary License Number (Establishment License).

c. *Block 3.* Enter the date CVB issued the Establishment License.

d. *Block 4.* Enter the True Name of the product as noted on the product license.

Do not abbreviate or add additional information. Spanish true names must be entered as listed on labels filed with CVB.

e. *Block 5.* Enter the manufacturer's trade name. The trade name must appear exactly as on an approved label that is on file with CVB. Provide the assigned APHIS label number in the accompanying cover letter that contains the listed trade name. If this field is not used, draw a diagonal line through block 5.

f. *Block 6.* Enter the USDA product code number, as listed on the product license.

g. *Block 7.* Enter the date the CVB issued the product license.

h. *APHIS Forms 2047 and 2047S require additional information*. The restrictions included on the certificate must appear exactly as listed on the product license. List only one biological product on each form for products with restrictions. Draw a diagonal line through unused space in blocks 4 through 7.

4) Additional or Appended Information

a. List a destination country in the empty space next to the signature block. Do not list any other information.

b. If the destination country requires additional details such as dose composition information or copies of labels or circulars, append these to the certificate. The information appended for certification must be already available in Outlines of Production or Special Outlines on file with CVB and it must be current. Product labels or circulars must also include their corresponding APHIS label number. Use only labels in "Active" status. You may append diluent labels with the required information on the page.

c. Appended information must include page numbers formatted to include "Page X of Y," to ensure the that CVB can identify the submission if pages are separated. This information must be consistent for all pages of the submission.

d. Include specific requests, such as statements regarding ingredients of animal origin and/or attestations of manufacturing practices to comply with the destination country's registration requirements, in a cover letter. Submit the request and completed certificates to CVB-Inspection and Compliance at the address indicated in Section A.2) of this memorandum. Submit attestations and ingredients of animal origin statements as CLI-appended documents. However, you may request certification for these as standalone documents.

e. A cover letter submitted with the certificate informs CVB of specific requests and details in reference to the submission. Submitters may also include shipping labels to provide alternative and traceable returns of certificates. Specify the certificates to be returned with the specific shipping label. Do not submit handwritten forms or double-sided pages.

5) CVB Processing

a. CVB assigns a certificate number and signs, dates, and embosses the requested pages with the official veterinary biologics seal on certificates verified by information in CVB files. CVB places the embossed seal and the certificate number on each single page certificate and on multi-page certificates but will only sign those pages bearing a signature line. All export documents reviewed and found sufficient, regardless of submission method, will be printed and processed. CVB returns a hard copy to the submitter or destination indicated in the request.

b. The NCAH Portal provides the status of electronic submissions only. An email will be sent with updates for completed NCAH Portal submissions. The CVB response files in the NCAH Portal provide copies of the processed certificate in a portable document format (pdf) file. CVB maintains electronic copies of portal submissions. Completed submissions will be visible in the NCAH Portal for up to sixty (60) days past the date of completion.

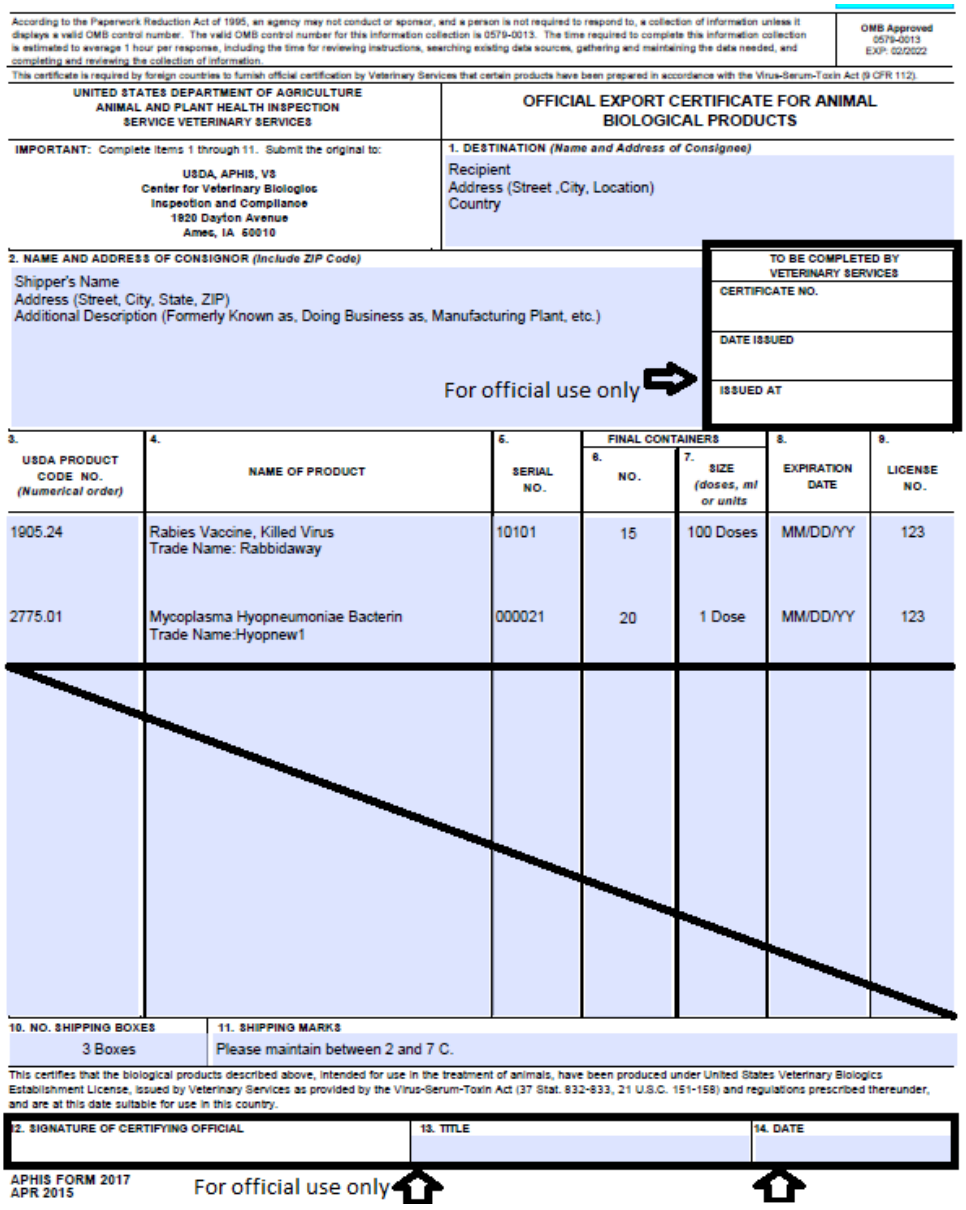
c. For hard copy submissions, CVB retains a copy of the signed certificate for its files and returns the original to the requester.

7. Implementation/Applicability

Updated policy in this memorandum is effective immediately.

Appendices

Appendix I
Official Export Certificate for Animal Biological Products



According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0013. The time required to complete this information collection is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0013
EXP: 02/2022

This certificate is required by foreign countries to furnish official certification by Veterinary Services that certain products have been prepared in accordance with the Virus-Serum-Toxin Act (9 CFR 112).

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES

OFFICIAL EXPORT CERTIFICATE FOR ANIMAL BIOLOGICAL PRODUCTS

IMPORTANT: Complete items 1 through 11. Submit the original to:

USDA, APHIS, VS
Center for Veterinary Biologics
Inspection and Compliance
1920 Dayton Avenue
Ames, IA 50010

1. DESTINATION *(Name and Address of Consignee)*
Recipient
Address (Street ,City, Location)
Country

2. NAME AND ADDRESS OF CONSIGNOR *(Include ZIP Code)*
Shipper's Name
Address (Street, City, State, ZIP)
Additional Description (Formerly Known as, Doing Business as, Manufacturing Plant, etc.)

For official use only

TO BE COMPLETED BY VETERINARY SERVICES
CERTIFICATE NO.
DATE ISSUED
ISSUED AT

3. USDA PRODUCT CODE NO. *(Numerical order)*	4. NAME OF PRODUCT	5. SERIAL NO.	FINAL CONTAINERS 6. NO.	7. SIZE *(doses, ml or units*	8. EXPIRATION DATE	9. LICENSE NO.
1905.24	Rabies Vaccine, Killed Virus Trade Name: Rabbidaway	10101	15	100 Doses	MM/DD/YY	123
2775.01	Mycoplasma Hyopneumoniae Bacterin Trade Name:Hyopnew1	000021	20	1 Dose	MM/DD/YY	123

10. NO. SHIPPING BOXES	11. SHIPPING MARKS
3 Boxes	Please maintain between 2 and 7 C.

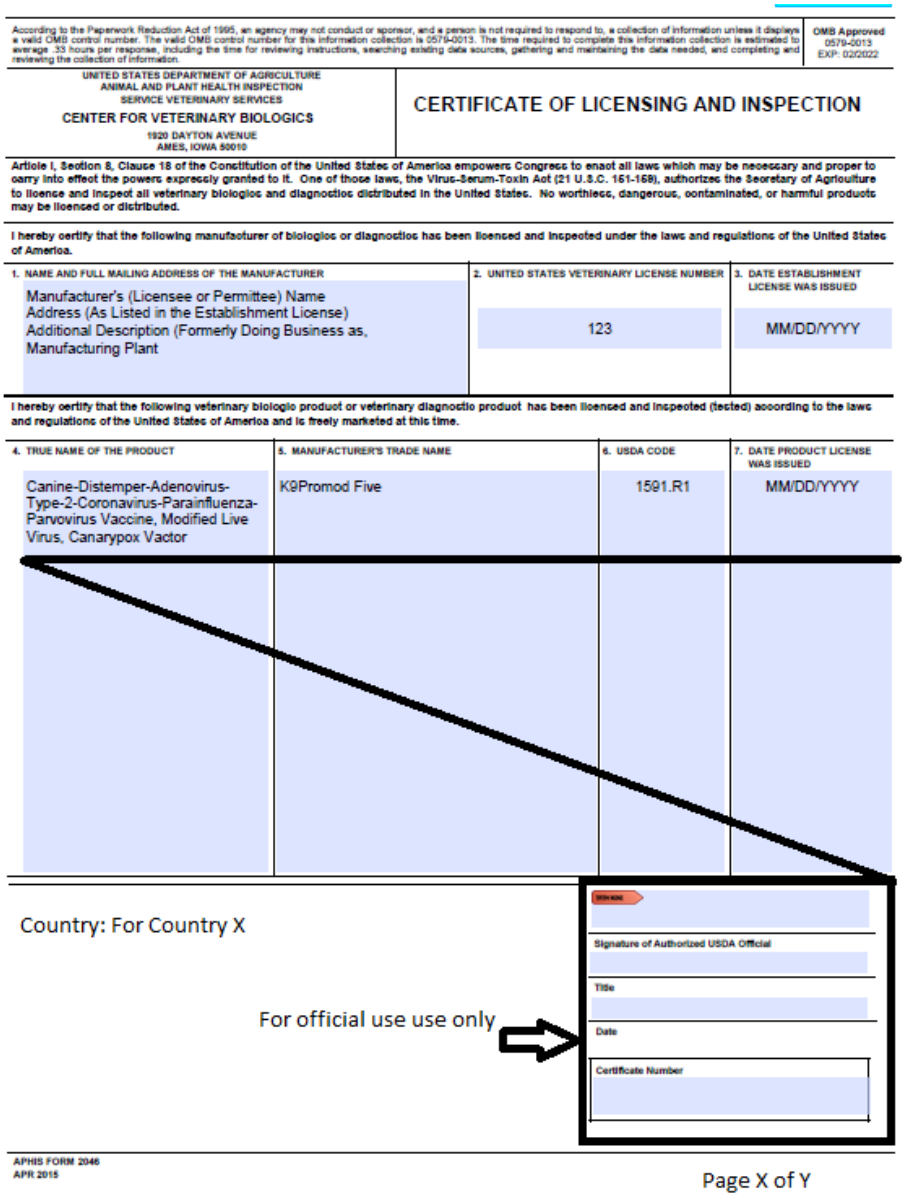
This certifies that the biological products described above, intended for use in the treatment of animals, have been produced under United States Veterinary Biologics Establishment License, issued by Veterinary Services as provided by the Virus-Serum-Toxin Act (37 Stat. 832-833, 21 U.S.C. 151-158) and regulations prescribed thereunder, and are at this date suitable for use in this country.

12. SIGNATURE OF CERTIFYING OFFICIAL	13. TITLE	14. DATE

APHIS FORM 2017
APR 2015

For official use only

Appendix II
Certificate of Licensing and Inspection (Non-Restricted Product)



According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0013. The time required to complete this information collection is estimated to average .33 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved 0579-0013 EXP: 02/2022

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES
CENTER FOR VETERINARY BIOLOGICS
1920 DAYTON AVENUE
AMES, IOWA 50010

CERTIFICATE OF LICENSING AND INSPECTION

Article I, Section 8, Clause 18 of the Constitution of the United States of America empowers Congress to enact all laws which may be necessary and proper to carry into effect the powers expressly granted to it. One of those laws, the Virus-Serum-Toxin Act (21 U.S.C. 151-159), authorizes the Secretary of Agriculture to license and inspect all veterinary biologics and diagnostics distributed in the United States. No worthless, dangerous, contaminated, or harmful products may be licensed or distributed.

I hereby certify that the following manufacturer of biologics or diagnostics has been licensed and inspected under the laws and regulations of the United States of America.

1. NAME AND FULL MAILING ADDRESS OF THE MANUFACTURER	2. UNITED STATES VETERINARY LICENSE NUMBER	3. DATE ESTABLISHMENT LICENSE WAS ISSUED
Manufacturer's (Licensee or Permittee) Name Address (As Listed in the Establishment License) Additional Description (Formerly Doing Business as, Manufacturing Plant	123	MM/DD/YYYY

I hereby certify that the following veterinary biologic product or veterinary diagnostic product has been licensed and inspected (tested) according to the laws and regulations of the United States of America and is freely marketed at this time.

4. TRUE NAME OF THE PRODUCT	5. MANUFACTURER'S TRADE NAME	6. USDA CODE	7. DATE PRODUCT LICENSE WAS ISSUED
Canine-Distemper-Adenovirus-Type-2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live Virus, Canarypox Vactor	K9Promod Five	1501.R1	MM/DD/YYYY

Country: For Country X

For official use use only

Signature of Authorized USDA Official

Title

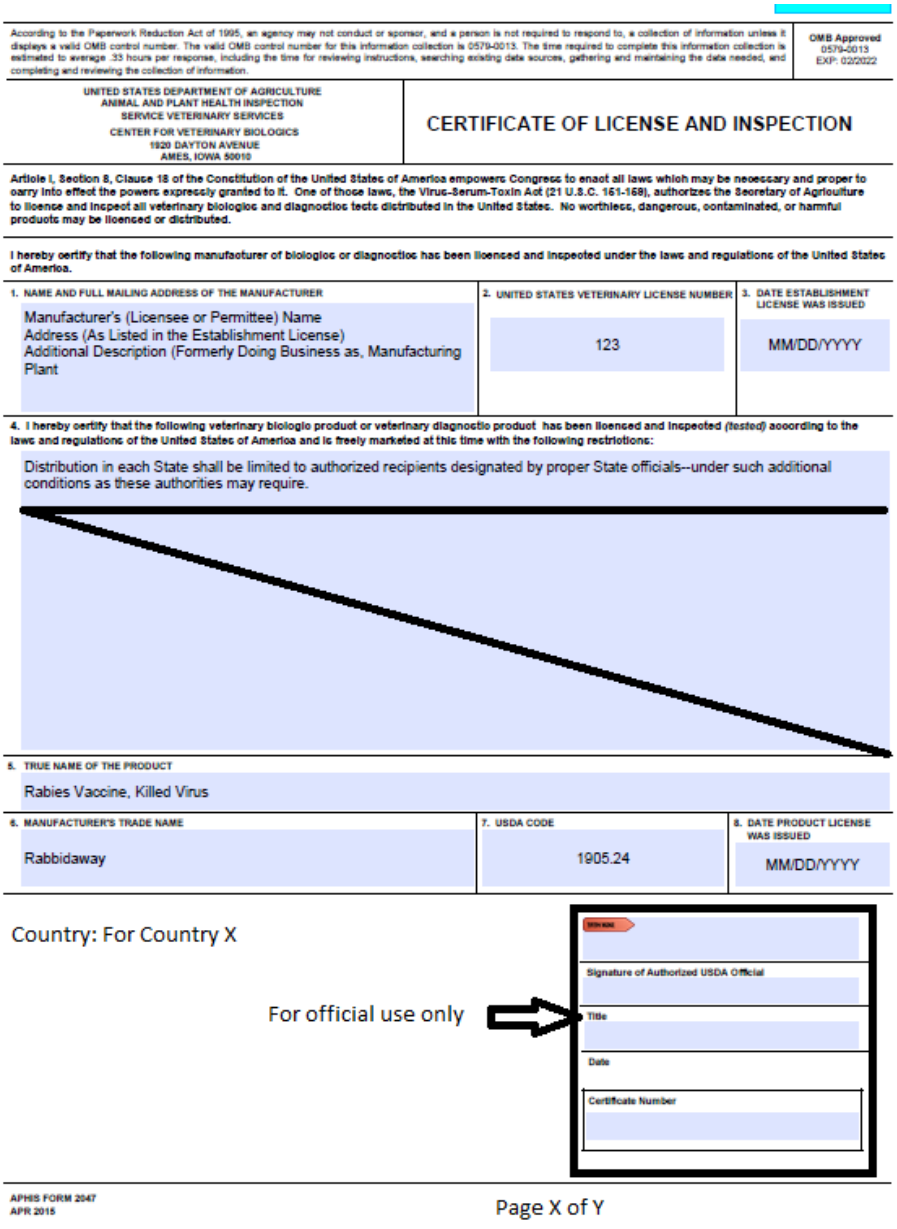
Date

Certificate Number

APHIS FORM 2046
APR 2015

Page X of Y

Appendix III
Certificate of Licensing and Inspection (Restricted Product)



According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0013. The time required to complete this information collection is estimated to average .33 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved 0579-0013 EXP: 02/2022

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION
SERVICE VETERINARY SERVICES
CENTER FOR VETERINARY BIOLOGICS
1920 DAYTON AVENUE
AMES, IOWA 50010

CERTIFICATE OF LICENSE AND INSPECTION

Article I, Section 8, Clause 18 of the Constitution of the United States of America empowers Congress to enact all laws which may be necessary and proper to carry into effect the powers expressly granted to it. One of those laws, the Virus-Serum-Toxin Act (21 U.S.C. 151-158), authorizes the Secretary of Agriculture to license and inspect all veterinary biologics and diagnostics tests distributed in the United States. No worthless, dangerous, contaminated, or harmful products may be licensed or distributed.

I hereby certify that the following manufacturer of biologics or diagnostics has been licensed and inspected under the laws and regulations of the United States of America.

1. NAME AND FULL MAILING ADDRESS OF THE MANUFACTURER	2. UNITED STATES VETERINARY LICENSE NUMBER	3. DATE ESTABLISHMENT LICENSE WAS ISSUED
Manufacturer's (Licensee or Permittee) Name Address (As Listed in the Establishment License) Additional Description (Formerly Doing Business as, Manufacturing Plant	123	MM/DD/YYYY

4. I hereby certify that the following veterinary biologic product or veterinary diagnostic product has been licensed and inspected *(tested)* according to the laws and regulations of the United States of America and is freely marketed at this time with the following restrictions:

Distribution in each State shall be limited to authorized recipients designated by proper State officials--under such additional conditions as these authorities may require.

5. TRUE NAME OF THE PRODUCT

Rabies Vaccine, Killed Virus

6. MANUFACTURER'S TRADE NAME	7. USDA CODE	8. DATE PRODUCT LICENSE WAS ISSUED
Rabbidaway	1905.24	MM/DD/YYYY

Country: For Country X

For official use only

Signature of Authorized USDA Official

Title

Date

Certificate Number

APHIS FORM 2047
APR 2015

Page X of Y