USDA
United States Department of Agriculture

VETERINARY SERVICES MEMORANDUM NO. 800.52

Animal and Plant Health Inspection Service

Veterinary Services

1400 Independence Ave, SW

Washington, DC 20250

To: Veterinary Services (VS) Leadership Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

From: for Jack A. Shere
Deputy Administrator

BURKE HEALEY Digitally signed by BURKE HEALEY
Date: 2018.06.27 18:09:56 -04'00'

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

I. PURPOSE

This memorandum describes the procedures for handling APHIS Form 2017, Official Export Certificate for Animal Biologics Products, and APHIS Forms 2046, 2046S, 2047, and 2047S, Certificates of Licensing and Inspection. The Centers for Veterinary Biologics (CVB) provides certification to licensees under title 9, *Code of Federal Regulations*, (9 CFR), section 112.2(e). VS is updating this memorandum to include the option of electronic submission via the National Centers for Animal Health (NCAH) portal for export documents. APHIS posts current forms on the APHIS Veterinary Biologics Web site at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/sa_bio_forms/ct_vb_forms.

II. CANCELLATION

This memorandum cancels VS Memorandum No. 800.52, dated March 19, 2015.

III. PROCEDURES FOR APHIS FORM 2017, OFFICIAL EXPORT CERTIFICATE FOR ANIMAL BIOLOGICAL PRODUCTS

A. Preparation and Submission

1. NCAH Portal users with USDA Level 2 eAuthentication and an APHIS Form 2007 on file with the CVB can submit APHIS Form 2017 through the portal. Portal users are only eligible to submit certificates from assigned establishments. The NCAH Portal Web site can be found at https://ncahappspub.aphis.usda.gov/NCAHPortal/public/.

2. The licensee can also submit an original paper copy of the completed APHIS Form 2017 to:

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

B. Required Information

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

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

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

4. *Block 4*. Enter the True Name of the product that corresponds to the product code; do not abbreviate. If the destination country requires trade names, list them here, after the True Name. Only hard copy submissions can list the trade name.

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

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

7. *Block 7*. Enter the applicable (doses or milliliter) size of the containers being exported. For diagnostic test kits, choose unit as the container size.

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

9. *Block 9*. Enter the veterinary biologics Establishment License number for the product listed in block 3.

You may list more than one biological product 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 the CVB on APHIS Form 2008, Veterinary Biologics Production and Test Report.

You must fill out Blocks 10 and 11, regarding the number of shipping boxes and shipping marks, before CVB review.

Do not include or append additional information to this form.

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

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

2. Unsatisfactory submissions. If the CVB finds discrepancies, we return the form for correction. (Common reasons for returned submissions are: serials not released by the CVB for sale and distribution, or incorrect information)

3. Disposition. After completion, the CVB retains a photocopy and returns the original to the licensee.

IV. PROCEDURES FOR APHIS FORMS 2046, 2046S, 2047, AND 2047S, CERTIFICATES OF LICENSING AND INSPECTION

A. Preparation and Submission. English and Spanish language variations of the Certificate of Licensing and Inspection (CLI) for restricted or non-restricted product are available via the NCAH Portal and also through hard copy submissions. Portal users are only eligible to submit certificates from assigned establishments. Follow the Portal user guidelines 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

B. 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 certificates. Only paper copy submissions can list the original licensing information in the CLI (block 3 and block 7). As an option, include a page detailing the original licensing information in the NCAH Portal submission.

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

2. *Block 2*. Enter the U.S. veterinary license number (Establishment License).

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

4. *Block 4*. Enter the True Name of the product, as noted on the product license. Do not abbreviate.

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

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

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

8. 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.

C. Additional or Appended Information

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

2. 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 current and already available in Outlines of Production or Special Outlines on file with the CVB. Product labels or circulars must also include their corresponding APHIS label number. NCAH Portal submissions with applicable appended labels must include the label number in the specified label field. Use only labels in "Active" status. You may append diluent labels with the required information on the page. However, do not enter the sterile diluent master label number in the NCAH Portal label field.

3. Appended information must include page numbers, formatted as "Page X of Y," to ensure that the CVB can identify the submission if pages are separated. This information must be consistent for all pages of the submission. The pages must be numbered from Page 2 of Y and forward. The system will create Page 1 of Y (the first page of the certificate).

4. 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 III.A. 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 in the NCAH Portal.

5. A cover letter submitted with the certificate informs the 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.

D. CVB Processing

1. The CVB assigns a certificate number, signs, dates, and embosses the requested pages with the official veterinary biologics seal on certificates verified by information in CVB files. The CVB places the embossed seal and the certificate number on each page of a multi-page certificate but will

sign only those pages bearing a signature line. All export documents reviewed and found sufficient, regardless of submission method, will be printed and processed. The CVB returns a hard copy to the submitter.

2. The NCAH Portal provides the current status of electronic submissions only via email with updates from completed submissions. The CVB response files in the NCAH Portal provide copies of the certificate in a portable document format (pdf) file.

   For hard copy submissions, the CVB retains a copy of the signed certificate for its files and returns the original to the requester. The CVB maintains electronic copies of portal submissions. Completed submissions will be visible in the NCAH Portal for up to 60 days.

V. IMPLEMENTATION/APPLICABILITY

This guidance is effective upon publication and applies to all documents submitted afterward.

Appendices

Appendix I
Official Export Certificate for Animal Biological Products

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

FORM APPROVED OMB NO. 0579-0013

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

OFFICIAL EXPORT CERTIFICATE
FOR ANIMAL BIOLOGICAL PRODUCTS

According to the Paperwork Reduction Act of 1995, no persons are 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 30 minutes 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.

IMPORTANT: Complete items 1 thru 11. Submit an 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
111 Road St.
City, Stte, Location
Country

2. NAME AND ADDRESS OF CONSIGNOR (Include Zip Code)
Shipper's Name
222 Street Rd.
City, State, ZIP
Country

Trade name may be added to meet the requirements of importing country.

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

3. PRODUCT CODE NO. (Numerical order)	4. NAME OF PRODUCT	5. SERIAL NO.	FINAL CONTAINERS 6. NO.	7. SIZE (cc, dose, test, or units)	8. EXPIRATION DATE	9. LICENSE NO.
1905.24	Rabies Vaccine, Killed Virus Trade Name: Rabidaway	10101	15	100 Doses	MM/DD/YYYY	123
2775.01	Mycoplasma Hyopneumoniae Bacterin	000021	20	1 ML	MM/DD/YYYY	123
2775.01	Mycoplasma Hyopneumoniae Bacterin	000022	25	10 ML	MM/DD/YYYY	123

10. NO. SHIPPING BOXES

11. SHIPPING MARKS

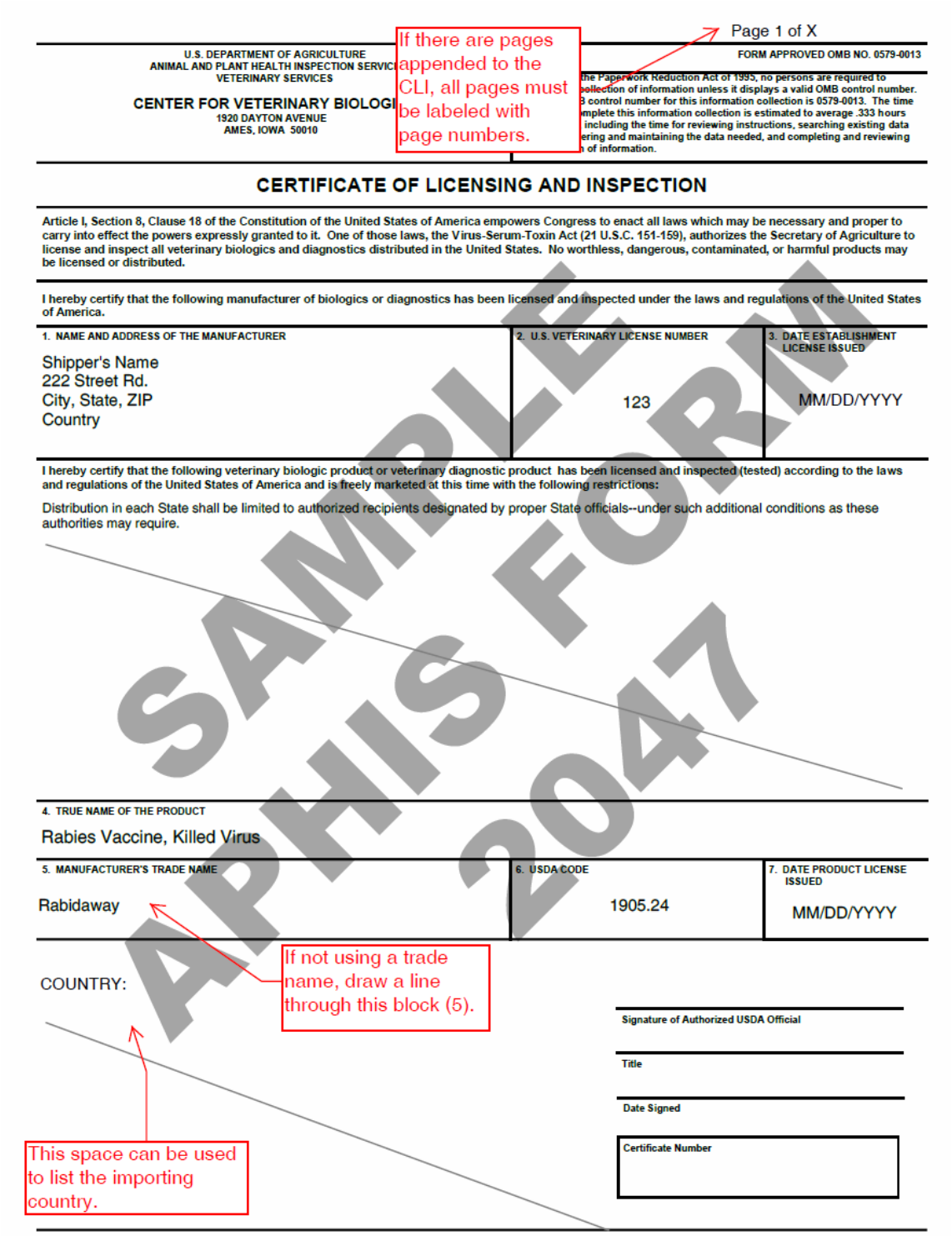
This certifies that the biological products described above, intended for use in the treatment of animals, have been produced under United States Veterinary Biologics Establishment License, issued by Veterinary Services as provided by the Virus-Serum-Toxin Act (37 Stat. 832-833, 21 U.S.C. 151-158) and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

12. SIGNATURE OF CERTIFYING OFFICIAL

13. TITLE

14. DATE

Appendix II
Certificate of Licensing and Inspection



Page 1 of X

If there are pages appended to the CLI, all pages must be labeled with page numbers.

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

CENTER FOR VETERINARY BIOLOGI
1920 DAYTON AVENUE
AMES, IOWA 50010

FORM APPROVED OMB NO. 0579-0013

...he Paperwork Reduction Act of 1995, no persons are required to ...ollection of information unless it displays a valid OMB control number. ...3 control number for this information collection is 0579-0013. The time ...mplete this information collection is estimated to average .333 hours ... including the time for reviewing instructions, searching existing data ...ering and maintaining the data needed, and completing and reviewing ...n of information.

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 ADDRESS OF THE MANUFACTURER	2. U.S. VETERINARY LICENSE NUMBER	3. DATE ESTABLISHMENT LICENSE ISSUED
Shipper's Name 222 Street Rd. City, State, ZIP Country	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 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.

SAMPLE APHIS FORM 2047

4. TRUE NAME OF THE PRODUCT
Rabies Vaccine, Killed Virus

5. MANUFACTURER'S TRADE NAME	6. USDA CODE	7. DATE PRODUCT LICENSE ISSUED
Rabidaway	1905.24	MM/DD/YYYY

If not using a trade name, draw a line through this block (5).

COUNTRY:

This space can be used to list the importing country.

Signature of Authorized USDA Official

Title

Date Signed

Certificate Number