VETERINARY SERVICES MEMORANDUM NO. 800.52

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

From: Jack A. Shere
       Deputy Administrator

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 Biological 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 recipient (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.
### 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

<table>
<thead>
<tr>
<th>FIELD</th>
<th>INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. DESTINATION (Name and Address of Consignee)</td>
<td>Recipient 111 Road St. City, State, Location Country</td>
</tr>
<tr>
<td>2. NAME AND ADDRESS OF CONSIGNOR (Include Zip Code)</td>
<td>Shipper's Name 222 Street Rd. City, State, ZIP Country</td>
</tr>
<tr>
<td>3. PRODUCT CODE NO. (Numerical order)</td>
<td>Rabies Vaccine, Killed Virus Trade Name Rabidaway</td>
</tr>
<tr>
<td></td>
<td>Mycoplasma Hyopneumoniae Bacterin</td>
</tr>
<tr>
<td></td>
<td>Mycoplasma Hyopneumoniae Bacterin</td>
</tr>
<tr>
<td>5. SERIAL NO.</td>
<td>10101 15 100 Doses MM/DD/YYYY 123</td>
</tr>
<tr>
<td></td>
<td>000021 20 1 ML MM/DD/YYYY 123</td>
</tr>
<tr>
<td></td>
<td>000022 25 10 ML MM/DD/YYYY 123</td>
</tr>
<tr>
<td>10. NO. SHIPPING BOXES</td>
<td></td>
</tr>
<tr>
<td>11. SHIPPING MARKS</td>
<td></td>
</tr>
<tr>
<td>12. SIGNATURE OF CERTIFYING OFFICIAL</td>
<td></td>
</tr>
<tr>
<td>13. TITLE</td>
<td></td>
</tr>
<tr>
<td>14. DATE</td>
<td></td>
</tr>
</tbody>
</table>
Appendix II
Certificate of Licensing and Inspection

<table>
<thead>
<tr>
<th>Certificate of Licensing and Inspection</th>
</tr>
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<tbody>
<tr>
<td>Article I, Section 3, Title 23 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. 155 et seq.), authorizes the Secretary of Agriculture to license and inspect all veterinary biologics and diagnostic products and to make the laws and regulations under which these laws and regulations are carried out.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name and Address of the Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shipper's Name</td>
</tr>
<tr>
<td>222 Street Rd.</td>
</tr>
<tr>
<td>City, State, ZIP</td>
</tr>
<tr>
<td>Country</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>U.S. Veterinary License Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>123</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Establish License Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>MM/DD/YYYY</td>
</tr>
</tbody>
</table>

I hereby certify that the following biologic product is licensed and inspected under the laws and regulations of the United States of America:

1. True Name of the Product
   Rabies Vaccine, Inactivated Virus

2. Manufacturer's Trade Name
   Rabidaway

3. Date Product License Issued
   1905.24

4. Signature of Authorized USDA Official
   [Signature]

5. Date Signed
   [Date]

Certificate Number

This space can be used to list the importing country.

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