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Veterinary Services Memorandum 800.67

Shipment of Experimental Veterinary Biological Products

1. Purpose and Background

   This memorandum establishes procedures to comply with title 9, *Code of Federal Regulations* (9 CFR), part 103.3, concerning shipment of all experimental veterinary biological products. The shipment of experimental veterinary biological products, including unlicensed products intended for licensure, within or from the United States for use in animals, is prohibited by the Virus-Serum-Toxin Act unless authorized under 9 CFR 103.3. To permit and encourage research and to allow required licensing activities, the Animal and Plant Health Inspection Service (APHIS) may authorize shipment of such products under certain conditions. For reference, 9 CFR 103.3 lists information APHIS requires to support requests to ship experimental veterinary biological products.

   Experimental products being shipped between different sites owned by the same firm and listed on their Establishment License do not require permission from the Center for Veterinary Biologics (CVB). CVB also does not need to provide permission to companies to ship materials to be used for hybridoma development in laboratory rodents.

2. Document Status

   A. Issue Date: This document is effective on the date reflected in the digital signature.

   B. This document replaces Veterinary Services Memorandum (VSM) 800.67 dated November 25, 2022, which is cancelled.

3. Reason for Reissuance

   This update clarifies the expectations for submitting final reports to CVB when products are administered in experimental studies.

4. Authority and References

   A. Authorities

   - 9 CFR 103.3
   - 9 CFR 104.4
   - 9 CFR part 113
   - 9 CFR 114.9

   B. References

   - VSM 800.50, Basic License Requirements and Guidelines for Submission of Materials in Support of Licensure

5. Audience

   VS employees and members of the biologics industry.

6. Guidance

   A. Experimental Product

      1) CVB considers experimental products to include any prelicense product up to and including those derived from Master Seeds and Master Cells, and any product or intermediate derived from them (excluding licensed product) if it will be used in animals.

      2) CVB considers unlicensed diagnostic products that fall under its authority to be experimental products.

      3) CVB considers shipment of licensed products with license restrictions for off-label use in animals to be experimental use of a product subject to CVB's approval.

   B. Requests for Authorizations

      Submit a request for authorization to ship experimental veterinary biological products, using an APHIS Form 2071, to:

      The Center for Veterinary Biologics
      Policy, Evaluation, and Licensing
      The National Centers for Animal Health
      1920 Dayton Avenue
      P.O. Box 844
      Ames, IA 50010

      Authorized National Centers for Animal Health (NCAH) Portal users should submit requests via the NCAH Portal. There are also links available on the CVB NCAH Portal Guidance webpage. Please follow the NCAH Portal User guidelines and training videos for submitting requests to ship experimental veterinary biological products.

   C. Information Required in Requests

      All pertinent information specified in 9 CFR 103.3 (subsections a-h), except the summary report of results, must accompany a request for authorization to ship experimental products for evaluation. See VSM 800.50, section IV.D, for guidance. To import experimental products, apply for a U.S. Veterinary Biological Product Permit for Research and Evaluation, and provide all pertinent information specified in 9 CFR 104.4. Guidance on the CVB import permit is available in the Import-Export section of the CVB website.

D. Letter of Permission from the Proper State or Foreign Animal Health Authorities

Include an identified address and study participant for each site using experimental product. Submit a copy of the permit or letter of permission from the proper state or foreign animal health authorities of each state or foreign country to which you will ship the product. Multi-site studies require permission from each participating state/country. The proper state animal health authority is usually the state veterinarian. Occasionally the state animal health authority is not a veterinarian but a designated commissioner. Some state or foreign authorities do not issue authorization letters, responding instead that they have no statutory authority to approve or disapprove the studies. When the regulatory authority involved received the opportunity to take a position but provided a neutral response, submit the neutral response to verify authorization was requested to ship experimental product. In the absence of State or foreign response, CVB may grant authorization to ship experimental product if it receives acceptable other documentation required for 9 CFR 103.3 shipments.

E. Description of the Product

1) *Products Pending Licensure.* If data from the study is to be used in support of a U.S. Veterinary Biological Product License, specify and describe the product according to the appropriate Outline of Production guidelines in 9 CFR 114.9 and identify the serial of product to be shipped.

2) *Products Not Intended for Licensure.* If data from the study is not intended to support licensure, provide the following information concerning the product:

a. The method of preparation.

b. The methods of testing and results.

c. The identity of the serial or serials.

F. Testing Experimental Serials

For each serial of experimental product, perform the following tests and submit a summary of the results on an APHIS Form 2008, the Veterinary Biologics Production and Test Report, or in another format acceptable to APHIS.

1) *Purity Tests*. All serials of experimental products must be tested for purity. Test results *must* be completed and found satisfactory for purity prior to shipment. On rare occasions, CVB may authorize shipments at risk prior to completion of purity testing, with the understanding that the results will be completed and satisfactory prior to use of the experimental product in animals. Conduct this testing as specified in pertinent parts of 9 CFR part 113 and/or filed Outlines of Production for studies

conducted in client-owned animals and studies intended to support licensure, where applicable, or as required by CVB. This testing is not required for diagnostic products.

2) *Safety Tests.* All serials of experimental products administered to client-owned animals in uncontained studies must have satisfactory safety test results. Conduct testing as specified in the pertinent parts of 9 CFR part 113, where applicable, or as CVB requires. For products administered to animals in contained studies where animals are housed in containment caging, laboratories, or facilities and are not client-owned, satisfactory safety testing results are recommended but not required. This will allow firms, at their discretion, to assess and address any safety issues in products with new or unique components. Safety testing is not required for diagnostic products. CVB may consider requests to waive safety testing of experimental veterinary biological products with acceptable justification.

3) *Additional Tests*. CVB may require additional testing, as needed.

G. Experimental Labels

1) 9 CFR 103.3 lists required elements of experimental labels. Include the following on the experimental labels:

a. The name, identification, or description of the product must clearly identify the agent, and whether it is live or killed.

1. The label must be clearly understandable to those who may come into contact with the product.

2. Do not use trade names, internal jargon, or other identifiers that do not disclose the composition and nature of the product.

b. Prominently display on the required warning: “Notice! For experimental use only – Not for Sale”.

2) Additional information such as serial number, manufacture date, storage conditions, or other pertinent information can also be included on the experimental label. The experimental label should not be styled as a product to be distributed and sold; that is, it must be clear that the product is experimental. For diagnostic products, place the experimental label on the carton.

H. APHIS Authorization

If APHIS authorizes shipment of the experimental product, CVB issues a letter or returns an APHIS Form 2071. Authorizations identify the name of the product, the serial number or numbers, the recipient’s name and address, describe all restrictions, and specify the state or states granting permission. APHIS returns date-stamped copies of the experimental labels. Authorizations usually have an expiration date of one (1) year past

the date of CVB approval unless the expiration date of the state authorization falls before that time. CVB may consider any requests for extended authorization periods if needed.

If the product is compromised during shipment or prior to use, one repeat shipment for the specified purpose may be made under the same CVB authorization.

I. Study Reports

Submit a summary report for pivotal studies for licensing and for studies performed in the field per 9 CFR 103.3(e). A study report is not required for terminal, non-pivotal studies conducted in containment unless CVB requests it pursuant to 9 CFR 103.3(h) (e.g., products made from exotic agents or products to treat diseases subject to an official APHIS control program).

J. Sale and Distribution of Experimental Products

Unique situations may arise when an unlicensed biologic is needed to protect against or diagnose new and/or emerging animal diseases. Contact the CVB reviewer assigned to the firm to discuss the viability of using the experimental product in an animal health event.

7. Implementation/Applicability

This update is effective immediately. Find additional guidance regarding the need for permission to ship experimental product under 9 CFR 103.3 on CVB's website.