USDA

Animal and Plant Health Inspection Service

Veterinary Services

1400 Independence Ave, SW

Washington, DC 20250

VETERINARY SERVICES MEMORANDUM NO. 800.59

TO: Veterinary Services Leadership Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

FROM: Jack A. Shere
Deputy Administrator

JACK SHERE

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SUBJECT: Veterinary Biological Product Samples

I. PURPOSE

This memorandum establishes policies and procedures for selecting, authenticating, and submitting veterinary biological product samples in accordance with title 9, *Code of Federal Regulations* (9 CFR), sections 113.3 and 113.52. It also provides instructions for identifying samples containing merthiolate (thimerosal) to facilitate their proper disposal.

II. REPLACEMENT

This memorandum cancels Veterinary Services (VS) Memorandum No. 800.59 dated September 4, 2013, and provides updated information on reducing the number of samples required for submission. This memo also incorporates submission of sample information through the National Centers for Animal Health (NCAH) Portal.

III. PROCEDURES

A. Authorizations

1. The Center for Veterinary Biologics−Inspection and Compliance (CVB-IC) is responsible for sampling activities. This includes training and designating authorized samplers.

2. The CVB-IC designates authorized samplers and gives the licensee or permittee and the National Veterinary Services Laboratories (NVSL) Laboratory Resources Unit, Sample Processing, a list of the names of authorized persons.

3. Licensed or permitted firms must either submit an APHIS Form 2007, “Qualifications of Veterinary Biologics Personnel,” or provide Form 2007 information through the NCAH Portal for each authorized sampler. See VS Memorandum No. 800.63.

CVB inspectors or other designated VS employees may also select samples during establishment visits.

4. An authorized sampler who has received USDA Level 2 eAuthentication and has provided that eAuthentication user name to the CVB may access the NCAH Portal, Sample Submission and will have the ability to generate a sample Packing Slip.

B. Sample Selection and Identification. The authorized sampler, CVB inspector, or other designated VS employee should select and identify samples as follows:

1. The sampler should select representative containers from each market serial or subserial according to 9 CFR 113.3 or as set forth in the establishment's Outline of Production filed with APHIS.

   a. From the representative samples, a subset of at least two containers or a sufficient quantity of containers to conduct potency testing requiring multiple containers (e.g., rabies) will be submitted to the CVB.

   b. When a serial of product is imported in more than one shipment, representative samples from each shipment must be selected by an authorized sampler and submitted to the CVB.

   c. The licensee or permittee will hold the selected containers not submitted to the CVB at the storage temperature recommended on the label while awaiting the CVB's request to submit the remaining samples. If additional samples are requested, mark "RESUBMISSION" in block 4 on the APHIS Form 2020, "Shipment and Receipt of Biologics Samples." Do not mix sample types on the same APHIS Form 2020.

   d. If the CVB does not request additional sample submission, additional samples may be returned to the serial inventory after the serial is released for marketing by the CVB.

   e. This reduced sample submission is a privilege for the licensee or permittee. If there are regulatory or compliance concerns, this privilege can be revoked. In this case, the licensee or permittee will be required to submit a full complement of samples as required in 9 CFR 113.3(b).

2. The sampler or designated employee should select and submit samples from Master Seeds, Master Cell Stocks, and Serials presented in support of an application for a license or permit, for an Outline of Production revision as required in 9 CFR 113.3(c), or as specified and authorized by the Center for Veterinary Biologics−Policy, Evaluation, and Licensing (CVB-PEL). Do not submit Master Seed samples until authorized by the reviewer. If the Master Seed is derived from recombinant technology, approval from the CVB's Institutional Biosafety Committee (IBC) must be obtained before the CVB can accept samples of the Seed.

IV. EXCEPTIONS

A. Exceptions to Number of Samples. The CVB may permit variations from the number of samples required in 9 CFR 113.3(b) and (c) for the following products:

1. Liquid products marketed or exported in large containers, either concentrated or as completed product.

2. High-value products.

3. Products marketed in low-volume serials.

4. Products whose testing requires substantially larger or smaller quantities than those specified.

B. Exceptions to Sample Quantities and Procedures. The CVB may accept the following exceptions to sample quantities and procedures stated in 9 CFR 113.3(b) and (c), if authorized in a filed Outline of Production:

1. Representative samples may be submitted in smaller containers, but the volume should be recovered from product filled in a final use container.

2. Samples may be selected in regular containers that are partially filled.

3. The number or volume of samples may be increased.

C. Autogenous Serials. See VS Memorandum No. 800.69.

V. SAMPLE IDENTIFICATION

A. Product Samples. Establishments should properly identify each sample from a market serial or subserial with a legible and indelible label showing:

1. The producer's name.

2. The license or permit number.

3. The true name of the product (abbreviations are acceptable).

4. The serial or subserial number.

5. The volume of contents.

6. The number of doses or tests.

7. The expiration date, if available.

8. The Product Code.

9. A red check mark, using permanent ink, if the contents contain thimerosal.

B. Identifying Master Seed and Master Cell Samples. Unless otherwise authorized by the CVB-PEL, establishments should identify samples of Master Seeds and Master Cell Stocks by a unique number or other identification which reflects the identity of material stored at the establishment and as specified in the Outlines of Production. REMINDER: If the Master Seed is derived from recombinant technology, approval from the CVB's IBC must be obtained before the CVB can accept samples of the Seed.

C. Use of APHIS Form 2020. On the APHIS Form 2020 that accompanies submitted samples, establishments should place an asterisk in front of the name of all products containing thimerosal. Use a separate form for each sample type indicated in block 4 of the form.

D. Use of the NCAH Portal. The NCAH Portal may be used in lieu of an APHIS Form 2020. The Sample Submission Form should be filled out as directed. A single packing slip may be generated for all samples that are contained within one shipment to the CVB. There will be a daily notification both through the NCAH Portal and email to the manufacturers of the assigned sample codes upon receipt and validation of the samples at the NCAH/CVB.

VI. ADDITIONAL SAMPLE REQUIREMENTS

A. Bulk Samples. The CVB-PEL will no longer conduct safety and potency tests on bulk samples, with the exception of tuberculin intradermic products. The CVB usually does not accept bulk samples for product other than tuberculin.

B. Serum Samples. Samplers should select, authenticate, and submit serum samples from host animal potency tests intended for confirmatory testing in accordance with the procedures specified in VS Memorandum No. 800.79. These submissions should NOT be entered through the NCAH Portal. They may be submitted on an APHIS Form 2020 in conjunction with serial release submission.

C. Panel Members. Panel members may be submitted to the CVB on an APHIS Form 2020 in conjunction with the serial release submission. These submissions should NOT be entered through the NCAH Portal.

D. Sampler Responsibility. Negligent or deliberate disregard for proper sampling procedures, specified in 9 CFR 113.3, may be grounds for revocation or suspension of product and/or establishment licenses or permits.

E. Reserve Samples. Samplers should select reserve samples as set forth in 9 CFR 113.3(e) and render them tamper-evident. The submitting firm should hold such samples in an approved secure storage area until at least six months after the expiration date of the serial or subserial, unless otherwise directed by the CVB-IC.

VII. SUBMISSION OF SAMPLES

Send the required number of samples, in appropriate and adequate packaging, and the APHIS Form 2020 or sample Packing Slip to:

Center for Veterinary Biologics
NVSL, Laboratory Resources Unit − Sample Processing
1920 Dayton Avenue
Ames, IA 50010

VIII. IMPLEMENTATION/APPLICABILITY

The implementation of the NCAH Portal is the alternative to submission of APHIS Form 2020 with the publication of this memorandum.