July 3, 2003

VETERINARY SERVICES MEMORANDUM NO. 800.59

Subject: Veterinary Biological Product Samples

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Director, National Veterinary Services Laboratories

I. PURPOSE

The purpose of this memorandum is to establish policies and procedures for selecting, authenticating, and submitting veterinary biological product samples according to 9 CFR 113.3 and 113.52, and to provide instructions for identifying samples containing merthiolate (Thimerosal) in order to facilitate their proper disposal.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.59 dated May 25, 1999.

III. PROCEDURES

A. Authorizations

The Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) is responsible for sampling activities. This includes training and designating authorized samplers. The CVB-IC authorizes samplers and provides the licensee or permittee and National Veterinary Services Laboratories-Biologics Material Processing Section (NVSL-BMPS) Sample Repository a list of the names of persons authorized. Firms must submit an APHIS Form 2007, Qualifications of Veterinary Biologics Personnel, for each authorized sampler. Inspectors or other designated Veterinary Services employees may also select samples during visits to establishments.

B. Sample Selection and Identification

The authorized sampler, inspector, or other designated Veterinary Services employee should select and identify samples as follows:

1. *Sampling Procedures* - The sampler should select representative containers from each market serial or subserial according to 9 CFR 113.3 or the filed Outline of Production. Select and submit samples from Master Seeds, Master Cell Stocks, and serials presented in support of an application for license or permit or for outline revision as specified and authorized by Center for Veterinary Biologics-Product Evaluation and Licensing (CVB-PEL).

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

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

b. Very expensive products,

c. Products marketed in very small serials, and

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

3. *Exceptions to Sample Quantities and Procedures* - 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:

a. Representative samples may be selected in smaller containers.

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

c. Smaller numbers of samples may be selected and submitted from each serial or subserial.

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

4. *Identifying Product Samples* - Firms should properly identify each sample from a market serial or subserial with a legible and indelible label showing:

a. The producer's name,

b. The license or permit number,

c. The true name of the product (abbreviations acceptable),

d. The serial or subserial number,

e. The volume of contents,

f. The number of doses,

g. The expiration date, if available,

h. The Product Code Number, and

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

5. *Use of APHIS Form 2020* – On the APHIS Form 2020 that accompanies submitted samples, 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.

6. *Bulk Samples* - Center for Veterinary Biologics, Laboratory (CVB-PEL) will ordinarily conduct safety and potency tests on bulk samples if such samples are authorized according to 9 CFR 113.3(a)(3).

7. *Identifying Master Seed and Master Cell Samples* - Unless otherwise authorized by CVB-PEL, firms 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 Outline(s) of Production

8. *Serum Samples* - Samplers should select, authenticate, and submit serum samples from host animal potency tests intended for confirmatory testing according to Veterinary Services Memorandum No. 800.79.

C. Sampler Responsibility

Negligent or deliberate disregard for proper sampling procedures is a violation of the regulations and grounds for revocation or suspension of product and/or establishment licenses or permits.

D. Submission of Samples

Send samples to:

Center for Veterinary Biologics
NVSL, BMPS - Sample Repository
P.O. Box 844
1800 Dayton Avenue
Ames, IA 50010

E. Reserve Samples

Samplers should select reserve samples according to 9 CFR 113.3 (e) and render them tamper-evident. The firm should hold such samples in an approved secure storage area until at least 6 months after the expiration date of the serial or subserial unless otherwise directed by CVB-IC.

/s/ Andrea M. Morgan for

W. Ron DeHaven
Deputy Administrator
Veterinary Services