INSTRUCTIONS FOR COMPLETING APHIS FORM 2020

Please refer to Veterinary Services Memorandum 800.59 for a complete detail of the policies and procedures for selecting, authenticating, and submitting veterinary biological product samples according to 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.

An APHIS Form 2020 (Form 2020) must accompany samples for each serial or subserial, Master Seeds and Master Cell Stocks, or serials in support of application for license or permit. Below are the requirements for the Form 2020 submission.

1. DATE SUBMITTED (self-explanatory)
2. FIRM LICENSE NO.: Use the establishment's USDA license or permit number.
   * *License or permit number should be on the Sample*
3. NAME AND MAILING ADDRESS OF FIRM (Include Zip Code): Establishment Name/ Mailing Address
   * *Producer's Name should be on the Sample*
4. PURPOSE:
   Only one type of sample group may be listed on each Form 2020
   a. Routine Concurrent Samples: When a manufacturer submits routine post-license samples to the CVB, they are eligible to be selected for confirmatory (check) testing.
   b. Retention Samples: Mark when CVB has requested the submission of the APHIS Reserve samples
   c. Master Seed – list the Special Test Request (STR) Authorization number in Block 16, Remarks
   d. Resubmission (Specify reason in Remarks): for additional samples submitted in response to CVB requests or other circumstance
   e. Cell Line – list the STR Authorization number in Block 16, Remarks
   f. Other (Specify in Remarks): for stock cultures, serums, or other type not specified. The sample type to be specified in Block 16, Remarks.
   g. Prelicensing – includes both prelicensing and outline change samples. List the STR Authorization number in Remarks
5. HOW IS PRODUCT SHIPPED: Samples shall be kept under refrigeration at 35º- 45ºF (2°-7°C) unless otherwise specified in the approved Outline of Production (9 CFR 114.11).
6. PRODUCT NAME (No trade names)
   **True Name should be on the Sample- abbreviations acceptable*
7. PRODUCT CODE
8. **The product code number should be on the Sample. Only one product code should be listed on each sample.* SERIAL NO.
   **The serial or subserial number should be on the Sample*
9. SAMPLE CODE: Do not fill out (For Gov't Use Only)
10. SAMPLE CONTAINERS SUBMITTED – NO.: Number of samples submitted
11. SAMPLE CONTAINERS SUBMITTED – SIZE: Volume per sample
    **The volume of contents should be on the Sample*
12. SAMPLE CONTAINERS SUBMITTED –FIELD DOSE: Doses per sample
    **The number of doses should be on the Sample*
13. INDICATE BULK OR FINAL

14. SIGNATURE OF AUTHORIZE GOVERNMENT SAMPLER: The Center for Veterinary Biologics – Inspection and Compliance (CVB-IC) is responsible for training and designating authorized samplers.
    Print the name along with the signature.
15. DATE: of signature for authorized sampler
16. REMARKS – List the STR authorization number, if applicable.
17. CONDITIONS AND REMARKS: Do not fill out (For Gov't Use Only)
18. RECEIVED BY (Signature): Do not fill out (For Gov't Use Only)
19. DATE RECEIVED: Do not fill out (For Gov't Use Only)

* 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.
7. The expiration date, if available.
8. The product code number. *Note: The approved final container label used for distribution and sale does not list the Product Code. If the samples are submitted with the label used for distribution and sale, please identify the Product Code using indelible ink.*
   When submitting samples frozen in liquid nitrogen, the product code number may be noted on the sleeve rather than on each vial.
9. A red check mark, using permanent ink, if the contents contain thimerosal.

Reminder:

When the serial number listed on the sample label does not match the information listed on the APHIS Form 2020, the Laboratory Resources Unit (LRU) – Sample Processing process is to contact the firm and confirm which is correct. If the sample label is correct, a pen and ink change will be made to the APHIS Form 2020. If the sample label is incorrect, new labels must be submitted to correct the product code or dose size. If the serial number on the sample is incorrect, the samples will be rejected and corrected samples must be resubmitted.

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