Processing APHIS Form 2008s if
Unsatisfactory Testing by the CVB and the Possible Challenge of the Test Results by the Manufacturer

Background

When an APHIS Form 2008, or equivalent, is submitted to the Center for Veterinary Biologics (CVB) by the manufacturers, it is expected that all manufacturing, prior to Section V of the approved Outline of Production, was in compliance with the Outline of Production and the applicable regulations.

Veterinary Services Memorandum 800.53 describes the policy and procedures to comply with title 9, *Code of Federal Regulations* (9 CFR), parts 113 and 116, sections 113.3, 113.6 and 116.7, for the release of biological products to licensees and permittees. A licensee or permittee shall withhold products from the market until a market determination has been made by APHIS.

In instances in which the CVB Laboratory does confirmatory testing and the results are unsatisfactory, but the manufacturer's test results are reported as satisfactory, the following process should be followed.

Process

1. The APHIS Form 2008 has been received and review has been performed, if necessary.

2. Within LSRTIS Signature Activity in Serial Release, the Specialist will review the test report to determine an APHIS Disposition. Usually performed by the Specialist, but can be the Program Coordinator.

    a. Determination of the conclusion should be based on valid testing by the CVB Laboratory (or some instances the National Veterinary Services Laboratories). In most cases, the Specialist should confirm with the Laboratory VMO/Micro who validated the test. The Specialist may also request copies of the bench records of the test from the CVB Laboratory to confirm the storage, processes, validity, and results are correct.

    b. The Specialist usually will base an APHIS Disposition on the CVB Laboratory testing; however, it is under the Delegation of Authority for Inspection and Compliance (IC) to assign an APHIS Disposition to a serial after evaluation of all testing.

3. If the manufacturer questions the unsatisfactory test result reported by CVB, the Specialist should request the following from the manufacturer:

    a. Confirm that the serial and testing question was prepared and tested in accordance with the filed Outline of Production. This can be done by evaluation of the manufacturing records by the Specialist.

b. Perform a double independent re-test and submit the results to CVB for review on an APHIS Form 2008.

c. Submit all bench records for the manufacturer's testing.
   i. These bench records should be reviewed by Specialist.
   ii. They may route them to the Laboratory VMO/Micro for concurrence.

4. If the double re-test performed by the firm results in Satisfactory testing, the Specialist may then choose the following:

a. Provide CVB testing bench records to the manufacturer and initiate a dialogue regarding possible differences between the testing laboratories.

b. Request the Laboratory to do a double independent retest and evaluate marketing release based on those results. Refer to **ICSOP0043**, *LSRTIS Special Test Request Procedures for Inspection and Compliance*, for further guidance.

   i. If the CVB test results are satisfactory, the APHIS Form 2008 will be processed as (Other – Serial Released for Market). A statement is typed on the APHIS Form 2008, "This rescinds the unsatisfactory results dated (need date of original release)."
      a. At this point, the event of different test conclusions by the CVB Laboratory should be brought to the attention of the Product Specialist or IC Section Leader.
      b. The Product Specialist should notify the Quality Management Section Leader of the need for a Process Review of the test in question as per **CVBQMSOP0004**, *Process Reviews*.

   ii. If the CVB test results are unsatisfactory, the APHIS Form 2008 will be processed as Tests Completed Unsatisfactory. A statement is typed on the APHIS Form 2008, "This confirms the unsatisfactory test results from (date of original release). Comments should also be added to the 2008 that "Destruction of the serial should be witnessed by an APHIS official."
      a. Add this as a release requirement within LSRTIS as well as typed hardcopy on the APHIS Form 2008.
      b. The Specialist should use an APHIS Form 2045 to document the destruction while on the next In-depth Inspection or at a Special Inspection, as determined by a Section Leader.

iii. At this point, the event of different test conclusions by the CVB and the firm should be brought to the attention of an IC Section Leader, the VMO/Micro in the Laboratory, and the Reviewer as it is imperative that the discrepancy between the testing be resolved.
    a. The Specialist should notify the Laboratory VMO/Micro that a Special Test Request will be placed on future serials of the fraction in question and perform the appropriate LSRTIS entry per **ICWI0103**, *Special Tests Requests Initiated by Inspection and Compliance Staff*.
    b. The event should be filed by the Specialist to follow up on inspection, if necessary.

5. If the double re-test performed by the manufacturer results in any Unsatisfactory testing, the original APHIS Disposition stands, and the CVB will file the APHIS Form 2008s as Other - File for Information Tested UNSATISFACTORY.

   The manufacturer must inform the CVB of the results and destruction information. This information should be provided to the CVB in a letter.