

Background:

VS Memorandum 800.87, Section IV.E., states that if a submission for a serial (samples, APHIS Form 2008 or CVB Test Request) has been received under the original Establishment, the serial will be released for marketing under the original Establishment, Product Code, and Serial Number.

That does not account for products in which a product license was not granted under the original Establishment license, but samples and the APHIS Form 2008 and prelicensing serial testing has been started/finished under the original Establishment license.

If CVB testing has not been requested and performed under the original Establishment license – this work instruction will not apply.

According to the **Reviewer's Manual**, *Section 5.1, Testing Biological Products, Requesting Tests at the CVB Laboratory – 3.2 Testing of Prelicense Completed/Finished Product*, requires the manufacturer to test the product and submit the results on an APHIS Form 2008. The Reviewer then will authorize submission of samples and request a Special Test.

Process: When CVB has received the 2008 submitted under the original Establishment, samples have been submitted and tested under the original Establishment:

1. The Form 2008 will be audited back by either the BCA or the Specialist
 - a. Reason for Audit – Serial Not Released by APHIS
 - b. Comment – Product licensed as Est. (NEW), Product Code (XXXX.XX), please resubmit information on new APHIS Form 2008 for processing.
 - c. Also indicate they need to submit two samples under the New Establishment, Product Code and Serial number

2. The new Form 2008 should reference the previous Establishment number, Product Code and Serial number. When the Form 2008 is received, it will be processed in accordance with normal prelicensing procedures:
 - a. CVB TEST REPORT – testing will not be transferred within the LSRTIS system.
 - b. The test report generated under the original Establishment will be printed
 - i. Use Testing Report: Lab Test Report for Serials – External (2 copies)
 - ii. Two copies needed – one for the CVB files, one for the firm
 - c. The original test report is attached to the new APHIS Form 2008
 - d. The original test report is scanned and attached to the LSRTIS record for the serial released under the new Establishment

Processing of APHIS Form 2008s for Prelicensing Serials related to Firm Mergers

