



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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**Serial Release - Processing of APHIS Form 2008s for Prelicensing  
Serials, Outline Changes,  
or Technology Transfers**

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**Notes:**

## Serial Release - Processing of APHIS Form 2008s for Prelicensing Serials, Outline Changes, or Technology Transfers

Source Document: Veterinary Services Memorandum No. 800.53

### Background:

APHIS Form 2008s (Form 2008s) that are received from the manufacturers may come in one of two ways: NCAH Portal electronic submission or hard copy. Either way is acceptable and will be processed the same way.

According to the **PEL 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.

It is the expectation that Form 2008s be submitted after all Section V testing is complete by the manufacturer and the entire testing summary is on the Form 2008 submitted for Final Disposition.

**Process:** When CVB has received the Form 2008 submitted as “Other – Prelicense”, “Technology Transfer”, or “Outline of Production Change”, an automated Mail Log will be sent as a child loop to the Reviewer assigned to the product with the following information. *Reviewer assignment is based on the firm selecting the correct Reviewer from a dropdown in the NCAH Portal.*

### Mail Log specifics (automatically created):

Brief Description: Prelicense/OP Change/Tech Transfer 2008

Submission Type: Product Correspondence

Submission Subtype: PEL 2008 Review

Tags: Submitted via Portal; Suppress Response from Portal

An Approval Step is added to the ML for these types of submissions: (see screen shot below)

### NCAH Portal Entries

| Type       | Description   | Roles | Response | Approved? |
|------------|---|-------|----------|-----------|
| APHIS 2008 | Submission Date Tue Nov 10 16:39:09 CST 2020 – Direct Submission to Srinivas, Javarajah |       |          |           |

To Approve 2008 - Edit Mail Log Item.

- Selecting Yes indicates that the 2008 supports the licensure or change request (If testing, wait for validation).
- Selecting No indicates that the 2008 does NOT support the licensure or change request (This typically means that a new submission is needed).

For further guidance, refer to the filed Work Instruction on this process.

**If acceptable by the Reviewer**

*This is typically because the serial(s) support licensure and the serial was tested satisfactory by the CVB Laboratory.*

1. The Reviewer will Edit the ML and mark YES in the approval area (see picture above). The Reviewer may attach any related MLs or attachments to the Mail Log for ease of searching.
2. Then the Reviewer closes their child loop. This will move the Mail Log back to the assigned Biologics Compliance Assistant (BCA) for the firm.

**If NOT acceptable by the Reviewer:**

*This is typically because the serial(s) do not support licensure and other serials are needed to be tested. Other instances are that the Reviewer needs additional testing or Outline updates. It is in the Reviewer's authority to license a product*

1. The Reviewer will edit the Mail Log and mark NO in the approval area (see picture above). The Reviewer may attach any related MLs or attachments to the Mail Log for ease of searching.
2. Then the Reviewer Closes their child loop.
3. The BCA can either audit the Form 2008 back to the firm with the comments/reason incorporated into the Audit remarks and close the ML as "Workflow Completed No Records management" or process the Form 2008 with the appropriate APHIS Disposition (usually Serial Not Released to Market)

*This ML will not be sent to the firm.*

**The BCA**

1. Will move the Form 2008 out of Initial Review, to the Specialist through Specialist Review following details within [CVB-SOP-0032](#).
2. Review and close the ML as "Workflow Completed No Records management". Ensure the ML has been marked appropriately by the CVB Reviewer. This ML will not be sent to the firm.

**The Specialist**

1. Upon review of the APHIS Form 2008, the Specialist should ensure a Serial Spec Sheet is created for the product license.
2. The Specialist should review the Form 2008 for compliance with Section V and VI of the Outline of Production. The Serial Stat should be reviewed for other testing, holds, or correspondence. Reference slips or Release criteria should be added if the 2008 requires it.

3. If testing by the CVB laboratory has been complete, the Specialist should review the test report for choosing the APHIS Disposition.
4. For 2008s which still have pending testing at the CVB laboratory, the Specialist should hold the 2008 in the Specialist Review area until notified of the testing. This is because the 2008 APHIS Disposition may change depending on the testing results.
5. Once reviewed by the Specialist, the Form 2008 will move to the Laboratory Actions, Pending Licensure area until the License Status changes to Active.
6. When product license becomes Active (or if a Form 2008 is audited), the Form 2008 will move to BCA Ready for Approval area for processing.  
*Refer to [CVB-WI-0129](#), Serial Release - APHIS Dispositions and Associated Information On Form 2008s, for the options for Dispositions of Prelicense, Outline Changes, or Technology Transfers.*
7. The BCA submits the Form 2008 to the Specialist for Signature and finalizing.
8. The Email Notification for Serial Release (ENSR) will be sent out to the firm, only if the firm has a valid email address in the LSRTIS system. If the Form 2008 was received via the NCAH Portal, notification will also be sent through that means.