

Processing of APHIS Form 2008s for Prelicensing Serials

Background: With the incorporation of LSRTIS 2014 and the NCAH Portal, enhancements were made to try and eliminate gaps of communication between IC and PEL units in regard to Prelicensing Serials. 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”, an automated email will be sent to the Reviewer(s) assigned to the manufacturer with the following information:

Subject: REVIEWER ACTION REQUIRED: A Prelicense or Outline Change 2008 has arrived

Attention Reviewers:

This 2008 will not be processed by IC until you confirm its acceptability by replying to this email.

1. Click on the "APHIS 2008 Info" hyperlink below to review the information submitted on the APHIS Form 2008 for acceptability. (Scroll down to the Attachment section of the APHIS 2008 record to see the full 2008 form.) The 2008 should be complete and acceptable as a FINAL 2008 for the purpose intended. It should not contain preliminary or partial results or reflect testing of a non-representative serial. If you are uncertain at this time whether the 2008 meets these criteria, wait to respond to this email.

2. HIGHLIGHT the statement below that reflects your disposition of this 2008. If the 2008 is not acceptable, add a reason.

A. This serial supports licensure/permitting of the product OR a change in the Outline of Production or Special Outline.

B. This serial does NOT support licensure/permitting of the product OR a change in the Outline of Production or Special Outline.

Reason:

3. Disposition:

If IC receives response A, the BCA will process the 2008. Prelicense 2008s will be held until licensure. 2008s for Outline Changes will be returned to the firm as soon as any scheduled testing is completed.

If IC receives response B, the BCA will immediately return the 2008 to the firm unprocessed (i.e., "audit back") – your reasons will be incorporated into the audit response.

Est: xxx

Product: xxxxxx

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Serial Number: xxxxxxxx

Firm Disposition: Other - Prelicense

Date Received: Fri Mar 17 12:53:00 CDT 2017

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1. If NOT acceptable by the Reviewer (Response B from the email), the Biologics Compliance Assistant (BCA) will audit the Form 2008 back to the firm with the comments/reason incorporated into the Audit remarks.
2. If acceptable by the Reviewer (Response A), the BCA will move the Form 2008 out of Initial Review, to the Specialist through Specialist Review.
3. Upon review, the Specialist should ensure a Serial Spec Sheet is created for the new product license.
4. 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.
5. If testing by the CVB laboratory has been complete, the Specialist should review the test report for choosing the APHIS Disposition.
6. 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.
7. Once reviewed by the Specialist, the Form 2008 will move to the Laboratory Actions, Pending Licensure area until the License Status changes to Active.
8. 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. The following APHIS Dispositions may be used for Prelicense serials:
 - a. Prelicense – Tests Completed Satisfactory
 - b. Prelicense – Tests Completed UNSATISFACTORY
 - c. Prelicense – EXPIRED
 - d. Prelicense Serial – Release for Market
9. The BCA submits the Form 2008 to the Specialist for Signature and finalizing.
10. The yellow prelicense folder should be removed from the Pending Drawer and all paper work sent to Records Management.

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11. 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.