Animal and Plant Health Inspection Service

Veterinary Services

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QA Process for Serial Release

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Notes:

Serial Release - QA Process for Released Serials

Source Document: CVB-SOP-0032, *Processing Serial Records*

The purpose of this document is to provide guidance on the quality assurance process for serial release. This process is performed daily after the Biologics Specialist who has been assigned Program Coordinator (PC) duty for the week has electronically and physically signed the APHIS Form 2008s (Form 2008s) that the Biologics Compliance Assistants (BCAs) have prepared for release. This document is to be used as a reference while performing this duty.

This function is a tool to ensure all documents have been appropriately reviewed prior to the 11:00 a.m. NCAH Portal release of information. Therefore, this should take place prior to this timeframe. Employees performing this task should be knowledgeable in the discrepancies that may occur with various requests from the biologics manufacturers.

Processing of Form 2008s

A. Hard Copy APHIS Form 2008s:

1. After the Form 2008s have been signed by the PC, they are returned to the BCA.
2. The hard copy forms are reviewed to ensure all forms are signed.
3. The APHIS Disposition in LSRTIS matches the hard copy.
4. The Test Report matches the APHIS Disposition.

B. Electronically submitted Form 2008s

1. The Product Manager, Lead BCA or their designee does a search on the Form 2008s processed and signed for the day. Under the "Serial Release tab," select "Serial Search." At the bottom of the screen choose "With an Action Of"=APHIS 2008 signed by Specialist. "Action Timestamp" From=current date To=current date

- Choose "Search," select "Excel" option.

2. Review the data on the generated report against the Form 2008 and Serial Stat and checks for the following:

- The Firm Disposition against the APHIS Disposition – do these match up correctly?
- The APHIS Disposition against Test Report – do these align appropriately?
- Any remarks from the NCAH Portal. Have these been reviewed adequately?
- All comment and FFMs in remarks have been adequately addressed
- Relevant Holds have been reviewed adequately and addressed
- Check for fill dates – is there a long lag between fill and submission?

3. Review if there are Serial Release Criteria. Does it have the appropriate drop-down selection?

4. Destroyed By Firm 2008s – check to see if there is a CVB Lab Test report. Contact a system admin to remove the test report from ENSR, if applicable.

5. File For Information – Have Serial Release Criteria's been completed and closed out from original 2008 submission?

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6. Check for Portal. If No is selected; ensure the hard copy 2008 was signed.

7. If discrepancies/issues are found on the list, follow up with the appropriate personnel to resolve the issues.

Flag the serial through the ENSR option. This can only be done by a System Administrator for LSRTIS. Contact the employees who have this function prior to 11 a.m. to hold the 2008.