USDA

**Animal and Plant
Health Inspection
Service**

Veterinary Services

**Center for Veterinary
Biologics**

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

(515) 337-6100

Serial Release - Mandatory 2008 Review (Mock Management) in LSRTIS

Document Number: CVB-WI-0085   **Revision: 02**

Previous Number: ICWI0054.01

Vault: CVB-Released

Section/Area: CVB-WI-IC

Effective Date: 20 May 2021

Notes:

Serial Release – Mandatory 2008 Review (Mock Management) in LSRTIS

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

Mock check determinations are maintained within the LSRTIS module, under the Serial Release heading, **Mandatory 2008 Review Mgmt**. The mandatory 2008 review is performed by the Biologics Compliance Assistant (BCA).

Criteria for a Mandatory 2008 Review include:

- Program diseases

- Products/fractions with a long term review hold (longer than 3-6 months) should be transferred to a Mandatory 2008 Review

- Newly licensed products – at least 1 year post licensure or a minimum of 3 serials produced with no compliance issues

    o Newly licensed products with tracking types of Breakout – uncomplicated, Split Manufacture, or For Further Manufacture do not need to be mandatory mock checked.

Serial specific items, short term review, or those with specific release criteria (i.e., bench record review) should be entered as Review Holds, and not Mandatory 2008 Review. Comments will not show up in the Serial Release Action Sheet. Therefore, it is implied that a review against the outline of production will be sufficient for the BCAs.

I. **SPECIALIST**: To enter a Mandatory 2008 Review (100% mock check)
   a. Within LSRTIS, Serial Release module, Click on "Mandatory 2008 Review Mgmt" subheading
   b. Click on "+ Create Mandatory 2008 Review" in the left margins
   c. Enter the known/relevant info (non-mandatory fields)
      i. Establishment
      ii. Product
      iii. Agent
      iv. Reason
      v. Comments
   d. Click on the "Create" button

At this point the Mandatory 2008 Reviews are active.

Once a 2008, that meets the criteria entered under Mock Management, has been logged in and pushed past BCA Initial Review tab in the Serial Release dashboard, then it should be grouped within the "Mandatory" category of the 2008 Review tab.

II.   **To Modify a Mandatory 2008 Review:**
    a. Under Mandatory 2008 Review Search, search on the known criteria of the hold:
        i. Establishment
        ii. Product
        iii. Agent
        iv. Reason
        v. Active?
    b. Click on the "Search"
    c. In results Area, Click on "Show" icon
    d. To Edit a record:
        i. Click on the "Edit" icon
        ii. Update the information within the Mandatory Aphis 2008 Review Screen
        iii. Click on "Update" icon

III.   **To Inactivete a record**:
    a. **SPECIALIST**:
        i. Provide justification for removal
        ii. Submit to Product Specialist or Section Leader for Removal
    b. **PRODUCT MANAGER OR SECTION LEADER:**
        i. Within LSRTIS, Click on the "Edit" icon
        ii. Choose the toggle under "Active" to remove the check mark
        iii. Click on "Update" icon

IV.   Mandatory 2008s Reviews that are entered in the system, may be reviewed by the Product Manager (or those acting in their capacity) quarterly; but at least annually.