Serial Release - Log APHIS Form 2008

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

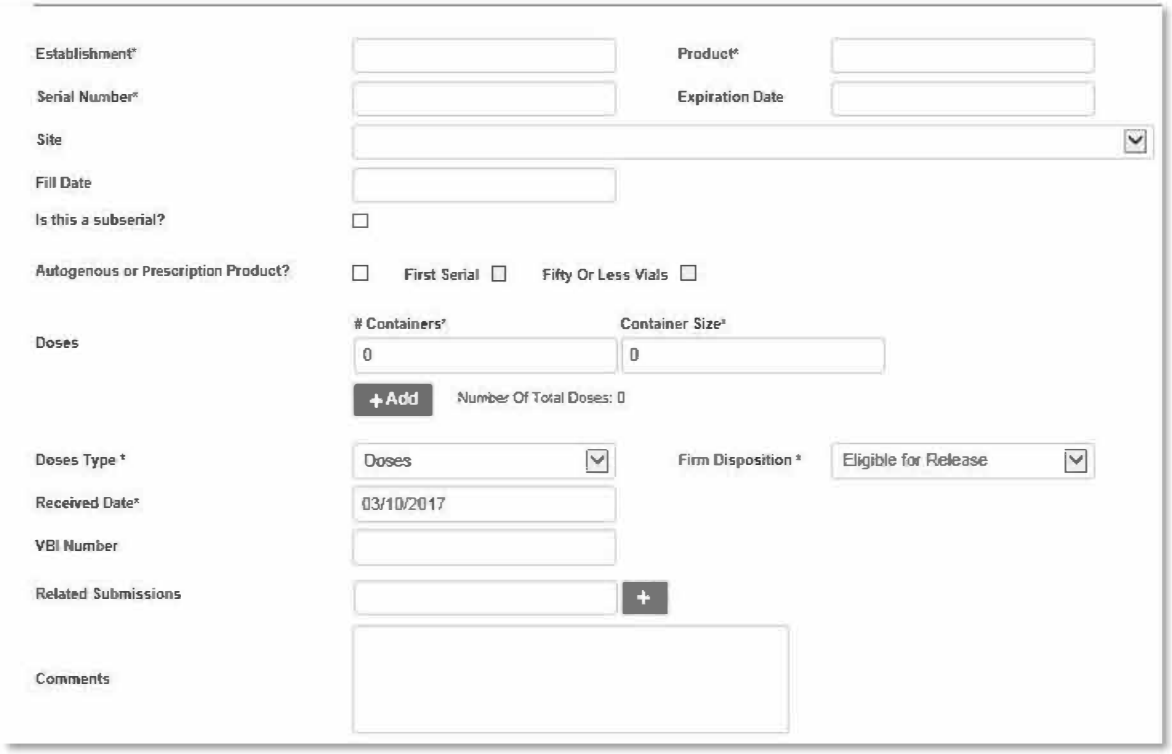
Complete hard copy APHIS Form 2008s (Form 2008s) are received and entered by the Inspection and Compliance group. Most Form 2008s are received from the licensed manufacturers through the NCAH Portal, in which case this work instruction is not applicable. All other Form 2008s are logged into LSRTIS by on-site personnel.

Form 2008s received from prelicense (unlicensed) entities cannot be received though the NCAH. These entities must submit these forms hardcopy. Licensed manufacturers may submit prelicense 2008, though.

2008s are stamped according to CVB-WI-0159.

The designated personnel enters the Form 2008s into LSRTIS under the **Serial Release** module**, Log APHIS 2008** section. The following are procedures to perform this duty.

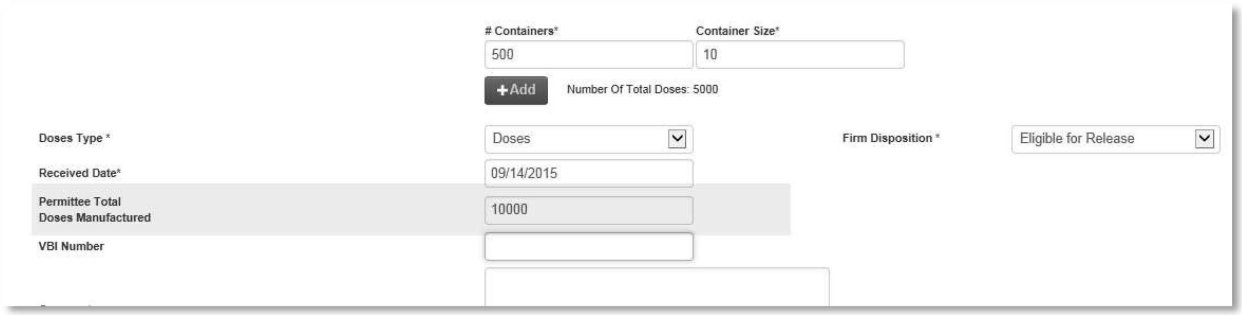
A. Click **Log APHIS 2008** and enter the following within the Create APHIS 2008 screen.



1. **Establishment number** (Block 2 on the Form 2008)
2. **Product code** (Block 5)
   No decimal point. Ensure this is a valid product code for the selected establishment or an error message will appear after you try and save.

3. **Serial number** (Block 7)
   a. Limit of 20 characters
   b. Alpha/numeric characters only – no spaces or hyphens. If the 2008 has a symbol, this is simply left out of the entry.
   c. If allergenic extract, no serial number is assigned by the manufacturer. CVB identifies each serial by designating it a number for each product code listed in their submission. The serial number will be the same for all; the only difference is the product code, i.e., 13Q4 translates:
      - last 2 digits of the calendar year of the submission
      - Q for quarter year
      - 1-4 for the quarter year it covers
        Jan-Mar = 1
        Apr-Jun = 2
        Jul-Sept = 3
        Oct-Dec = 4
4. **Expiration Date** (if applicable) (Block 6)
   i.e., MM/DD/YYYY
5. **Site** – drop down field of available sites for the firm.
6. **Fill Date** (if applicable) (Block 4)
   i.e., MM/DD/YYYY
7. **Is this a subserial?** – An optional field to indicate if a serial is a part of a subserial product. If this is selected, a field to enter related subserials appears.
8. **Autogenous or Prescription Product**
   a. Check if the Product is an autogenous product (1015.xx, 2051.00, 2052.xx, 2053.xx, 4500.xx) or a prescription product (9Pxx.xx)
   b. First Serial – check if the firm indicates the serial is a 1st serial of a harvest (no samples are needed for release)
   c. Fifty or Less Vials – check if the inventory is less than 50 containers (if yes, no samples are needed for release)
   d. Autogenous Agents – If available, and known, enter the agent(s) listed on the Form 2008. If an agent is not listed at all by the firm, this should be audited, printed, and mailed back to the firm.
9. **Inventory**
   a. Doses:
      - # Containers (Block 10A)
      - Container Size (Block 10B)
      - Select +Add if there are multiple container sizes
   b. If no inventory is shown, leave blank

c. **NOTE**: If the manufacturer is a permittee, there will be two separate dose field entries (Permittee Total Doses Manufactured and doses received in the United States). Serials that are made in foreign countries that are FFM (For further manufacture) may not have total doses manufactured.
   - Follow the A.9.a. directions above for container/container size(s) for doses received in the United States (Block 10C)
   - Total Doses the foreign entity manufactured - amount in Block 11



d. If allergenic extracts, enter:
   - Total # containers
   - 1 in container size (Decimal may be entered, example 0.5).

e. Check running total shown against total inventory in Block 10C.

f. If a serial is a first serial autogenous, the only inventory field that will show is the number of total doses.

10. Dose Type
   - doses, mL, or units only (see Unit of Measure work instruction **CVB-WI-0157**, *Unit of Measure Use and Conversion for Data Entry into LSRTIS*)

11. Firm Disposition (Block 12)

a. Click on the LOV to select firm's disposition (See **CVB-WI-0129**, *APHIS Dispositions and Associated Information on Form 2008s*, for the entire list of Firm Dispositions)

b. "Reprocess & Retest"
The new product code and serial number indicated in Block 11 of Form 2008 appears at the bottom of the screen. Select +Add if there is more than one new serial number.

c. "Other - Rebottling"

The new product code and serial number indicated in Block 11 of Form 2008 appears at the bottom of the screen. Select +Add if there is more than one new serial number.

d. "Other - Transfer Request"
Once you enter this disposition, enter the establishment, product code, and serial that the inventory is being transferred to as indicated in Block 11 of Form 2008.

12. **Received Date (Stamp date on the Form 2008)**
    a. The entry default as today's date
    b. Ability to back date is available
13. **VBI Number**
    Format (10-001). This field points directly to the investigation module within LSRTIS, use only valid investigation numbers. Ensure to select from drop down.
14. **Related Submissions (mail log #)** This field will point directly to either IC or PEL Mail log numbers, if references on the Form 2008. Multiple MLs may be selected.
15. **Comments**
    Add any applicable comments in comment field
16. Click **Create** complete the entry

B. Once the Form 2008s have been logged in, the Logger will distribute all Form 2008s to the assigned Biologics Compliance Assistant in their Incoming 2008s folder.

C. Form 2008s received after 2 p.m. may be held, stamped, and logged into LSRTIS the next business day. Although, hard copy 2008s may not be entered the day of receipt, they will be backdated to the date of actual receipt.