

## Log APHIS Form 2008

Complete hard copy APHIS Form 2008s (Form 2008s) are received and entered by the Inspection and Compliance group. Some forms are received from the NCAH Portal, in which case this work instruction is not applicable. The Form 2008s are logged into LSRTIS, which is typically done between 10 a.m. and 1 p.m. CST.

The assigned Logger 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.

The screenshot shows the 'Create APHIS 2008' form with the following fields and options:

- Establishment\***: Text input field.
- Product\***: Text input field.
- Serial Number\***: Text input field.
- Expiration Date**: Text input field.
- Site**: Dropdown menu.
- Fill Date**: Text input field.
- Is this a subserial?**:
- Autogenous or Prescription Product?**:  **First Serial**  **Fifty Or Less Vials**
- Doses**: **# Containers\*** (0) and **Container Size\*** (0) input fields. Below them is a blue **+ Add** button and the text **Number Of Total Doses: 0**.
- Doses Type \***: Dropdown menu (Doses).
- Firm Disposition \***: Dropdown menu (Eligible for Release).
- Received Date\***: Text input field (03/10/2017).
- VBI Number**: Text input field.
- Related Submissions**: Text input field with a blue **+** button.
- Comments**: Large text area.

#### 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)

- Limit of 20 characters
- Alpha/numeric characters only – no spaces or hyphens
- 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

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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

**8. Autogenous or Prescription Product**

- Check if the Product is an autogenous product (1015.xx, 2051.00, 2052.xx, 4500.xx or 9Pxx.xx)
- First Serial – check if the firm indicates the serial is a 1<sup>st</sup> serial (no samples are needed for release)
- Fifty or Less Vials – check if the inventory is less than 50 vials (if yes, no samples are needed for release)

**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, enter 0

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).

- Follow the A.5.a. directions above for container/container size(s) for doses received in the United States (Block 11)
- Total Doses the foreign entity manufactured - amount in Block 10C

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A screenshot of the APHIS Form 2008 data entry interface. The form includes several input fields and dropdown menus. At the top, there are fields for '# Containers\*' (containing '500') and 'Container Size\*' (containing '10'). Below these is a red '+Add' button and the text 'Number Of Total Doses: 5000'. The 'Doses Type\*' dropdown is set to 'Doses'. The 'Firm Disposition\*' dropdown is set to 'Eligible for Release'. The 'Received Date\*' field contains '09/14/2015'. The 'Permitted Total Doses Manufactured' field is highlighted in yellow and contains '10000'. The 'VBI Number' field is empty.

- d. If allergenic extracts, enter:
  - Total # containers
  - 1 in container size
- e. Check running total shown against total inventory in Block 10C
- f. If a serial is a first serial autogenous serial, the only inventory field that will show is the number of total doses

A screenshot of the APHIS Form 2008 data entry interface for autogenous products. The 'Autogenous or Prescription Product (platform)?' checkbox is checked. The 'First Serial' checkbox is checked, and the 'Fifty Or Less Vials' checkbox is unchecked. The 'Number of Total Doses' field is highlighted in yellow and is empty. The 'Doses Type\*' dropdown is set to 'Doses'. The 'Firm Disposition\*' dropdown is set to 'Eligible for Release'. The 'Received Date\*' field contains '09/14/2015'.

### 10. Dose Type

- doses, mL, or units only (see Unit of Measure work instructions **ICWI0710**, *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 **ICWI0130**, *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.

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**13. Received Date** (Stamp date on the Form 2008)

- a. Default as today's date
- b. Ability to back date is available

**14. VBI Number**

Format (10-001). This field points directly to the investigation module within LSRTIS, use only valid investigation numbers.

**15. Related Submissions (mail log #)** This field will point directly to either IC or PEL Mail log numbers, if references on the Form 2008.

**16. Comments**

Add any applicable comments in comment field

**17.** Click  complete the entry

**B.** After all Form 2008s are logged in:

**1.** Click **Reports & Searching**

**2.** Click on **APHIS 2008 Search**

**3.** In the outlined box:

- a. Click on the LOV to "APHIS 2008 Logged In"
- b. Enter dates
- c. Select name of logger in "Action Performed By"
  - enter your name if you want a list of your entries
  - leave blank if you want all entries

**4.** Click on the Excel icon to generate data entry list

**5.** Compare data entry sheet against Form 2008s

**6.** If corrections are needed:

- a. Find the entry on the Action Sheet
- b. Click on 2008, then click on the "Aphis 2008 Info" link on the serial stat to make corrections
- c. Click
- d. After appropriate changes are made, click

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

**D.** Form 2008s received after 2 p.m. may be held, stamped, and logged into LSRTIS the following day. Hard copy 2008s may not be entered the day of receipt, though they will be backdated to the date of actual receipt.