

Log APHIS Form 2008

All complete APHIS Form 2008s (Form 2008s) are received and entered by the Inspection and Compliance group. Some forms are received from the Policy, Evaluation, and Licensing group via processes described in **ICWI0240, Receipt of "Electronic Submissions" from PEL APHIS Form 2007s and APHIS Form 2008**, though the majority of Form 2008s are received directly from the licensed/permitted manufacturers. 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.

Create APHIS 2008

Establishment*	<input type="text"/>	Product*	<input type="text"/>
Serial Number*	<input type="text"/>	Expiration Date	<input type="text"/>
Autogenous or Prescription Product (platform)?	<input type="checkbox"/> First Serial <input type="checkbox"/> Fifty Or Less Vials <input type="checkbox"/>		
# Containers*	<input type="text" value="0"/>	Container Size*	<input type="text" value="0"/>
	<input type="button" value="+ Add"/> Number Of Total Doses: 0		
Doses Type *	<input type="text" value="Doses"/> <input type="button" value="v"/>	Firm Disposition *	<input type="text" value="Eligible for Release"/> <input type="button" value="v"/>
Received Date*	<input type="text" value="09/15/2015"/>		
VBI Number	<input type="text"/>		
Comments	<input type="text"/>		

- 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
 - 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

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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. Inventory

a. Enter:

- # 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

# Containers*	Container Size*		
<input type="text" value="500"/>	<input type="text" value="10"/>		
<input type="button" value="+Add"/>	Number Of Total Doses: 5000		
Doses Type *	Doses <input type="button" value="v"/>	Firm Disposition *	Eligible for Release <input type="button" value="v"/>
Received Date*	<input type="text" value="09/14/2015"/>		
Permittee Total Doses Manufactured	<input type="text" value="10000"/>		
VBI Number	<input type="text"/>		

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

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Autogenous or Prescription Product (platform?) First Serial Fifty Or Less Vials

Number of Total Doses

Doses Type * Firm Disposition *

Received Date *

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*)

7. Firm Disposition (Block 12)

a. Click on the LOV to select firm's disposition

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.

8. Autogenous info (check if applicable)

a. If autogenous

b. If First serial (will usually be sent on a 1st serial summary form)

c. If Fifty or Less Vials – refer to Block 10A to determine if the number of containers is 50 or less.

d. NOTE: Code ██████ for Est. ████ is marked as an autogenous serial

9. Received Date (Stamp date on the Form 2008)

a. Default as today's date

b. Ability to back date is available

10. VBI Number

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

11. Comments

Add any applicable comments in comment field.

12. Click **Create** complete the entry

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- 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 2008sIf 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 2:30 p.m. may be held, stamped, and logged into LSRTIS the following day.