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Service

Veterinary Services

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## Serial Release - APHIS Dispositions and Associated Information on Form 2008s

**Document Number:** CVB-WI-0129

**Revision:** 02

**Previous Number:** ICWI0130.03

**Vault:** CVB-Released

**Section/Area:** CVB-WI-IC

**Effective Date:** 20 Jul 2020

**Notes:**

## Serial Release - APHIS Dispositions and Release Criteria On Form 2008s

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

The table below outlines the possible Establishment Dispositions available on an APHIS Form 2008 and the corresponding APHIS Dispositions. Some dispositions authorize market release of a serial, while others prohibit shipment of the serial. In addition, the firm may submit requests to the Center for Veterinary Biologics (CVB) using the APHIS Form 2008. Based upon the firm request submission, APHIS may approve or deny these requests through the corresponding APHIS Disposition.

### I. Disposition Criteria

*\* Notates the Default Disposition by LSRTIS for the applicable Establishment Disposition.*

Establishment Disposition	APHIS Disposition	<i>Criteria for Selecting APHIS disposition (if needed)</i>
Eligible for Release	Not to be Tested*	The serial was not tested by the CVB. This disposition authorizes market release.
	Tests Completed Satisfactory	The serial was tested by CVB and the results were satisfactory. This disposition authorizes market release.
	Tests Completed UNSATISFACTORY	The serial was tested by CVB and the results were unsatisfactory. Additional Comment may be included as a part of the APHIS Form 2008 – “UNSATISFACTORY RESULTS – NOT TO BE RELEASED. Disposition to be made under the supervision of APHIS.” This disposition PROHIBITS shipment.
	Other - Serial Released for Market	The serial was tested by the CVB and the results were either a No Test (NT) or Inconclusive (I) with no reason to suspect that the serial does not meet requirements. The serial is released for marketing based on the firm’s test results reported. This disposition authorizes market release.
	Other – Serial NOT RELEASED FOR MARKET	There is reason to suspect the serial does not meet the requirements, either due to testing conducted by CVB that resulted in a No Test (NT) or Inconclusive (I) or other information received by CVB. This disposition PROHIBITS shipment.
	Other - UNSATISFACTORY Based on Firms Results	Information reported on the APHIS Form 2008 indicates the firm’s test results were unsatisfactory or inconclusive. The serial does not meet the requirements for marketing. This disposition PROHIBITS shipment.

<b>Establishment Disposition</b>	<b>APHIS Disposition</b>	<b>Criteria for Selecting APHIS disposition (if needed)</b>
	Conditional Release Granted	A firm may request conditional release of a serial, based on the criteria listed in CVB-WI-0151. The request must be reviewed by a Specialist and approved by IC Management. There may be other conditions regarding the release of the serial. This disposition authorizes market release.
Destroyed by Firm	Destroyed By Firm Acknowledged *	Acknowledgement of an unreleased serial that has been destroyed by the firm. NOTE: It is not an intent to destroy.
Reprocess & Retest	Reprocessing & Retesting Approved *	Approval for a request to rebottle a serial in accordance with 9 CFR 114.18.
	Reprocessing & Retesting DENIED	Denial for a request to rebottle a serial in accordance with 9 CFR 114.18.
Other - Expiration Date Correction	Other – Expiration Date Correction Acknowledged *	Acknowledges the Firm's expiration date correction.
Other - Prelicense	Prelicense - Expired	A serial used to support the licensure of a product, may have been tested by CVB and the results were satisfactory, but expired prior to licensure. This disposition PROHIBITS shipment.
	Prelicense - Tests Completed Satisfactory	A serial used to support the licensure of a product, tested by CVB and the results were satisfactory. This disposition authorizes market release.
	Prelicense - Tests Completed UNSATISFACTORY	A serial submitted in support of licensure, tested by CVB and the results were unsatisfactory. This disposition PROHIBITS shipment.
	Prelicense Serial - Release for Market	A serial submitted in support of licensure, tested by CVB and the results were either a No Test (NT) or Inconclusive (I) with no reason to suspect that the serial does not meet requirements. The serial is released for marketing based on the firm's test results reported. This disposition authorizes market release.
Other - For Further Manufacture	Other – Release For Further Manufacturing *	This disposition authorizes shipment of the material.
Other - Extension of Dating	Other – Extension of Dating Approved *	Approval for a request to extend dating of a serial in accordance with 9 CFR 114.14.
	Other – Extension of Dating Denied	Denial for a request to extend dating of a serial in accordance with 9 CFR 114.14.
Other - File for Information	Other – File for Information Acknowledged *	Information submitted to CVB on a serial or bulk material that already has an APHIS disposition. It may be at the request of CVB or additional information provided by the firm. May or may not impact marketability of the serial.

Establishment Disposition	APHIS Disposition	Criteria for Selecting APHIS disposition (if needed)
	Other - File for Information Tested Satisfactory	Information submitted to CVB on a serial or bulk material, usually related to a veterinary biologics investigation and has been tested by CVB and the results were satisfactory. May impact marketability of the serial or use of the bulk in final product.
	Other - File for Information Tested UNSATISFACTORY	Information submitted to CVB on a serial or bulk material, usually related to a veterinary biologics investigation and has been tested by CVB and the results were unsatisfactory. May impact marketability of the serial or use of the bulk in final product.
Other - Inventory Correction	Other - Inventory Correction Acknowledged *	Acknowledges the Firm's inventory correction.
Other – Rebottling	Other - Rebottling Approved *	Approval for a request to rebottle a serial in accordance with 9 CFR 114.17.
	Other - Rebottling DENIED	Denial for a request to rebottle a serial in accordance with 9 CFR 114.17.
Other - Subsequent Shipment	Other - Subsequent Shipment Approved *	A second or subsequent shipment of a serial that was previously imported under US Veterinary Biologics Permit for Sale and Distribution and was found suitable for marketing. This disposition authorizes market release.
	Other - Subsequent Shipment DENIED	A second or subsequent shipment of a serial that was previously imported under US Veterinary Biologics Permit for Sale and Distribution that is unsuitable for market, either because of shipping errors, tests conducted by CVB, or other regulatory reasons. This disposition PROHIBITS shipment.
Other - Transfer	Other - Transfer Approved *	Approval for a request to transfer all or partial inventory for a serial already released to the market to another code.
	Other - Transfer DENIED	Denial for a request to transfer all or partial inventory for a serial already released to the market to another code.
Other - Shorten Dating	Shorten Dating Approved *	Approval for a request to market a lyophilized or frozen serial that does not meet the titer required for release, but is above the titer required at end of dating. This meets the intent of regulatory flexibility since these products often times cannot be reprocessed to increase the potency titer. This disposition authorizes market release.
	Shorten Dating DENIED	Denial for a request to market a lyophilized or frozen serial that does not meet the titer required for release. This disposition PROHIBITS shipment.

<b>Establishment Disposition</b>	<b>APHIS Disposition</b>	<b>Criteria for Selecting APHIS disposition (if needed)</b>
Other – Outline of Production Change	Dependent on if testing is conducted or not – follow Eligible for Release. Not to be Tested most likely to be used.	When PEL has requested testing by the firm to confirm an Outline of Production change, the firm should indicate this by this disposition or remarks.
Other – Technology Transfer	Dependent on if testing is conducted or not – follow Eligible for Release. Not to be Tested most likely to be used.	When PEL has requested testing by the firm to confirm a technology transfer request, the firm should indicate this by this disposition or remarks.

**II.** Additional Information in conjunction with the Market Release Process – This is usually on the second or subsequent APHIS Form 2008 submitted in order to change or confirm a marketing disposition for a serial. In order to confirm the disposition or to change the disposition, the Specialist may request additional information. A new/revised APHIS Form 2008 must also be submitted for processing. Blocks 16, 17, 18, and 19 should be blank.

<b>Original APHIS Disposition</b>	<b>Revised or Confirmed APHIS Disposition</b>	<b>Explanatory Comment – included as a part of the APHIS Form 2008</b>
Other-UNSATISFACTORY Based on Firms Results	Other - Serial Released for Market	This rescinds the UNSATISFACTORY ACTION previously reported. Serial may be released for market.
Other-UNSATISFACTORY Based on Firms Results	Other - UNSATISFACTORY Based on Firms Results	This confirms the UNSATISFACTORY ACTION previously reported. This disposition PROHIBITS shipment.
Tests Completed UNSATISFACTORY	Tests Completed UNSATISFACTORY	This confirms the UNSATISFACTORY ACTION previously reported. Disposition to be made under supervision of APHIS This disposition PROHIBITS shipment.
Tests Completed UNSATISFACTORY	Tests Completed SATISFACTORY	This rescinds the UNSATISFACTORY ACTION previously reported. Serial may be released for market.
*Conditional Release Granted	Depends on CVB Test Status	This completes the conditional release granted by CVB.
*Conditional Release Granted	Tests Completed UNSATISFACTORY	This rescinds the conditional release granted by CVB. Serial to be immediately recalled.

\* Does not require another submission of the APHIS Form 2008 from the firm.

- A. When a serial has been submitted that is at the Bulk Stage, the following is added to the APHIS Form 2008:
- The APHIS Disposition may be granted as “File for Information.”
  - The additional info to be added “**Bulk.**”

**III.** CVB-IC personnel may choose to set Release Requirements for the manufacturers to perform specific actions as stipulations of release of a serial as part of Extension of Dating Requests, Reprocess and Retesting Requests, or other reasons. Examples of these release requirements may be additional potency testing near the end of dating, or submission of adverse events for the serial. See **CVB-WI-0082**, *Specialist Review Action within LSRTIS*, for examples on when to add these requirements.

**a.** How to set a release requirement:

- i.** When in Specialist Review – Choose the “Review” link
- ii.** Click in the check box for “Release Criteria Required?”.
- iii.** Choose the applicable drop down for “Release Criteria”.
- iv.** If you expect an Action from the firm, pick a due date.
- v.** Enter the “Release Criteria Comments”.

**1.** Remember these are seen by the Firms within the ENSR and Portal views

**2.** Choose specific dates (not just 3, 6, 12, months for example).

**3.** Examples:

*Potency testing at 12 and 24 months (Initiate by November 1, 2020 and November 1, 2021), and report to the CVB within a week of validation.*

or

*Potency testing at mid and end of dating (Initiate by April 1, 2021 and April 1, 2021), and report to the CVB within a week of validation.*