



## VETERINARY SERVICES MEMORANDUM NO. 800.53

Animal and Plant  
Health Inspection  
Service

Veterinary Services

1400 Independence  
Ave, SW

Washington, DC  
20250

**TO:** Veterinary Services Leadership Team  
Directors, Center for Veterinary Biologics  
Biologics Licensees, Permittees, and Applicants

**FROM:** Jack A. Shere  
Deputy Administrator

**SUBJECT:** Release of Biological Products

### I. PURPOSE

This memorandum conveys policy and procedures to comply with title 9, *Code of Federal Regulations* (9 CFR), parts 113 and 116, sections 113.3, 113.6, and 116.7, for the marketing release of biological products. A licensee or permittee shall withhold products from the market until APHIS makes a market determination. For the purpose of this memorandum, the term “release” is defined as the process used by APHIS in this determination.

### II. REPLACEMENT

This memorandum cancels Veterinary Services (VS) Memorandum No. 800.53, dated July 20, 2016. It is being updated to harmonize procedures for serials intended for immediate marketing, prelicense evaluation, and supporting changes to the Outline of Production. It also clarifies that electronic submission via the National Centers for Animal Health (NCAH) Portal is the preferred method for submitting documents to support release of biological products.

### III. PROCEDURES FOR SHIPMENT AND RECEIPT OF BIOLOGICS SAMPLES (APHIS FORM 2020)

- A. Licensees and permittees are encouraged to send APHIS Form 2020 data from an authorized firm representative through the NCAH Portal. APHIS Form 2020 on the Biologics Forms page within the Center for Veterinary Biologics (CVB) Web site and previous editions are also acceptable for submission as hard copies. Licensees or permittees must either generate a packing slip through the NCAH Portal or prepare an APHIS Form 2020 for each shipment of samples. A separate Form must be used for each sample type indicated in block 4 (Purpose). If additional samples are requested by the CVB, use a separate Packing Slip or APHIS Form 2020 and mark “RESUBMISSION” in block 4. For more information, refer to VS Memorandum No. 800.59 or the instructions on the CVB Web site for submitting APHIS Form 2020.

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APHIS will acknowledge receipt of samples with entries in blocks 9 and 17 through 19. A signed copy of the APHIS Form 2020, with the assigned sample number notated, will be returned to the licensee or permittee if a hard copy was submitted. Alternatively, a response within the NCAH Portal will include the sample number assigned.

Send shipments of biological samples, with accompanying packing slip or APHIS Form 2020, to the following address:

Center for Veterinary Biologics  
NVSL, Laboratory Resources Unit – Sample Processing  
1920 Dayton Avenue  
Ames, IA 50010

#### IV. PROCEDURES FOR SUBMISSION OF VETERINARY BIOLOGICS PRODUCTION AND TEST REPORT (APHIS FORM 2008 and APHIS FORM 2008A)

- A. Licensees and permittees are encouraged to submit APHIS Form 2008 data from an authorized firm representative through the NCAH Portal. Paper copies of APHIS Form 2008 on the Biologics Form page within the CVB Web site or an approved substitute may also be used. Forms not previously approved by the CVB should be submitted for review and approval prior to use.
- B. The submission of APHIS Form 2008 or 2008A information is considered confirmation by the licensee or permittee that all manufacturing, including that prior to section V of the approved Outline of Production, was in compliance with the Outline of Production and the applicable regulations.
- C. When completed product samples in bulk form have been submitted to APHIS, an APHIS Form 2008 showing the manufacturer's test results on bulk samples must be submitted and clearly marked as a "BULK" submission. This release of bulk material does not exempt a licensee or permittee from submitting an APHIS Form 2008 for the release of finished product.
- D. Licensees and permittees must submit APHIS Form 2008 information for each serial or subserial prepared. All completed APHIS Form 2008s, regardless of whether the serial was intended for release immediately or upon product licensure, should be submitted to CVB-Inspection and Compliance (CVB-IC).
  1. Licensees and permittees are encouraged to submit electronically to the CVB through the [NCAH Portal](#). Employees with the Liaison or Serial Release role and Level 2 eAuthentication may submit the information to the CVB through the NCAH Portal.

2. Alternatively, submit a paper APHIS Form 2008 with an original signature, and one copy, to:

CVB – Inspection and Compliance  
USDA-APHIS-VS  
1920 Dayton Avenue  
P.O. Box 844  
Ames, IA 50010

3. Serials prepared for prelicensing evaluation

Serials may be prepared for various reasons during the product licensing process, but typically three serials are prepared for prelicense evaluation that may become eligible for release when the license is issued. Firms should discuss this requirement with their reviewer in advance of serial preparation. This section does not apply to preliminary or partial data that may be requested by the CVB prior to availability of all testing data or to testing of experimental product.

For APHIS Form 2008s meeting the above criteria, ensure “Other” is marked in block 12 and add the word “Prelicense.” If submitting via the NCAH Portal, the Disposition by Firm should be “Other-Prelicensing”(see section III.E.12.d). Licensing reviewers in CVB-Policy, Evaluation, and Licensing (CVB-PEL) will be notified when APHIS Form 2008 data have been submitted for prelicense serials. Cite the APHIS Form 2008 submission date in any subsequent related correspondence to the CVB-PEL in which a copy of APHIS Form 2008 historically would have been included.

4. Serials supporting Outline of Production revisions

Changes may be made to the Outline of Production after product licensure. Certain changes may not be approved by the CVB until the CVB satisfactorily tests at least one serial produced and/or tested under the new methods. Such Outline changes typically include, but are not limited to, changes in section V covering testing methods or material changes to manufacture that may impact product quality. Testing requirements should be discussed with the reviewer by the firm.

When a licensee or permittee is directed by its licensing reviewer to provide a serial or serials for confirmatory testing to support a proposed Outline change, the Disposition by Firm on APHIS Form 2008 for the applicable serial should be “Other-Outline Change.” As with other APHIS Form 2008 data, any correspondence with the licensing reviewer should cite the submission date of the APHIS Form 2008 data to the CVB-IC.

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- E. Complete the paper APHIS Form 2008 as follows (see NCAH Portal User Guide for guidance on corresponding NCAH Portal fields):
1. *Block 1.* Enter the page number. For subsequent pages, use APHIS Form 2008A or an acceptable equivalent.
  2. *Block 2.* Enter the license or permit number (9 CFR, parts 102 and 104, sections 102.4(c) and 104.7(a)).
  3. *Block 3.* Enter the name and mailing address of the licensee or permittee.
  4. *Block 4.* Enter the date the final containers were filled. Enter N/A (not applicable) for bulk submissions.
  5. *Block 5.* Enter the Veterinary Biologics product code number from the current product license or permit (9 CFR, parts 101 and 102, sections 101.3(k) and 102.5(b)(3)). For prelicense serials, enter the assigned product code.
  6. *Block 6.* Enter the expiration date to be used on the final container labels. Compute the expiration date in accordance with the Outline of Production (9 CFR, parts 101 and 114, sections 101.4(f) and 114.13).
  7. *Block 7.* Enter the serial or subserial number (9 CFR, part 101, sections 101.3(h) and (i) and 101.4(e)). Serial and subserial numbers are limited to no more than 15 alphanumeric characters.
  8. *Block 8.* Enter the true name of the veterinary biological product as stated on the current product license or permit (9 CFR, part 101, section 101.4(d)). For autogenous biologics, include the identification of the component organisms and the host animal species for which the product is intended.
  9. *Block 9.* Enter all tests conducted to support release of the serial or subserial as defined in section V of the Outline of Production, including no tests and inconclusive tests. If the space in block 9 is not adequate, use APHIS Form 2008A or an acceptable equivalent to report additional test results.
    - a. *Block 9A.* Enter the test reference by entering the paragraph identification from the filed Outline of Production in which the specific test is described (e.g., V.C.2) and, if applicable, 9 CFR reference.
    - b. *Blocks 9B and 9C.* Enter the Started and Concluded dates for each test conducted on bulk or final product. For animal potency tests, the dates entered in 9B and 9C should be all inclusive for the complete test, including vaccination, challenge, and/or serological testing dates.

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- c. *Block 9D.* Enter all test results, including the validity and control requirements for each test needed to determine the test conclusion.
  - d. *Block 9E.* Insert the letter code as noted on the APHIS Form 2008 that corresponds to the test conclusion. Explain in block 11, Remarks, the basis for a "No Test" or "Inconclusive" entry.
    - (1) A satisfactory (S) test designation is a final conclusion given to a valid test with results that meet the release criteria stated in the filed Outline of Production or 9 CFR Standard Requirement.
    - (2) An unsatisfactory (U) test designation is a final conclusion given to a valid test with results that do not meet the release criteria stated in the filed Outline of Production or 9 CFR Standard Requirement.
    - (3) An inconclusive (I) test designation is used for an initial test when a sequential test design established in the filed Outline of Production or Standard Requirement allows further testing if a valid initial test is not satisfactory. When the initial or any subsequent test is declared inconclusive, the reasons shall be reported in the test records, the result shall not be considered as final, and the test may be repeated as established in the filed Outline of Production or Standard Requirement. If a test is designated inconclusive and the biological product is not further tested, the test designation of unsatisfactory is the final conclusion.
    - (4) A No Test (NT) designation is used when a deficiency in the test system has rendered a test unsuitable for drawing a valid conclusion. When the initial or any subsequent test is declared a No Test, the reasons shall be reported in the test records, the results shall not be considered as final, and the test may be repeated. If a test is designated a No Test and the biological product is not further tested, the test designation of unsatisfactory is the final conclusion.
10. *Block 10.* Enter the inventory of product containers or quantities to which testing and disposition apply. For serials or subserials designated as "Eligible for Release," this quantity is the entire inventory of product prepared for marketing. For serials or subserials designated as "Destroyed by Firm" or "Other—not to be marketed," indicate at least an estimated quantity. For imported material, enter the entire inventory of a completed serial prepared for marketing.
- a. *Block 10A.* Enter the number of containers, using a separate line for each size of container. Entities must maintain accurate accountability of product. If an inventory of product reported on the APHIS Form 2008 is inaccurate and falls outside the control limits as determined by the

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manufacturer, an amended APHIS Form 2008 or acceptable equivalent should be submitted with a corrected inventory.

- b. *Block 10B.* Indicate the quantity or test in each container or kit (doses, mL, or units). Enter doses for vaccines and bacterins. For product with more than one dose size, enter the maximum number of doses that could be marketed. Enter number of tests, not plates, for diagnostic test kits. Products “For Further Manufacture” (FFM) that are not shipped in final container should indicate the volume in milliliters (mL). Specify which unit of measure is being used for each entry.
- c. *Block 10C.* Enter the total quantity (10A x 10B) for each line of inventory and include the unit of measure for each size (doses, ml, or units).
- d. Total columns A and C and enter the respective totals, including the unit of measure for each (doses, mL, or units).

11. *Block 11.* Place any pertinent remarks in this block.

- a. Enter information explaining the reason a test conclusion was considered a “No Test” or “Inconclusive,” as noted in block 9E.
- b. Serials of finished product which contain material from FFM serials must indicate the establishment number, product code, and serial number of all FFM serials contained in the finished product serial.
- c. The amount of imported product shipped for marketing in the United States should be noted. An authorized sampler at the permittee’s quarantine facility must certify the amount and condition of inventory received per shipment of product imported for sale and distribution. Include the date the product was received at the permittee’s quarantine facility. For more information, refer to VS Memorandum No. 800.101.
- d. Indicate whether the submission is in support of prelicensing or a revision to the Outline of Production.
- e. Reference test results previously submitted on another subserial’s APHIS Form 2008.
- f. Indicate if the submission is for a “Bulk” sample.
- g. If the serial is the result of an approved reprocessing or rebottling submission, note the original product code and serial number.

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- h. If the serial is the result of an approved for transfer submission, note the original establishment number, product code, and serial number.
- i. If the serial has been reprocessed by adding one completed serial of product to another completed serial of product, note both serial numbers.
- j. Indicate the identity and expiration date of all reference preparations used for potency testing of serials.

12. *Block 12.* Mark the applicable firm disposition block.

- a. “Eligible for Release” is a certification by the licensee/permittee that the serial is prepared and tested in accordance with the Outline of Production and is considered eligible for market release.
- b. “Destroyed” is a certification of actual destruction and not the intent to destroy. Indicate the date of destruction. If destruction is for a reason other than unsatisfactory tests, state the reason in block 11.
- c. “To be Reprocessed and Retested” is a request that must be approved in accordance with 9 CFR 114.18 and VS Memorandum No. 800.62.
- d. Use “Other” for prelicense serials, inventory or expiration date corrections, extensions or shortening of dating, rebottling, transfer requests, serials to support Outline of Production changes, or additional information to be filed. Provide an appropriate explanation in block 12. Additional remarks may be recorded in block 11.

13. *Block 13.* The APHIS Form 2008 or acceptable equivalent must have the original signature of a person whose authorization has been previously filed with APHIS, in accordance with 9 CFR 114.7(a) and VS Memorandum No. 800.63.

14. *Block 14.* Enter the title for the person whose signature appears in block 13.

15. *Block 15.* Enter the date the APHIS Form 2008 was signed.

F. Preparation of APHIS Form 2008A or acceptable equivalent. All instructions given for APHIS Form 2008 apply to APHIS Form 2008A or acceptable substitute. Block 5 of APHIS Form 2008A is not applicable and need not be completed.

G. If section V testing is performed by the manufacturer after APHIS marketing release, unsatisfactory testing must be reported to the CVB-IC in adherence to 9 CFR 116.5. Satisfactory testing performed after marketing release does not

need to be reported to the CVB-IC unless requested, but testing records shall be maintained by the manufacturer.

**V. PROCEDURE FOR MARKET DETERMINATION BY APHIS**

- A. The APHIS Form 2008 or acceptable equivalent will be reviewed for compliance with release requirements. When exceptions are noted, the licensee or permittee will be notified of the necessary corrections or additions. The Audit and Correction Transmittal may be used by the CVB for this purpose. When signed by an authorized representative of APHIS, the APHIS Form 2008 is the exclusive disposition document for marketing decisions. A released product, by definition, is a finished product released for marketing after all requirements have been satisfied. If release is not granted or is subject to restrictions, an explanation is provided on the APHIS Form 2008. Other documents may be attached for information.
- B. Market Serials Not Selected for Testing. Disposition by APHIS will be granted or withheld by completion of blocks 16 through 19 on the APHIS Form 2008 or acceptable equivalent.
- C. Market Serials Selected for Testing
  - 1. The CVB-PEL laboratory may select serials for testing within 7 calendar days after receipt of representative samples. Diagnostic test kits may be selected for testing within 3 calendar days of receipt of samples. Exceptions to the initiation of tests within 7 or more days after the receipt of serial or test samples may be made under special circumstances. Licensees will be notified whenever such exceptions are made.
  - 2. The CVB-IC may select a serial for testing based on results submitted on the APHIS Form 2008. The selection by the CVB-IC may occur after the selection period for sample receipt.
  - 3. Disposition by APHIS will be granted or withheld by completion of blocks 16 through 19 on the APHIS Form 2008 or acceptable equivalent.
- D. Distribution. APHIS will retain the completed original APHIS Form 2008 or acceptable equivalent. One completed copy of the APHIS Form 2008 or acceptable equivalent, with additional documentation, as applicable, will be sent to the licensee or permittee.



**VI. CENTER FOR VETERINARY BIOLOGICS-LABORATORY TEST REPORTS**

**A. Preparation and Processing**

1. *Serials for Marketing.* The CVB-PEL Laboratory will report test results to the CVB-IC on each serial or subserial tested by the CVB-PEL. Supplementary reports will be appended if additional data and explanatory comments, beyond those included on a standard report, are warranted.
2. *Serials Involved in Prelicensing Evaluation or Outline of Production Revisions.* The CVB-PEL Laboratory will report test results to the CVB-PEL with supplementary reports, if indicated. The CVB-PEL will make recommendations to the CVB-IC on the final APHIS disposition.

B. Distribution. The completed test report will be sent by the CVB-IC to the licensee or permittee. APHIS will retain copies, as appropriate.

**VII. EXCEPTIONS**

**A. First Serial Autogenous Biologics**

1. Refer to VS Memorandum No. 800.69.
2. If the disposition of the serial is “Destroyed By Firm” (DBF), the date of final disposition and the reason the serial was destroyed should be included in the “Remarks” column.
3. Test results for specific serials shall be made available to the CVB on request.

**VIII. ELECTRONIC NOTIFICATION OF MARKETING AUTHORIZATION  
(SERIAL RELEASE)**

A. Electronic same-day notification for final disposition of serials is provided. This notification process will be used for all APHIS Forms 2008 received by the CVB. See Appendix I for an example electronic notification.

1. A licensee or permittee will receive e-mail notification from APHIS-CVB Serial Release, [cvb.serialrelease@aphis.usda.gov](mailto:cvb.serialrelease@aphis.usda.gov), for each APHIS Form 2008 processed by the CVB. The e-mail notifications may regard any APHIS disposition, including notifications that a serial is not eligible for marketing. The recipient is responsible for reviewing the APHIS disposition and taking appropriate action based on the market status of the serial as determined by APHIS.

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2. The establishment may market the product in accordance with the final APHIS disposition on receipt of the electronic notification.
  3. There is no U.S. regulatory requirement that a signed hard copy of the APHIS Form 2008 must be physically at the manufacturing site before shipping an approved serial. The electronic notification is the official notification for marketing purposes.
- B. The following statement will be included on each electronic notification:
- This electronic notification is equivalent to an APHIS Form 2008 signed by an Authorized APHIS Representative and is appropriate for marketing authorizations. See Veterinary Services Memorandum No. 800.53, Release of Biological Products, for more information.**
- C. APHIS Dispositions authorizing the market release of serials are as follows:
1. Not to be Tested
  2. Tests Completed Satisfactory
  3. Shorten Dating Approved
  4. Other – Release for Further Manufacture
  5. Other – Serial Released for Market
  6. Other – Subsequent Shipment Approved (for permitted product)
  7. Other – Conditional Release Granted
  8. Prelicense – Test Completed Satisfactory
  9. Prelicense Serial – Release for Market
- D. The following APHIS Dispositions prohibit shipment of the serial:
1. Test Completed UNSATISFACTORY
  2. Shorten Dating DENIED
  3. Other – UNSATISFACTORY Based on Firm’s Results
  4. Other – Serial NOT RELEASED FOR MARKET
  5. Other – Subsequent Shipment DENIED
  6. Prelicense – EXPIRED
  7. Prelicense – Tests completed UNSATISFACTORY
- E. If a hard-copy APHIS Form 2008 was submitted for processing, the signed hard-copy APHIS Form 2008 and related CVB test reports will be returned to the establishment’s mailing address weekly by the U.S. Postal Service. Only one route of submission should be used per serial submission. APHIS Forms for export purposes (i.e., 2017, 2046, 2046S, 2047, and 2047S) will continue to be processed by hard copy and could also be used to certify a serial or product if needed by an importing country.

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- F. Audit and correction transmittals will be sent through electronic notification. Conditions of release (Release Requirements) will be noted within the electronic notification, if applicable.

**IX. IMPLEMENTATION/APPLICABILITY**

Updated policy in this memorandum is effective immediately.

**Appendix I**



U.S. Department of Agriculture  
Animal and Plant Health Inspection Services  
**Veterinary Biologics Marketing Notification**

Name, Mailing Address of Licensee or Permittee	License or Permit No.
[REDACTED]	[REDACTED]

True Name of Product	Product Code	Serial Number	Expiration Date
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

APHIS Disposition Date	APHIS Disposition
August 24, 2016	Not to be Tested

Authorized APHIS Representative - William Huls, Biologics Specialist

This electronic notification is equivalent to an APHIS Form 2008 signed by an Authorized APHIS Representative and is appropriate for marketing authorizations. See Veterinary Services Memorandum 800.53, Release of Biological Products for more information.

**For Official Use Only**