



July 30, 2013

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 13-11

Animal and Plant
Health Inspection
Service

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

Veterinary Services

Center for Veterinary
Biologics

FROM: Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*
Director
Center for Veterinary Biologics

1920 Dayton Avenue
PO Box 844
Ames, IA 50010

SUBJECT: Changes to the Final Disposition Notification for Release of Biological
Products

(515) 337- 6100

I. PURPOSE

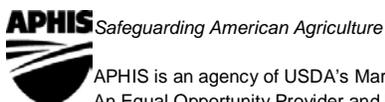
The purpose of this Notice is to inform interested parties of changes to the Center for Veterinary Biologics (CVB) notification of Biological Product Release actions.

II. BACKGROUND

Veterinary Services Memorandum 800.53, *Release of Biological Products*, outlines the process required for submission of test summaries for each serial prepared by a licensee or permittee, as required by Title 9, Code of Federal Regulations (9 CFR) Part 116.7. These test summaries are submitted on an APHIS Form 2008 and are evaluated by APHIS, along with any testing conducted by the Center for Veterinary Biologics, for a final disposition of the serial as required in 9 CFR 113.6.

Historically, the processed APHIS Form 2008 and related CVB test reports have been sent back to the licensee or permittee, either by the U.S. Postal Service at no cost to the establishment or by a courier service paid for by the establishment. Evaluation of data collected from the licensees indicates this “hard copy” notification process could result in a 1-3 day delay from the actual final disposition of the product by APHIS.

The CVB is implementing an electronic same day notification for final disposition of serials. This notification process will be used for all APHIS Forms 2008 received by the CVB. The establishment may market the product in accordance with the final disposition designated by APHIS upon receipt of the electronic notification. There is no United States regulatory requirement for the hard copy APHIS Form 2008 to be on site prior to shipment of an approved serial.



APHIS is an agency of USDA's Marketing and Regulatory Programs
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Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339

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III. ACTION

The process for submission, review, and approval of the APHIS Form 2008 will remain unchanged. APHIS Forms 2008 that are audited back to the firm will be sent by the U.S. Postal Service on the day of the audit.

Each current establishment will need to submit one (1) e-mail address for the licensee or permittee to CVB. This address must be submitted in writing by August 12, 2013 to:

Center for Veterinary Biologics
Inspection and Compliance
1920 Dayton Avenue
Ames, Iowa 50010

A licensee or permittee will receive e-mail notification from APHIS-CVB Serial Release, cvb.serialrelease@aphis.usda.gov, for each APHIS Form 2008 processed by CVB. The e-mail notifications may be any APHIS disposition, including notifications that a serial is not eligible for marketing. The recipient is responsible for review of the APHIS disposition and appropriate action based on the market status of the serial as determined by APHIS. Attached to this notice are several examples of the reports that will be attached to the e-mail notification. A legend explaining the codes utilized on the reports will be provided to the licensee or permittee.

The signed, hard-copy, APHIS Form 2008 and related CVB test reports will be returned to the establishment's mail address weekly by the U.S. Postal Service. If an e-mail address has not been submitted to the CVB, this will be the only means for notification of final disposition after September 30, 2013.

IV. IMPLEMENTATION/ APPLICABILITY

Effective Monday, September 30, 2013, the notification of final disposition of Veterinary Biological Products will be transmitted electronically to the e-mail address provided to the CVB by each establishment. This notification will take place prior to noon, central time. APHIS Forms 2008 not completely processed by noon may have notification of final disposition electronically transmitted later the same day.

Attached (Sample Reports)



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

Name & Mailing Address of Licensee or Permittee US Biologics 1111 2 nd Street Anytown, AnyState 00000	License or Permit No. 123	APHIS Disposition Date May 9, 2013
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True Name of Product	Product Code	Serial Number	APHIS Disposition
Animal Vaccine, Modified Live	1234.56	ABCD	Tests Completed SAT

PTO 000.01 Modified Live Titration, ANIMAL VIRUS

On Test Date	Off Test Date	Result	Unit	Parameter	Value Type	Conclusion
05/06/13	05/08/13	5.5	TCID ₅₀	Titration	Release	ST

Authorized APHIS Representative – John Smith, Biologics Specialist

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

Name & Mailing Address of Licensee or Permittee US Biologics 1111 2 nd Street Anytown, AnyState 00000	License or Permit No. 123	APHIS Disposition Date May 9, 2013
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True Name of Product	Product Code	Serial Number	APHIS Disposition
Animal Bacterin, Killed	2345.67	EFGH	Not to be Tested

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Animal and Plant Health Inspection Services
Veterinary Biologics Marketing Notification

Name & Mailing Address of Licensee or Permittee US Biologics 1111 2 nd Street Anytown, AnyState 00000	License or Permit No. 123	APHIS Disposition Date May 9, 2013
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True Name of Product	Product Code	Serial Number	APHIS Disposition
Animal Bacterin, Killed	B345.67	WWWW	For Further Manufacture Approved

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Animal and Plant Health Inspection Services
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Name & Mailing Address of Licensee or Permittee US Biologics 1111 2 nd Street Anytown, AnyState 00000	License or Permit No. 123	APHIS Disposition Date May 9, 2013
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True Name of Product	Product Code	Serial Number	APHIS Disposition
Animal Bacterin, Killed	2345.67	IJKL	Other – FFI Approved

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Animal and Plant Health Inspection Services
Veterinary Biologics Marketing Notification

Name & Mailing Address of Licensee or Permittee US Biologics 1111 2 nd Street Anytown, AnyState 00000	License or Permit No. 123	APHIS Disposition Date May 9, 2013
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True Name of Product	Product Code	Serial Number	APHIS Disposition
Animal Vaccine, Modified Live	1234.56	LMNO	Destroyed by Firm Approved

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Name & Mailing Address of Licensee or Permittee US Biologics 1111 2 nd Street Anytown, AnyState 00000	License or Permit No. 123	APHIS Disposition Date May 9, 2013
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True Name of Product	Product Code	Serial Number	APHIS Disposition
Animal Vaccine, Modified Live	1234.55	XYZ	Tests Completed UNSAT

PTO 000.01 Modified Live Titration, ANIMAL VIRUS

On Test Date	Off Test Date	Result	Unit	Parameter	Value Type	Conclusion
05/06/13	05/08/13	1.2	TCID ₅₀	Titration	Release	UN

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