



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 17-08

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

FROM: Byron E. Rippke
Director

SUBJECT: Retention of Policy Documents Posted to Center for Veterinary Biologics Website

I. PURPOSE

The purpose of this Notice is to inform interested parties of standardized retention periods for policy documents posted to the Center for Veterinary Biologics (CVB) Website.

II. BACKGROUND

The CVB posts Veterinary Services Memoranda (VSM) and CVB Notices relevant to the biologics program on its Website at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/biologics-regulations-and-guidance/ct_regs_guidance. Document retention periods have been standardized to keep Web content current and manageable.

III. ACTION

A. Veterinary Services Memoranda

VSMs are used to publish CVB regulatory policy and do not have a standard retirement date. VSMs are posted on the Website until they are specifically superseded by another VSM or formally retired without a replacement.

1. If superseded, the obsolete memo will be removed 60 days after the replacement memo is published. Superseded memos are listed in the "Cancellation" section of the replacement VSM. Additional rescinded memos also may be listed there if their content is incorporated into the newly published memo.
2. When a VSM is retired without a direct replacement or incorporation into another document, a CVB Notice will be published to announce the retirement prior to 60 days removing it from the Website.

B. CVB Notices

1. Routine Notices

CVB Notices are used to publish administrative announcements regarding the veterinary biologics program. Many of the announcements are routine and do not have long-term relevance. The following retention periods have been established for routine Notices:

Description	Retention Period (Years) after Publication
Quarterly announcement of new license issuances	1
Yearly announcement of doses produced/destroyed	1
Announcement of new conditional license	1
Announcement of new version of biologics forms	1
Announcement of change in contact info	1
Announcement of retired VSM	1
Announcement of new or retired Supplemental Assay Method (SAM)	3
Announcement of new/retired reagent or change in reagent dating	3
Announcement of acceptance of applications for new class of biologic	Upon licensure of first applicable product
Solicitations for new biological products (e.g., vaccine bank)	1
Taxonomic name changes	1

2. Non-Routine Notices

CVB Notices also may be used as an expedited means to publish new regulatory policies or procedures, but these are typically followed by a more permanent document, like a VSM.

This type of Notice may be retired when the follow-up document, containing information covered in the Notice, is published. Procedural notices also may be retired when the information contained in them is no longer applicable.

IV. IMPLEMENTATION/APPLICABILITY

Documents listed in the Appendix of this Notice will be removed from the Website 60 days after the date of this Notice. Individuals wishing to keep archival copies of these documents should download them from the Website within that 60-day grace period. From then on,

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documents will be removed from the Website, according to the retention schedule in this Notice, without further notification.

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Appendix. Documents Currently Eligible to be Removed from CVB Website*Routine CVB Notices*

ID	Title
00-05	Issuance of a Conditional License for Lawsonia Intracellularis Vaccine, Avirulent Live Culture
00-12	Issuance of a Conditional License for Mycoplasma Bovis Bacterin
00-13	Issuance of a Conditional License for Avian Influenza Vaccine, Killed Virus, H5 Subtype
00-15	Issuance of New Supplemental Assay Method
00-16	Issuance of New Supplemental Assay Method
00-17	Issuance of a Conditional License for Sarcocystis Neurona Vaccine, Killed Protozoa
02-08	Diagnostic Test Kits for Scrapie and Chronic Wasting Disease
04-08	Diagnostic Test Kits for Bovine Spongiform Encephalopathy
06-21	Replacement of the CVB Killed Veterinary Rabies Reference
10-04	Replacement of the CVB Killed Veterinary Rabies Reference
78	Veterinary Biological Products in Licensed Establishments Produced and Destroyed 01/01/2010 through 12/31/2010
11-03	Issuance of Licenses
11-04	Expiration Date Extension and Discontinued Reagents: Salmonella Standard Reference Bacterins
11-05	Replacement of the Center for Veterinary Biologics Escherichia coli, HRP-labeled K88 Monoclonal Antibody
11-06	Cancellation of Veterinary Services Memorandum 800.96 and Notice of Example Data Files
11-07	Distribution of a New Lot of Leptospira grippotyphosa Polyclonal Antibody, IRP 511-04
11-08	Issuance of Licenses
11-11	Replacement Lots of the Center for Veterinary Biologics' Mycobacterium Tuberculosis Sensitinogen, Escherichia coli Anti-K99 Pilus Horseradish Peroxidase (HRP)-Labeled Monoclonal Antibody, and Clostridium tetani Antitoxin 5.0 AU/mL (guinea pig origin)
11-13	Distribution of a new lot of Leptospira kirschneri Serogroup grippotyphosa Mouse Ascites (also designated as Leptospira grippotyphosa Monoclonal Antibody (LG MAb) IRP 04-505
11-15	Discontinued Reagents: Standard Reference Preparations and Test Reagents for Virus Biological Products
11-16	Issuance of Licenses
11-17	Withdrawal of Supplemental Assay Method (SAM) for the Mikrozone Electrophoretic Separation of Blood Fractions Used in Veterinary Biologics, SAM 509
11-19	Avian Influenza (H5 and H7 Subtypes) Vaccine Bank
11-20	Supplemental Assay Methods

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ID	Title
11-21	Issuance of Licenses
11-20	Supplemental Assay Methods
11-22	Routine Distribution and Replacement of the Center for Veterinary Biologics' Bacterial Testing Reagents
11-23	Issuance of a Conditional License for West Nile Virus Vaccine, Killed Virus
79	Veterinary Biological Products in Licensed Establishments Produced and Destroyed 01/01/2011 through 12/31/2011
12-01	Issuance of Licenses
12-02	Change in Contact Information for the Policy, Evaluation, and Licensing, Operational Support Section
12-08	Issuance of Licenses
12-10	Issuance of a Conditional License for Corynebacterium Pseudotuberculosis Bacterin
12-13	Issuance of a Conditional License for Foot and Mouth Disease Virus Vaccine, Live Adenovirus Vector
12-16	Issuance of Licenses
12-19	Issuance of a Conditional License for Polyprenyl Immunostimulant
12-20	Issuance of Licenses
12-22	Issuance of a Conditional License for Equine Rhinitis A Vaccine
12-23	Issuance of a Conditional License for Canine Lymphoma Monoclonal Antibody
12-24	Issuance of a Conditional License for Streptococcus Uberis Bacterin
80	Veterinary Biological Products in Licensed Establishments Produced and Destroyed 01/01/2012 through 12/31/2012
13-01	Issuance of Licenses
13-04	Discontinued Bacterial Challenge Cultures
13-07	Issuance of Licenses
13-08	Extension of Dating for Erysipelothrix Rhusiopathiae Bacterin, IRP 529(05)
13-09	Issuance of Licenses
13-12	Issuance of a Conditional License for Rift Valley Fever Vaccine, Modified Live Virus
13-14	Issuance of Licenses
13-15	Issuance of a Conditional License for Bronchitis Vaccine, Georgia Type, Live Virus
13-16	Availability of New and Revised Biologics Forms
81	Veterinary Biological Products in Licensed Establishments Produced and Destroyed 01/01/2013 through 12/31/2013
14-01	Issuance of Licenses
14-02	Availability of Porcine Epidemic Diarrhea Virus (PEDV)
14-03	Issuance of a Conditional License for Canine Lymphoma Monoclonal Antibody

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ID	Title
14-04	Availability of Revised APHIS Form 2007
14-05	Availability of Swine Influenza Virus (SIV) Isolates
14-07	Issuance of a Conditional License for Feline Interleukin-2 Immunomodulator, Live Canarypox Vector
14-08	Extension of Dating for Erysipelothrix Rhusiopathiae Bacterin, IRP 529 (05)
14-09	Issuance of Licenses
14-11	Availability of Porcine Delta Coronavirus Isolate
14-12	Issuance of a Conditional License for Porcine Epidemic Diarrhea Vaccine
14-13	Issuance of Licenses
14-14	Issuance of Licenses
82	Veterinary Biological Products in Licensed Establishments Produced and Destroyed 01/01/2014 through 12/31/2014
15-01	Issuance of Licenses
15-05	Issuance of Licenses
15-09	Issuance of Licenses
15-10	Issuance of a Conditional License for Canine Atopic Dermatitis Immunotherapeutic
15-11	Issuance of a Conditional License for Canine Lymphoma Vaccine, DNA
15-12	Issuance of Licenses
83	Veterinary Biological Products in Licensed Establishments Produced and Destroyed 01/01/2015 through 12/31/2015
16-01	Issuance of Licenses
16-04	Issuance of a production platform-based license for Prescription Product, RNA Particle
16-06	Issuance of Licenses
16-08	Name Change for Biologicals Containing Arcanobacterium pyogenes
16-10	Issuance of Licenses
16-11	Final solicitation for Eurasian (EA) highly pathogenic Avian Influenza (HPAI) Virus H5 vaccine

Other CVB Notices

ID	Title	Reason for Retirement
00-04	Collaborative Studies on Moisture and Formaldehyde	Collaboration opportunity ended
00-10	Courtesy Notification of Serial Release Actions	New procedure incorporated into VSM 800.53
02-02	Change in Finished Label Submission Requirement	Incorporated into 9CFR 112 and VSM 800.54
05-05	Confidence Interval Estimation in Serological Interference Studies	Incorporated into VSM 800.203

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ID	Title	Reason for Retirement
06-13	Transfer of Food Safety and Inspection Service (FSIS) Support of Adjuvant Reviews from FSIS to the Animal and Plant Health Inspection Service (APHIS)	Current procedure described in VSM 800.51
07-17	Labeling of Equine Influenza and Swine Influenza Vaccines	Incorporated into VSM 800.54
13-03	Change in Issuance of Permits for General Sale and Distribution	All affected permits have been converted.
13-11	Changes to the Final Disposition Notification for Release of Biological Products	Current procedure described now in VSM 800.53
13-13	Electronic Submissions for Policy, Evaluation, and Licensing	Superseded by procedures described in NCAH Portal User Guide for CVB
15-02	Recognized ISO 15223-1 Symbols on Labeling for Diagnostic Test Kits	Incorporated into VSM 800.54
16-09	Submission of Foreign Language Labels	Incorporated into VSM 800.54

VSMs being retired due to incorporation in VSM 800.54

ID	Title
800.76	Trade Names and Logos on Licensed Veterinary Biological Products
800.80	Distributor Labels