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Newly Published Information

Last Modified:

This page lists veterinary biologics information published in the last 90 days.

CVB Draft Guidance Documents for Comment

Title	ID	Comments Due Date	Posted Date
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There are no documents for comment at this time

CVB Notices

Title	ID	Publication Date	Posted Date
Issuance of Licenses (260.93 KB)	23-14	January 24, 2024	February 6, 2024
Issuance of a Conditional License for Rabbit Hemorrhagic Disease Virus (277.99 KB)	23-15	January 24, 2024	February 6, 2024
Request Input on Proposed Enhancement for Export Certification (292.26 KB)	24-01	January 24, 2024	February 6, 2024
Issuance of Licenses (304.67 KB)	24-02	February 4, 2024	February 6, 2024
Posting of Selected Center for Veterinary Biologics Notices and Veterinary Services Memoranda on the CVB Web Pages for Comment	24-04	March 14, 2024	March 20, 2024

Title	ID	Publication Date	Posted Date
<u>Availability of a Pilot Project to Implement a Focused Review Option for Review of Outlines of Production Submitted Through the NCAH Portal</u>	24-05	March 13, 2024	March 20, 2024
<u>Availability of Highly Pathogenic Avian Influenza (HPAI) virus genomic sequence (H5 clade 2.3.4.4b)</u>	24-06	April 9, 2024	May 30, 2024
<u>Issuance of Licenses</u>	24-07	April 18, 2024	May 03, 2024
<u>National Animal Health Laboratory Network (NAHLN) Requirements for Veterinary Biologics Manufacturers to Meet for Diagnostic Products Detecting Transboundary and Foreign Animal Diseases to be Used in the NAHLN</u>	24-08	April 29, 2024	May 03, 2024
<u>Notification of U.S. Department of Agriculture's (USDA) Request for Information for Highly Pathogenic Avian Influenza (HPAI) Vaccines for Use in Cattle</u>	24-09	May 01, 2024	May 03, 2024
<u>Veterinary Biological Products in Licensed Establishments Produced and Destroyed 01/01/2023 through 12/31/2023</u>	91	March 22, 2024	May 23, 2024
<u>Veterinary Vaccines and Veterinary Diagnostic Products Targeting Avian Metapneumovirus (all subtypes)</u>	24-10	June 11, 2024	June 11, 2024
<u>Veterinary Vaccines Targeting Highly Pathogenic Avian Influenza in Livestock</u>	24-11	July 22, 2024	July 22, 2024

Veterinary Services Memoranda (new or revised)

Title	ID	Publication Date	Posted Date
<u>Basic Licensing Requirements and Guidelines for Diagnostic Products</u>	800.73	May 1, 2024	May 3, 2024

Rulemaking

There are no newly published documents at this time.

Proposed Rulemaking

There are no newly published documents at this time.

Notices of Availability

There are no newly published documents at this time.

Supplemental Assay Methods

Title	ID	Document Date	Posted Date
<u>Potency Testing <i>Clostridium perfringens</i> Type C Beta Antigen</u>	201	August 24, 2023	December 27, 2023
<u>Potency Testing <i>Clostridium perfringens</i> Type D Epsilon Antigen</u>	203	August 24, 2023	December 27, 2023
<u>Potency Testing <i>Clostridium novyi</i> Type B Alpha Antigen</u>	207	August 10, 2023	December 27, 2023
<u>Potency Testing <i>Clostridium sordellii</i> Antigen</u>	212	August 10, 2023	December 27, 2023
<u>Sterility Testing of Preparations Other Than Live Vaccines</u>	906	May 12, 2023	December 27, 2023
<u>Sterility Testing of Live Viral Vaccines and Master Seed Virus Samples</u>	908	May 12, 2023	December 27, 2023
<u>Sterility Testing of Live Viral Vaccines of Chicken Embryo Origin Recommended for Nonparenteral Injection</u>	909	May 12, 2023	December 27, 2023
<u>Titration of Pseudorabies Virus in Vaccines</u>	118	August 7, 2023	February 20, 2024
<u>Titration of Pseudorabies Virus Neutralizing Antibody (Constant Virus-Varying Serum Method)</u>	119	August 7, 2023	February 20, 2024
<u>Titration of Neutralizing Antibody</u>	300	August 22, 2023	February 20, 2024
<u>Titration of Neutralizing Antibody - Canine Distemper</u>	301	August 22, 2023	February 20, 2024
<u>Detection of Extraneous Hemadsorbing Agents in Master Seed Virus</u>	313	August 23, 2023	February 20, 2024

Testing Protocols

Title	ID	Document Date	Posted Date
Standard Bacterial Plate Count	CVB-SOP-0104	March 15, 2024	March 22, 2024

Reagent Data Sheets

Title	Lot ID	Publication Date	Posted Date
Mycoplasma synoviae	17Apr12-MS	November 22, 2023	January 18, 2024
Mycoplasma orale	18Apr12	November 22, 2023	January 18, 2024
Mycoplasma hyorhinis	16Apr12	November 22, 2023	January 18, 2024
Secondary Reference Serum-Bovine IgG; Stock for Bovine IgG Species Standard	10848	November 22, 2023	January 18, 2024
Secondary Reference Serum-Equine IgG; Stock for Equine IgG Species Standard	10849	November 22, 2023	January 18, 2024
Clostridium perfringens Type D (epsilon) Antitoxin	IRP 249	November 22, 2023	January 18, 2024
Clostridium tetani Antitoxin 5.0 AU/mL (guinea pig origin)	IRP 466	December 8, 2023	January 18, 2024
Clostridium chauvoei Flagella-specific (7D11/YD7) Monoclonal Antibody (MAb)	IRP 608	December 7, 2023	January 18, 2024
Clostridium perfringens type C (beta) toxin	IRP 624	December 8, 2023	January 18, 2024
Clostridium perfringens Type C (beta) Antitoxin	IRP 637	December 8, 2023	January 18, 2024
Clostridium novyi Type B Toxin	IRP 636	December 8, 2023	January 18, 2024
Clostridium septicum Antitoxin	IRP 687	December 8, 2023	January 18, 2024
Escherichia coli Anti-F41 Pilus Polyclonal Antibody (F41 PAb)	IRP 693	December 8, 2023	January 18, 2024
Clostridium perfringens Type D (epsilon) Antitoxin	IRP 249	February 28, 2024	March 11, 2024

Title	Lot ID	Publication Date	Posted Date
<u>Clostridium novyi Type B (alpha) Antitoxin</u>	IRP 507 (04)	February 28, 2024	March 11, 2024
<u>Clostridium sordellii antitoxin</u>	IRP 501 (04)	February 28, 2024	March 11, 2024
<u>Clostridium perfringens type C (beta) toxin</u>	IRP 624	February 29, 2024	March 11, 2024
<u>Clostridium chauvoei Spore Preparation</u>	IRP 631	February 28, 2024	March 11, 2024
<u>Clostridium novyi Type B Toxin</u>	IRP 636	February 28, 2024	March 11, 2024
<u>Clostridium sordellii Toxin</u>	IRP 675	February 28, 2024	March 11, 2024
<u>Clostridium perfringens type D (epsilon) toxin</u>	IRP 632	February 27, 2024	March 12, 2024

Other

Title	ID	Publication Date	Posted Date
Organizational Chart: <u>CVB Management</u>	DB-3	November 19, 2023	July 09, 2024
Organizational Chart: <u>Assistant Director</u>	DB-4	November 19, 2023	July 09, 2024
Organizational Chart: <u>Inspection and Compliance</u>	DB-4	December 3, 2023	July 09, 2024
Policy, Evaluation and Licensing Reviewer Manual: <u>Precedents for International Label Noncompliance</u>	CVB- WI- 0183	December 12, 2023	January 18, 2024
<u>Current Veterinary Biologics Product Catalog</u>		January 10, 2024	February 20, 2024

Title	ID	Publication Date	Posted Date
Inspection and Compliance Manual Chapter: Log APHIS Form 2008	CVB-WI-0163	January 9, 2024	February 20, 2024
Inspection and Compliance Manual Chapter: Conditional Serial Release	CVB-WI-0151	July 20, 2020	February 20, 2024
Inspection and Compliance Manual Chapter: Inspection Tools - Requested Documents and Observations	CVB-WI-0074	December 21, 2023	February 20, 2024
Inspection and Compliance Manual Chapter: Investigation Procedures Following a Report of a Disease Outbreak in an SPF Flock Which Supplies SPF Eggs or Chickens for Use in Vaccine Production	CVB-WI-0122	December 21, 2023	February 20, 2024
Historical Summary Report of CVB Policy Management for: 9 CFR Regulation/CVB Public Notice/CVB Routine Notice/Veterinary Services Memorandum		February 1, 2024	February 22, 2024
Organizational Chart: Safety and Security Unit	DB-8	February 25, 2024	March 12, 2024
Organizational Chart: Policy, Evaluation and Licensing	DB-9	February 16, 2024	July 09, 2024
NCAH Portal User Guide: Logging In and IT Security Awareness Training	1	March 20, 2024	March 22, 2024
NCAH Portal User Guide: Qualifications of Veterinary Biologics Personnel	4	March 22, 2024	March 22, 2024
NCAH Portal User Guide: Submitting Labels to CVB- Policy, Evaluation and Licensing	11	March 22, 2024	March 22, 2024

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