Veterinary Services Memoranda

Last Modified:

Number	Title	Issue Date
800.50	Basic License Requirements and Guidelines for Submission of Materials in Support of Licensure	April 2, 2018
800.51	Additives in Administered Animal Biological Products	August 17, 2018
800.52	Export Certificates and Certificates of Licensing and Inspection for Animal Biological Products	December 9, 2021
800.53	Serial Release of Licensed Biological Products	July 15, 2020
800.54	Guidelines for the Preparation and Review of Labeling Materials	September 17, 2018
800.55	Concurrent and Confirmatory Tests of Market Serials	February 17, 1986
800.56	Disposal of Unsatisfactory and Undesirable Materials	March 12, 2008
800.57	Market Suspensions and Post Marketing Temperature Deviations	June 11, 2018
800.58	Sublicensing of Veterinary Biological Products	October 18, 2007
800.59	Veterinary Biological Product Samples	July 20, 2016
800.60	Biological Products Returned to Licensed or Permitted Establishments	March 11, 2008

Number	Title	Issue Date
800.61	Split Manufacturing of Veterinary Biological Products	October 21, 1999
800.62	Relabeling, Rebottling, and Reprocessing Veterinary Biological Products	December 22, 1999
800.63	Personnel at Licensed Establishments	December 19, 2016
800.64	Preparation of Experimental Products at Licensed Establishments	March 14, 2012
800.65	Eggs and Chickens for Production of Veterinary Biological Products	May 03, 2016
800.66	Freedom of Information Act Requests Involving Veterinary Biological Products	October 21, 1999
800.67	Shipment of Experimental Veterinary Biological Products	January 29, 2026
800.68	*Retired*	--
800.69	Guidelines for Autogenous Biologics	November 22, 2021
800.70	Rabies Vaccine Immunogenicity Test Protocols	April 27, 2000
800.73	Basic Licensing Requirements and Guidelines for Diagnostic Products	May 1, 2024
800.74	Preparation and Distribution of Sterile Diluents	November 4, 1999
800.75	Reissuance of Product Licenses for Products Under Conditional Licenses	July 14, 2022
800.77	Unsatisfactory Product Stability	July 14, 1986
800.78	Preparation and Submission of Facilities Documents	September 24, 2019
800.79	Submission of Host Animal Serum Samples for In Vitro Potency Tests	March 20, 2013
800.81	Chicken Bursa Origin Bursal Disease Vaccines	March 30, 2001

Number	Title	Issue Date
800.83	Export of Serials Before Completion of Serial Release Testing	November 14, 2011
800.84	*Canceled*. Superseded by VSM 800.50 (167.33 KB)	--
800.85	Avian Influenza Vaccines	July 13, 2020
800.86	Exemption from Mycoplasma Testing in Accordance with Title 9, Code of Federal Regulations, Part 113.200 (c) (3)	November 4, 1999
800.87	Guidelines for Licensing Establishments with Separated Premises	May 13, 2005
800.88	Testing for Reticuloendotheliosis Virus Contamination	August 23, 1999
800.89	Chicken Anemia Virus	December 22, 1999
800.90	*Retired*. Incorporated into VSM 800.112 (88.47 KB)	--
800.91	Inspection of U.S. Veterinary Biologics Licensed and Permitted Establishments	December 8, 2020
800.92	*Retired*. Incorporated into VSM 800.206 (495.98 KB) and 800.53	--
800.94	Food and Drug Administration's Export Reform and Enhancement Act of 1996	May 10, 2011
800.95	GB Texas Newcastle Disease Challenge Virus	September 2, 2015
800.97	Standard Reference Preparations, Test Reagents, and Seed Cultures for Laboratory Test Reagents	June 12, 2014
800.98	Advertising and Promotional Materials	July 25, 2008
800.99	Guidelines for Using In Vitro Relative Potency Tests to Determine the Antigen Content of Inactivated Bovine Rhinotracheitis Vaccine	April 26, 2001
800.100	Exemption from Using Heat or Ionizing Radiation to Treat Equine Plasma Used in Manufacturing Plasma Products for Oral or Parenteral Administration to Horses Under 9 CFR 113.450(e)(1) and Exemption from the Mouse Safety Test Under 9 CFR 113.450 (i)	July 29, 2002

Number	Title	Issue Date
800.101	U.S. Veterinary Biological Product Permits for Distribution and Sale	November 1, 2016
800.102	Exemption from Leptospira Bacterin Testing Under 9 CFR 113.101-104 and the Associated References and Studies	December 12, 2013
800.103	Reissuance of Product Licenses for Autogenous Products and Guidance Concerning Restrictions on the Production and Use of Veterinary Biologics	July 18, 2018
800.104	*In Vitro* Serial Release Potency Test for Completed Product Containing *Clostridium chauvoei*	December 13, 2018
800.106	Exemption to Sterility Test Requirement for Allergenic Extract Prescription Product	February 16, 2022
800.107	Policy for Changing Cells and Cell Substrates of Licensed Vaccines	November 25, 2002
800.108	Inventory and Disposition Records	January 15, 2003
800.109	Master Seed and Master Cell Stock Testing Report Submission	May 26, 2004
800.110	Label Warnings Concerning Bovine Rhinotracheitis Vaccine, Modified Live Virus, and Bovine Virus Diarrhea Vaccine, Modified Live Virus, for Pregnant Cows or Calves Nursing Pregnant Cows	June 30, 2017
800.111	Viral Strain Changes in Equine Influenza and Swine Influenza Vaccines (Killed Virus)	September 19, 2007
800.112	Guidelines for Validation of In Vitro Potency Assays	April 10, 2015
800.113	Production, Testing and Storage of Master Seed and Master Cell Stocks at Alternate Locations	September 17, 2008
800.114	Alternative Test Procedure for Tuberculin, PPD Bovis, Intradermic	April 13, 2012
800.115	Potency and Safety Testing by Unlicensed Facilities	April 11, 2019
800.116	Laboratory and Target Animal Batch Safety Testing Exemption	May 22, 2025

Number	Title	Issue Date
800.117	Guidance for Inactivation Studies	August 12, 2013
800.119	Exemptions to title 9, Code of Federal Regulations (9 CFR), Part 113.28, Detection of Mycoplasma Contamination	March 19, 2014
800.120	Dilution of Preservative Screening for Sterility Testing of Veterinary Biologics	June 27, 2014
800.121	Autologous Therapeutic Biologics	June 21, 2017
800.122	Electronic Recordkeeping and Compliance with 9 CFR Part 116	November 3, 2017
800.123	Coccidiosis Vaccines	November 8, 2018
800.124	Guidelines for Potency Specifications of Biological Products Administered to Animals	October 2, 2020
800.125	Preparation and Submission of Adverse Event Reports for Biological Products by Licensees and Permittees	August 17, 2020
800.126	Efficacy and Safety Studies for Cancer Immunotherapeutics	September 2, 2020
800.127	Guidelines for Conducting Product Stability Studies	March 29, 2022
800.200	General Licensing Considerations: Study Practices and Documentation	June 12, 2014
800.201	General Licensing Considerations: Backpassage Studies	January 25, 2018
800.202	General Licensing Considerations: Efficacy Studies	October 26, 2016
800.203	General Licensing Considerations: Compatibility of Components	January 16, 2007
800.204	General Licensing Considerations: Field Safety Studies	January 25, 2018
800.205	General Licensing Considerations: Biotechnology-derived Veterinary Biologics Categories I, II, and III	May 28, 2003

Number	Title	Issue Date
800.206	General Licensing Considerations: Preparing Outlines of Production for Vaccines, Bacterins, Antigens, and Toxoids and Diagnostic Test Kits	November 13, 2018
800.207	General Licensing Considerations: Target Animal Safety (TAS) Studies Prior to Product Licensure - VICH Guideline 44	July 6, 2010
800.208	Special Labels for Product for Export	October 21, 2010
800.209	Bovine Corona Virus and Rotavirus Master Reference Qualification by Colostral Antibody Titers	December 8, 2010
800.210	Manufacturing Deviations Identified Prior to Marketing Release	May 31, 2018
800.211	Guidance for Master Reference Qualification, Requalification, Dating, and Monitoring	February 8, 2023
800.212	Licensing Considerations: Vaccine Claims for Protection of the Fetus Against Bovine Virus Diarrhea Virus	November 14, 2011
800.213	Licensing Guidelines for Production Platform-Based, Non-Replicating, Nonviable Products	March 12, 2018
800.214	Prescription Platform Product Biologics	March 12, 2018
800.215	Guidelines Regarding the Revision to Animal and Plant Health Inspection Service (APHIS) Implementing Procedures for the National Environmental Policy Act (NEPA)	January 31, 2019
800.300	Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products	July 26, 2001
800.301	Good Clinical Practices (See CVB Notice 01-11 (556.14 KB) for additional guidance regarding application of this VS Memo)	July 26, 2001

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