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CVB Policy, Evaluation, and Licensing: Reviewer Manual

Last Modified:

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1. General

- [Overview of the Review and Licensing Process](#) (364.68 KB) CVB-SOP-0056 (May 26, 2017)
- [APHIS Policy on Confidential Business Information](#) (32.27 KB) (August 19, 2010)
- [True Names, Product Codes and Establishment Codes](#) (132.14 KB) CVB-SOP-0057 (March 26, 2018)
- [Reviewer Staff Meetings](#) (383.65 KB) CVB-SOP-0058 (January 11, 2021)
- [Preparing Product Licensing Plans](#) (3.16 MB) CVB-SOP-0059 (January 6, 2021)
- Transfer of firms
- Ex parte communication

2. Office Procedures

- General guide formatting correspondence, routing documents for processing & supervisor approval

- Process for checking in daily mail
- Fileroom organization
- Targeted distribution of correspondence to other CVB personnel
- [Final Steps for Licensure](#) (3.17 MB) (Preparing a licensing package) CVB-SOP-0063 (May 21, 2021)
- [List of Standard License Restrictions](#) (139.09 KB) CVB-WI-0175 (September 19, 2024)
- [Quarterly Submission Acknowledgement Summaries](#) (228.86 KB) CVB-SOP-0064 (September 13, 2023)

3. Types of Licenses/Limits of Authority

- [Establishment Licenses](#) (2.02 MB) CVB-SOP-0065 (February 23, 2023)
- [Conditional Licenses](#) (2.16 MB) CVB-SOP-0066 (May 17, 2019)
- [Exemptions to the Virus-Serum-Toxin Act](#) (193.54 KB) CVB-WI-0176 (May 23, 2014)
- [Food and Drug Administration-Export Reform and Enhancement Act \(aka DERE\)](#) (2.04 MB) CVB-WI-0177 (June 3, 2019)
- [Text of FDA-ERE regulation \(U.S. Code 382\)](#)
- [Memorandum of Understanding with Food and Drug Administration](#) (division of authority)
- [Regulation of veterinary vaccines that reduce colonization/shedding of organisms that are mainly human pathogens](#) (15.37 KB) (2005 agreement with FDA) CVB Notice 05-07
- Federal Preemption and Veterinary Biologics

4. Reviewing Specific Submissions

- [Outlines of Production & Special Outlines](#) (1.58 MB) CVB-SOP-0067 (August 14, 2023)
- Section V.C Potency Assay Tests
- [Considerations to Requests for Changes to Outlines of Production for Bacterial Products](#) (2.19 MB) CVB-WI-0180 (May 21, 2021)
- [Validating Alternate Techniques for the Detection of Mycoplasmas](#) (1.49 MB) CVB-WI-0181 (August 20, 2019)
- [Dilution of Preservative Studies](#) (328.66 KB) CVB-WI-0182 (August 20, 2019)
- [Labels](#) (278.31 KB) CVB-SOP-0068 (July 5, 2018)

- [Precedents for International Label Non-compliance](#) (8.2 MB) CVB-WI-0183 (December 12, 2023)
- [Study Protocols](#) (521.69 KB) CVB-SOP-0069 (December 9, 2015)
- [Efficacy Studies](#) (1.91 MB) CVB-SOP-0070 (including Interference Studies) (June 30, 2017)
- Efficacy/Reference Qualification by Serology
- Master Reference Qualification and Requalification
- [Companion Overview for 800.211 Guidance for Master Reference Qualification, Requalification, Dating and Monitoring](#) (211.58 KB) CVB-REF-5109
- Efficacy Requirements for Specific Antigens
- [Field Safety Studies](#) (292.48 KB) CVB-SOP-0073 (September 14, 2015) (see also VS Memo [800.204](#) (167.18 KB))
- [Target Animal Safety Testing Exemption](#) (263.68 KB) CVB-SOP-0074 (September 18, 2018)
- Potency Test Development & Validation Studies
- [Potency Test References - introduction to terminology](#) (391.04 KB) CVB-WI-0187 (May 30, 2014)
- [Hold-over Information from Veterinary Services Memorandum No. 800.90](#) (170.53 KB) (posted on September 13, 2019)
- [Proposals for Estimating Relative Potency](#) (1.15 MB) CVB-WI-0188 (February 25, 2023)
- [Diagnostic Test Kits](#) (671.09 KB) CVB-SOP-0076 (see also VS Memo [800.73](#)) (March 31, 2017)
- APHIS Directive 6910.1 (process for coordinating licensing and approval for diagnostics used in official control programs)
- [Antibody Products](#) (44.96 KB) CVB-SOP-0077 (September 23, 2016)
- [Adjuvants and Excipients](#) (1.17 MB) CVB-SOP-0078 (February 26, 2020)
- Adjuvant spreadsheet
- Stability
- Evaluation of Confirmation of Dating Studies
- [Patent Term Extensions](#) (1.23 MB) CVB-WI-0192 (November 12, 2019)
- [Office Procedure for Routing & Processing SIFs and RAs](#) (1.39 MB) CVB-WI-0193 (May 21, 2021)
- [Outline for Content of Risk Assessment](#) (56.78 KB) CVB-WI-0194 (July 9, 2015)
- [SIF/RA Worksheet](#) (587.92 KB) CVB-WI-0195 (May 21, 2021)
- [Regulatory Process for Biotech Products](#) (17.18 KB) CVB-WI-0196 (July 01, 2016)
- [Master Seeds/Cells/Sequences](#) (773.22 KB) CVB-SOP-0080 (April 8, 2016)

- [Preservatives in biologics](#) (175.54 KB) CVB-SOP-0081 (September 1, 2010)
- [Sterile diluents](#) (143.82 KB) CVB-SOP-0082 (March 8, 2013)
- [Autogenous Biologics](#) (204.05 KB) CVB-SOP-0083 (May 13, 2014)
- [Import Permits for Distribution and Sale](#) (2.93 MB) CVB-SOP-0084 (July 21, 2020)

5. Testing Biological Products

- [Testing of Biological Products](#) (844.14 KB) CVB-SOP-0085 (June 23, 2017)
- Issuing Special Request for Lab Testing Master Seeds and Master Cells
- Issuing Special Request for Lab Testing of Prelicensing Serials
- [Section V testing at Alternate Locations](#) (772.23 KB) CVB-WI-0171 (April 8, 2016)
- [Antimicrobial Resistance Policy](#) (810.89 KB) CVB-SOP-5114 (January 11, 2021)

6. Shipping/Use of Experimental Products

- [Shipping Experimental Product](#) (1.58 MB) CVB-WI-0172 (August 23, 2022)
- Instructions for processing 103.3 forms
- [Shipping Animal Pathogens and Select Agents](#) (1.49 MB) CVB-WI-0292 (also info about movement of serum) (May 06, 2019)
- [Import Permits for Research and Evaluation or Transit Shipment Only](#) (3.32 MB) CVB-SOP-5109 (July 20, 2020)

7. Statistics

- [Overview of Statistics](#) (104.09 KB) CVB-WI-0293 (October 31, 2016)

8. Guidance for New Firms

- [Guidance for Reviewers on Portal Access for New Firms](#) (184.85 KB) CVB-WI-5233 (October 28, 2020)
- [New Firm Informational Packet for Antivenin Products](#) (270.31 KB) CVB-WI-5234 (October 28, 2020)
- [New Firm Informational Packet for Cancer Products and Immunomodulatory Products that Require Client Owned Animals Efficacy and Safety Studies](#) (309.28 KB) CVB-WI-5235 (October 2, 2020)
- [New Firm Informational Packet for Diagnostic Test Kits](#) (289.75 KB) CVB-WI-5236 (October 28, 2020)

- [New Firm Informational Packet for Live and Inactivated Vaccines Including Recombinants](#) (280.34 KB) CVB-WI-5237 (October 28, 2020)

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