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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 (66.06 KB) CVB-WI-0175 (March 23, 2018)
- 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 DEREA) (2.04 MB) CVB-WI-0177 (June 3, 2019)
- Text of FDA-EREA 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)
- 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 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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