Biologics Regulations and Guidance

Last Modified:

Regulations and Regulatory Guidance

- Virus-Serum-Toxin Act of 1913, as Amended 1985 (16.44 KB)
- Code of Federal Regulations (9 CFR)
- Veterinary Services Memoranda
- Center for Veterinary Biologics Public Notices
- Single Tier Label Claim Industry Guidance
- Risk Analysis/Summary Information Formats

Testing

- Supplemental Assay Methods
- Protocols and Standard Operating Procedures (SOPs)
- Reagent Data Sheets
- Center for Veterinary Biologics Reagent Catalog (560.14 KB)

Other Guidance and Instructional Materials

- NCAH Portal Guidance for CVB Submitters
- Submission Compliance Guide: Submitting Complete and Accurate License Applications, Outlines, and Labels (1.58 MB)
  For Paper Submissions Only (March 8, 2021)

- Root Cause Analysis Podcast - Transcript (2.26 MB)
- Polymerase Chain Reaction (PCR) Seminar Series
- Principles and Practices of Good Manufacturing as Required by the Virus-Serum-Toxin Act
- CVB Data Guide (how to submit data to PEL) (1.64 MB)

CVB Procedure Manuals

- Inspection and Compliance Manual
- Policy, Evaluation, and Licensing (Reviewer) Manual
- Operations Manual (19.54 MB)
- Decision Tracker Guidance

Rulemaking and Policy Development

- Rulemaking Activities
- Draft Guidance Documents for Comment

Other

- CVB Statement of Scope (523.37 KB)
- Statistical Methods (STATWIs)
- Vaccine Use Following Brucellosis and Pseudorabies Eradication (64.56 KB) (August 2006)
- Memorandum of Understanding Between APHIS and FDA
- Jurisdiction Determination Process Charter for the USDA CVB/FDA CVM Jurisdiction Committee (406.05 KB)

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