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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](#) (171 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- [Draft Guidance Documents for Comment](#)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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