

## Breadcrumb

1. [Home](#)
2. Print
3. Pdf
4. Node
5. Entity Print

# Veterinary Services Memoranda

Last Modified:

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

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

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

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

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

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

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