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# Veterinary Services Memoranda

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<a href="#">800.50</a> (167.33 KB)	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
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<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
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<a href="#"><u>800.60</u></a>	Biological Products Returned to Licensed or Permitted Establishments	March 11, 2008
<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
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<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	November 25, 2022
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

Number	Title	Issue Date
<a href="#">800.81</a>	Chicken Bursa Origin Bursal Disease Vaccines	March 30, 2001
<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

<b>Number</b>	<b>Title</b>	<b>Issue Date</b>
<a href="#"><u>800.100</u></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
<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

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<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
<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

<b>Number</b>	<b>Title</b>	<b>Issue Date</b>
<a href="#"><u>800.205</u></a>	General Licensing Considerations: Biotechnology-derived Veterinary Biologics Categories I, II, and III	May 28, 2003
<a href="#"><u>800.206</u></a>	General Licensing Considerations: Preparing Outlines of Production for Vaccines, Bacterins, Antigens, and Toxoids and Diagnostic Test Kits	November 13, 2018
<a href="#"><u>800.207</u></a>	General Licensing Considerations: Target Animal Safety (TAS) Studies Prior to Product Licensure - VICH Guideline 44	July 6, 2010
<a href="#"><u>800.208</u></a>	Special Labels for Product for Export	October 21, 2010
<a href="#"><u>800.209</u></a>	Bovine Corona Virus and Rotavirus Master Reference Qualification by Colostral Antibody Titers	December 8, 2010
<a href="#"><u>800.210</u></a>	Manufacturing Deviations Identified Prior to Marketing Release	May 31, 2018
<a href="#"><u>800.211</u></a>	Guidance for Master Reference Qualification, Requalification, Dating, and Monitoring	February 8, 2023
<a href="#"><u>800.212</u></a>	Licensing Considerations: Vaccine Claims for Protection of the Fetus Against Bovine Virus Diarrhea Virus	November 14, 2011
<a href="#"><u>800.213</u></a>	Licensing Guidelines for Production Platform-Based, Non-Replicating, Nonviable Products	March 12, 2018
<a href="#"><u>800.214</u></a>	Prescription Platform Product Biologics	March 12, 2018
<a href="#"><u>800.215</u></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="#"><u>800.300</u></a>	Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products	July 26, 2001
<a href="#"><u>800.301</u></a>	Good Clinical Practices (See <a href="#"><u>CVB Notice 01-11</u></a> (556.14 KB) for additional guidance regarding application of this VS Memo)	July 26, 2001

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