

VS 800 series Memoranda and CVB Notices - Historical Summary of Proposed Documents

ID	Title	Document Type	Date Closed for Comment	Current Status	Final Disposition	Final Disposition Date
595	Testing Biologics for Seneca Valley Virus	CVB Notice	11/9/2017	Active		
593	Revise memo 800.210 (process deviations)	VS Memorandum	6/19/2017	Active		
589	revision of 800.78 (facility documents)	VS Memorandum	4/24/2017	Finalized	Published as VSM 800.78	8/18/2017
583	revision 800.110 (exemption for live IBR/BVD vaccines)	VS Memorandum	12/19/2016	Finalized	Published as VSM 800.110	6/30/2017
580	revise VSM 800.98	VS Memorandum	1/23/2017			
579	revise VSM 800.54 (labeling)	VS Memorandum	12/26/2016	Finalized	Published as VSM 800.54	5/21/2017
576	new memo: Electronic Record Keeping & Compliance with 9 CFR Part 116	VS Memorandum	3/16/2017	Active		
574	APHIS-supplied test panels for diagnostic test kits	CVB Notice	1/16/2017	Finalized	Published as CVB Notice 17-10	7/11/2017
568	revise VSM 800.50 (basic licensing requirements)	VS Memorandum	10/10/2017	Active		
567	Autologous Therapeutic Biologics	VS Memorandum	3/13/2017	Finalized	Published as VSM 800.121	6/21/2017
565	revise memo 800.101 (permitted products)	VS Memorandum	9/12/2016	Finalized	Published as VSM 800.101	11/1/2016
563	revise VSM 800.51 (additives)	VS Memorandum	7/25/2016	Finalized	Published as VSM 800.51	11/1/2016
562	True name change--Arcanobacterium to Trueperella pyogenes	CVB Notice	6/6/2016	Active	Published as CVB Notice 16-08	6/13/2016
561	split out validation guidance from VSM 800.73 and place remainder of old memo text in 800.206 (companion doc 561)	VS Memorandum	5/15/2017	Active		
560	update VSM 800.116 (target animal safety exemption) to include GL55 on live vaccines	VS Memorandum	8/15/2016	Finalized	Published as VSM 800.116	8/14/2017
559	Categories of Inspection for Licensed Veterinary Biologics Establishments	VS Memorandum	5/9/2016	Active	Published as VSM 800.91	6/28/2016
558	Revise VSM 800.201--backpassage	VS Memorandum	10/2/2017	Active		
557	revise VSM 800.59 to incorporate portal submission procedures for APHIS 2020	VS Memorandum	7/5/2016	Finalized	Published as VSM 800.59	7/20/2016
554	800.53 revision to incorporate submission procedures for portal	VS Memorandum	7/5/2016	Finalized	Published as VSM 800.53	10/25/2016
550	General Licensing Considerations: Efficacy Studies	VS Memorandum	3/7/2016	Active	Published as VSM 800.202	10/26/2016

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549	Eggs and Chickens for Production of Veterinary Biological Products	VS Memorandum	2/8/2016	Finalized	Published as VSM 800.65	5/3/2016
547	In-Depth Inspection Report Format	CVB Notice	12/14/2015	Finalized	Published CVB Notice 16-07	5/16/2016
546	revise VSM 800.204	VS Memorandum	3/13/2017	Active		
544	revise 800.63 (personnel at establishments)	VS Memorandum	11/7/2016	Finalized	Published VSM 800.63	12/19/2016
532	Changes to the Administrative Inspection Review Program	CVB Notice	5/4/2015	Finalized	Published CVB Notice 15-08	6/10/2015
531	Additives in Administered Animal Biological Products	VS Memorandum	5/18/2015	Finalized	Published revision VSM 800.51	9/30/2015
530	Option to Remove Back-titration Hamsters from In Vivo Potency Tests for Leptospira Serogroups Canicola and Icterohaemorrhagiae	CVB Notice	8/27/2015	Finalized	Published CVB Notice 15-13	10/8/2015
529	Recognized ISO 15223-1 Symbols on Labeling for Diagnostic Test Kits	CVB Notice	2/23/2015	Finalized	Published as CVB Notice 15-02	3/6/2015
528	Viral Strain Changes in Equine Influenza and Swine Influenza Vaccines (Killed Virus)	VS Memorandum	1/16/2015	Active		
527	Licensing Guidelines for Production Platform-Based, Non-Replicating, Nonviable Products	VS Memorandum	1/16/2015	Finalized	Published VSM 800.213	4/29/2015
525	Release of Biological Products	VS Memorandum	5/26/2014	Finalized	Published as VSM 800.53	6/27/2014
521	Submission of Labels for Export	CVB Notice	3/17/2014	Inactive	Incorporated into VSM 800.54 instead	NA
518	Safety Data to Support Using Multiple Strains of Potentially Immunosuppressive Viruses in the Same Modified Live Product	CVB Notice	2/3/2014	Finalized	CVB Notice 14-06	3/18/2014
517	Discontinuing the Use of RelPot Software	CVB Notice	11/18/2013 (extended)	Finalized	Published as CVB Notice 13-18	12/9/2013
515	Summary of Changes for Related Study Protocols	CVB Notice	11/18/2013 (extended)	Finalized	Published as CVB Notice 13-17	12/9/2013
513	Nomenclature and Level of Identification Required for Leptospira Master Seed Bacteria and Challenge Cultures	CVB Notice	5/26/2014	Finalized	Published as CVB Notice 15-04	4/3/2015
511	Summary Information Format, Category IV: Production Platform for Veterinary Biologics [attachment to Draft Memo 460]	VS Memorandum attachment	7/22/2013	Finalized	Published	8/12/2013

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510	Exemptions to title 9, Code of Federal Regulations (9 CFR), part 113.28, Detection of Mycoplasma Contamination	CVB Notice	2/17/2014	Finalized	VSM 800.119	3/19/2014
509	Changes to the Final Disposition Notification for Release of Biological Products	CVB Notice	7/22/2013	Finalized	Published as CVB Notice 13-11	7/30/2013
508	General Licensing Considerations: Preparing Outlines of Production for Vaccines, Bacterins, Antigens, and Toxoids	VS Memorandum	11/18/2013 (extended)	Finalized	Published as VSM 800.206	4/13/2012
506	Changes to the Rabies Virus NIH Potency Test Validity Requirements	CVB Notice	7/22/2013	Finalized	Published as CVB Notice 13-10	7/26/2013
502	Veterinary Biological Product Samples	VS Memorandum	6/10/2013	Finalized	Published as VSM 800.59	9/4/2013
501	Release of Biological Products	VS Memorandum	6/24/2013	Finalized	Published as VSM 800.53	10/30/2013
496	The Use of Minimum Age Animals in Licensure Studies	VS Memorandum	4/29/2013	Inactive		
495	Submission of Host Animal Serum Samples for In-Vitro Potency Tests	VS Memorandum	2/25/2013	Finalized	Published as VSM 800.79	3/20/2013
492	Change in Issuance of Permits for General Sale and Distribution	CVB Notice	12/24/2012	Finalized	Published as CVB Notice 13-03	1/14/2013
484	Use of Polymerase Chain Reaction (PCR) Assays to Measure Potency of Inactivated Protein-Based Biologicals	CVB Notice	2/4/2013	Finalized	Published as CVB Notice 13-05	3/4/2013
480	New Policy on Biological Product Samples Submitted to the Center for Veterinary Biologics and the Confirmatory Testing Selection Period	CVB Notice	11/5/2012	Finalized	Published as CVB Notice 12-25	12/12/2012
478	Quarterly Acknowledgement Summaries for Selected Submissions	CVB Notice	12/3/2012	Finalized	Published as CVB Notice 13-02	1/14/2013
476	General Requirements for Test Kits Intended for the Diagnosis of Animal Diseases	VS Memorandum	3/29/2013 (extended)	Finalized	Published as VSM 800.73	1/15/2015
473	Conducting Dilution of Preservative Studies for Live Bacterial Vaccines	CVB Notice	10/1/2012	Finalized	Published as CVB Notice 12-21	10/15/2012
472	Revised Procedure for Depletion of Existing Inventories of Superseded Labels	CVB Notice	7/9/2012	Finalized	Published as CVB Notice 12-14	7/13/2012
467	Dilution of Preservative Screening for Sterility Testing of Veterinary Biologics	VS Memorandum	6/10/2013	Finalized	Published as VSM 800.120	6/27/2014

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465	Use of Humane Endpoints and Methods in Animal Testing of Biological Products	CVB Notice	4/30/12 (extended)	Finalized	Published as CVB Notice 12-12	5/25/2012
463	Submission of Master Seeds and Master Cell Stocks to the Center for Veterinary Biologics for Confirmatory Testing	CVB Notice	1/30/2012	Finalized	Published as CVB Notice 12-08	4/4/2012
462	Exemption from Leptospira Bacterin Testing Under 9 CFR 113.101 – 104 and the Associated References and Studies	VS Memorandum	8/5/2013	Finalized	Published as VSM 800.102	12/12/2013
460	Guidelines for Obtaining a Conditional Veterinary Biologics License for Production Platform Derived, Recombinant, Non-replicating, Nonviable Constructs	VS Memorandum	5/20/2013	Finalized	Published as VSM 800.213	8/12/2013
458	Exemption to Shipping a Sample of Inactivated lot or Bulk Rabies Antigen to the Center for Veterinary Biologics	CVB Notice	1/16/2012	Finalized	Published as CVB Notice 12-03	2/15/2012
453	Animal Safety Testing Exemption	VS Memorandum	12/24/2012 (re-posted)	Finalized	Published as VS Memo 800.116	7/31/2013
449	Virulent Systemic Feline Calicivirus Label Claims	CVB Notice	4/23/2012 (re-posted)	Finalized	Published as CVB Notice 12-11	5/21/2012
448	Appropriate Use of Controls for CAV PCR Testing and Availability of an Extraneous Agent PCR Testing Protocol	CVB Notice	8/29/2011	Finalized	Published as CVB Notice 12-04	3/7/2012
444	Product Licensing Plans	CVB Notice	5/2/2011	Finalized	Published as CVB Notice 11-12	5/9/2011
443	Discontinued Reagents: Standard Reference Preparations and Test Reagents for Virus Biological Products	CVB Notice	5/9/2011	Finalized	Published as CVB Notice 11-15	6/27/2011
440	Guidelines for Determining Release and Throughout-Dating Potency Specifications	VS Memorandum	3/31/2014	Active		
439	Guidelines for Master Reference Qualification and Requalification	VS Memorandum	4/4/2011	Finalized	Published as VS Memo 800.211	6/28/2011
438	Testing Exemptions for Antibody Product Donor Animals	CVB Notice	11/21/2011	Finalized	Published as CVB Notice 12-05	3/29/2012
437	Paper Reduction Initiatives	CVB Notice	4/18/2011	Finalized	Published as CVB Notice 11-10	4/25/2011
430	General Licensing Considerations: Preparing Outlines of Production for Vaccines, Bacterins, Antigens, and Toxoids	VS Memorandum	2/21/2011	Finalized	Published as VS Memo 800.206	4/13/2012

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426	Export of Serials Before Completion of Serial Release Testing	VS Memorandum	8/15/2011	Finalized	Published as VSM 800.83	11/14/2011
424	U.S. Veterinary Biological Product Permits for Distribution and Sale	VS Memorandum	10/1/2012	Finalized	Published as VSM 800.101	6/6/2013
422	The Management and Disposition of Eggs, Chickens and Biological Products Following a Chicken Anemia Virus (CAV) Outbreak in a Source Flock	CVB Notice	9/27/2010	Finalized	Published as CVB Notice 11-01	1/3/2011
420	Use of Symbols on Labeling for Diagnostic Test Kits	CVB Notice	4/18/2011 (extended)	Finalized	Published as CVB Notice 11-14	6/6/2011
414	Obtaining the Testing Plan for Authorized Master Seed/Master Cell Sample submission	CVB Notice	8/30/2010	Finalized	Published as CVB Notice 10-11	12/6/2010
413	Generation and Implementation of Draft Policy	CVB Notice	8/30/2010	Finalized	Published as CVB Notice 11-02	2/2/2011
412	Preparation of Experimental Products at Licensed Establishments	VS Memorandum	2/28/2011	Finalized	Published as VS Memo 800.64	3/14/2012
406	Preparation and Submission of Facilities Documents	VS Memorandum	8/9/2010	Finalized	Published as VS Memo 800.78	11/11/2010
405	Special Labels for Product for Export	VS Memorandum	9/27/2010 (extended)	Finalized	Published as VS Memo 800.208	10/21/2010
402	Alternative Test Procedure for Tuberculin, PPD Bovis, Intradermic	VS Memorandum	3/21/2011 (extended)	Finalized	Published as VS Memo 800.114	4/13/2012
395	Minor Temperature Deviations of Biological Products	VS Memorandum	8/16/2010	Finalized	Published as VS Memo 800.210	12/22/2010
380	Expiration Date Extension and Discontinued Reagents: Salmonella Standard Reference Bacterins	CVB Notice	6/8/2009	Finalized	Published as CVB Notice 09-23	10/29/2009
368	Rabies Safety Tests per 9 CFR Part 113.209	CVB Notice	7/19/2010	Finalized	CVB Notice 11-18	7/20/2011
367	Qualification of Leptospira Canicola, Leptospira Grippotyphosa, Leptospira Icterohaemorrhagiae, and Leptospira Pomona Reference Bacterins for Products Intended for Use in Swine and/or Cattle	CVB Notice	6/8/2009	Finalized	Published as CVB Notice 09-16	8/3/2009
363	Potency Testing by Unlicensed Facilities	VS Memorandum	4/15/2013 (reposted)	Finalized	Published as VS Memo 800.115	6/21/2013
361	Changes to the Administrative Inspection Review Program	CVB Notice	10/6/2008	Finalized	Published as CVB Notice 08-18	11/3/2008
360	Disposal of Classical Swine Fever Virus Seeds	Federal Register Notice	2/4/2009		Published for Comment	1/5/2009
356	Appendix III - Guidance for Validating ELISA Relative Potency Assays	VS Memorandum Appendix	4/18/2011 (extended)	Finalized	Appendix to VSM 800.112	8/29/2011

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352	Conversion Formulas for SP Ratio to Titer in Diagnostic Kit Inserts	CVB Notice	12/8/2008	Finalized	Published as Notice 09-04	3/18/2009
351	Guidelines for Live Master References	VS Memorandum	1/26/2009	Finalized	VSM 800.118	12/12/2013
350	Bovine Coronavirus and Rotavirus Reference Qualification by Colostral Antibody Titers	VS Memorandum	11/10/2008	Finalized	Published as VS Memo 800.209	12/8/2010
345	General Licensing Consideration: Efficacy Studies	VS Memorandum	8/25/2014	Finalized	Published as VSM 800.202	10/27/2014
344	General Licensing Consideration: Study Practices and Documentation	CVB Notice	3/17/2014	Finalized	Published as VSM 800.200	6/12/2014
337	Follow-up Sterility Check Testing	CVB Notice	2/12/2010	Finalized	Published as CVB Notice 10-10	12/20/2010
336	Electronic Freedom of Information Act Involving Veterinary Biological Products	VS Memorandum	4/28/2008	Inactive	Waiting on one-tier label claim regulation	
335	Guidelines for Autogenous Biologics	VS Memorandum	5/18/2009	Finalized	Published as VS Memo 800.69	8/7/2009
334	Dilution of Preservative Screening for Plate-Based Sterility Tests	CVB Notice	6/22/2009	Finalized	Published as CVB Notice 09-25	12/31/2009
331	General Licensing Considerations: Target Animal Safety Studies Prior to Product Licensure	VS Memorandum	9/14/2009	Finalized	Published as VS Memo 800.207	7/6/2010
330	Reinstatement and Dating Extension for Erysipelothrix Rhusiopathiae Standard Reference Bacterin, Serial 5	CVB Notice	2/4/2008	Finalized	Published as CVB Notice 08-04	3/3/2008
329	Guidelines for Submitting Electronic Data Files for Statistical Analysis	VS Memorandum	5/19/2008	Finalized	Published as VS Memo 800.96	12/17/2008
328	Reporting Inactivation Test Results on APHIS Form 2008 for Inactivated Veterinary Biological Products with the Restriction "For Further Manufacture (FFM)"	CVB Notice	12/3/2012	Finalized	Published as CVB Notice 13-06	3/19/2013
327	Studies to Support Revaccination Claims	CVB Notice	8/9/10 (extended)	Inactive		
321	General Licensing Considerations: Backpassage Studies,	VS Memorandum	2/4/2008	Finalized	Published as VS Memo 800.201	6/25/2008
320	Market Suspension	VS Memorandum	12/30/2011	Finalized	Published as VS Memo 800.57	3/29/2012

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315	Consistency of Avian Safety Testing Parameters in Outlines of Production for Multi-fraction Avian Products	CVB Notice	10/22/2007	Finalized	Published as CVB Notice 09-05	3/20/2009
314	Vaccine Claims for Protection of the Fetus Against Bovine Virus Diarrhea Virus	VS Memorandum	11/15/2010	Finalized	VSM 800.212	11/14/2011
313	Labeling of Equine Influenza and Swine Influenza Vaccines	CVB Notice	8/6/2007	Finalized	Published as CVB Notice 07-17	10/31/2007
284	Qualification of Leptospira pomona and Leptospira canicola Reference Bacterins for Products Intended for Use in Dogs	CVB Notice	7/9/2007	Finalized	Published as CVB Notice 07-12	7/10/2007
270	Sublicensing of Veterinary Biological Products	VS Memorandum	6/25/2007	Finalized	Published as VS Memo 800.58	10/18/2007
269	Export Certificates and Certificates of Licensing and Inspection for Animal Biological Products	VS Memorandum	6/26/2007	Finalized	Published as VS Memo 800.52	3/19/2015
268	Biological Products Returned to Licensed or Permitted Establishments	VS Memorandum	12/3/2007	Finalized	Published as VS Memo	3/11/2008
267	Disposal of Unsatisfactory and Undesirable Materials	VS Memorandum	12/10/2007	Finalized	Published as VS Memo 800.56	3/12/2008
166	Additives in Animal Biological Products	VS Memorandum	6/25/2007	Finalized	Published as VS Memo 800.51	10/18/2007
155	Product Stability Studies	CVB Notice	8/2/10 (extended)	Active		
132	Guidelines for Preparing Outlines of Production for Vaccines, Bacterins, Antigens, and Toxoids	VS Memorandum	4/2/2007	Finalized	Published as VS Memo 800.206	7/11/2007
131	Electronic Maintenance of Paper Records	CVB Notice	2/11/2008	Finalized	Published as CVB Notice 08-19	11/24/2008
129	Post Challenge Observation Periods for Efficacy Studies	CVB Notice	3/19/2007	Finalized	Published as CVB Notice 07-07	5/11/2007
125	General Licensing Considerations: Field Safety Studies	VS Memorandum	1/8/2007	Finalized	Published as VS Memo 800.204	3/16/2007
121	Submission of Outsourced Studies	CVB Notice	2/26/2007	Finalized	Published as CVB Notice 07-04	3/27/2007
116	Preparation and Testing of Experimental Biological Products that are Derived from Biotechnology	CVB Notice	4/30/2007	Finalized	Published as CVB Notice 07-06	5/11/2007

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113	Potency Reference Preparation Summaries	VS Memorandum	3/19/2007	Finalized	Published as VS Memo 800.92	10/18/2007
111	Guidance for Inactivation Studies	VS Memorandum	5/7/2012 (re-posted) (extended)	Finalized	Published as VSM 800.117	8/12/2013
110	Guidelines for Validation of In Vitro Potency Assays	VS Memorandum	4/16/2007	Finalized	Published as VS Memo 800.112	6/25/2008
109	Viral Strain Changes in Equine Influenza and Swine Influenza Vaccines (Killed Virus)	VS Memorandum	2/20/2007	Finalized	Published as VS Memo 800.111	9/19/2007
108	General Licensing Considerations: Antigen Interference	VS Memorandum	10/23/2006	Finalized	Published as VS Memo 800.203	1/16/2007
105	Advertising and Promotional Materials	VS Memorandum	7/2/2007	Finalized	Published as VS Memo 800.98	7/25/2008