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
663	Use of Nonproprietary Names from the USAN as True Names for Vet Biologics Immunotherapeutics	CVB Notice	10/19/2020	Active		
662	Revision to VSM 800.91	VS Memorandum	10/5/2020	Active		
660	Name Change for Bioloigcs Containing Haemophilus and Clostridium	CVB Notice	7/13/2020	Finalized	Published Notice 20-05	8/4/2020
656	Guidance regarding a process by which firms can request exemption to lab animal batch safety testing exemption in line with VICH document GL59.	VS Memorandum	4/28/2020	Active		
650	Revision to VSM 800.116	VS Memorandum	8/31/2020	Active		
648	Revision to VSM 800.117	VS Memorandum	8/17/2020	Active		
640	Review of Labels for Use in Countries that are Members or Observers of VICH	CVB Notice	10/19/2020	Active		
638	Revision to VSM 800.69	VS Memorandum	7/16/2020	Active		
637	Preparation and Submission of Adverse Event Reports	VS Memorandum	11/19/2019	Finalized	Published VSM 800.125	8/17/2020
636	Availability of new Inactivated Rabies Reference	CVB Notice	9/30/2019	Finalized	Published Notice 19-15	12/19/2019
632	Name Change for Test Kits to Detect Canine or Feline Heartworm Antigen	CVB Notice	5/13/2019	Finalized	Published Notice 19-05	6/17/2019
631	Formal Approval of Changes to Manufacturing Methods	CVB Notice	6/3/2019	Inactive	n/a	n/a
629	Revision to VSM 800.53	VS Memorandum	6/3/2019	Finalized	Published VSM 800.53	715/2020
628	Name Change for Biologics containing M. Avium paratb	CVB Notice	4/22/2019	Finalized	Published Notice 19-04	5/6/2019
627	Discontinued Availability of Pasteurella Multocida 169 (Porcine)	CVB Notice	5/6/2019	Finalized	Published Notice 19-07	7/19/2019
625	Revision to VSM 800.78	VS Memorandum	4/11/2019	Finalized	Published 800.78	9/24/2019
621	Labeling of Vaccines containing PCV Type 2	CVB Notice	8/20/2018	Finalized	Published Notice 18-13	11/29/2018
616	Revision to VSM 800.54	VS Memorandum	6/11/2018	Finalized	Published 800.54	9/17/2018
613	Revision to VSM 800.103	VS Memorandum	5/14/2018	Finalized	Published 800.103	7/18/2018
612	Testing Requirements for Equine Origin Ab products	CVB Notice	4/9/2018	Finalized	Published Notice 19-03	4/5/2019
610	Regulation of Allergenic Extracts	CVB Notice	8/20/2018	Active		
608	Guidelines to APHIS Implementation of NEPA	VS Memorandum	7/16/2018	Finalized	Published 800.215	1/31/2019
600	Revision to VSM 800.57	VS Memorandum	1/23/2017	Finalized	Published 800.57	6/11/2018
597	Cancer Immunomodulators	VS Memorandum	4/10/2020	Finalized	Published VSM 800.126	9/21/2020
595	Testing Biologics for Seneca Valley Virus	CVB Notice	11/9/2017	Finalized	Published as CVB Notice 18-05	3/30/2018
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
586	revision of 800.67 (shipment of experimental produc)t	VS Memorandum	7/2/2018	Finalized	Published as VSM 800.67	10/10/2018
584	Update VSM 800.206 Preparing Outlines of Production	VS Memorandum	6/25/2018	Finalized	Published VSM 800.206	11/13/2018

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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	Active		
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	Finalized	Published VSM 800.122	11/3/2017
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	Finalized	Published as VSM 800.50	4/2/2018
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	Finalized	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	Finalized	Published as VSM 800.73	10/2/2018
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	Finalized	Published as VSM 800.91	6/28/2016
558	Revise VSM 800.201--backpassage	VS Memorandum	10/2/2017	Finalized	Published as VSM 800.201	1/25/2018
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
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		
545	revision of VSM 800.115 Potency and Safety Testing in Unlicensed Facilities	VS Memorandum	8/20/2018	Active		
544	revise 800.63 (personnel at establishments)	VS Memorandum	11/7/2016	Finalized	Published VSM 800.63	12/19/2016
540	revise VSM 800.102	VS Memorandum	5/18/2020	Active		

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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
512	Update VSM 800.104 In vitro Serial Release Test for Completed Product Containing Clostridium chauvoei	VS Memorandum	9/17/2018	Finalized	Published	12/13/2018
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
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	Finalzed	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

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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
499	Coccidiosis Vaccine General Guidelines	V.S. Memo	5/14/2018	Finalized	Published as VSM 800.123	11/8/2018
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
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

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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	2/24/2020	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
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

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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 in Federal Register, Vol 74,		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
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 Conisderation: 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	Discontinued	Incorporated into single tier labeling regulation	Discontinued
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

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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	Pubslished as VS Memo 800.57	3/29/2012
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 800.60	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	2/24/2020	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

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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
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