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Newly Published Information

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CVB Draft Guidance Documents for Comment

Title	ID	Comments Due Date	Posted Date
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There are no newly published documents at this time.

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CVB Notices

Title	ID	Publication Date	Posted Date
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Issuance of Licenses (379.96 KB)	25-01	January 16, 2025	January 16, 2025
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Veterinary Services Memoranda (new or revised)

Title	ID	Publication Date	Posted Date
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There are no newly published documents at this time.

Rulemaking

There are no newly published documents at this time.

Proposed Rulemaking

Title	Publication Date	Posted Date
Historical Summary of Proposed Documents (35.57 KB)	February 12, 2025	March 24, 2025

Notices of Availability

There are no newly published documents at this time.

Supplemental Assay Methods

Title	ID	Document Date	Posted Date
Supplemental Assay Method for Bacterial Plate Count of <i>Erysipelothrix rhusiopathiae</i> Vaccines (211.92 KB)	612	January 17, 2025	March 24, 2025
Supplemental Assay Method for Testing for Preservative Interference with Sterility Tests (207.47 KB)	903	January 17, 2025	March 24, 2025
Supplemental Assay Method for Potency of Live Avirulent <i>Mannheimia haemolytica</i> Vaccine (225.09 KB)	905	January 17, 2025	March 24, 2025
Supplemental Assay Method for Detection of Extraneous Bacteria and Fungi in Live Bacterial Vaccines and Master Seed Bacteria Samples (223.63 KB)	928	January 3, 2025	March 24, 2025
Potency Testing <i>Clostridium perfringens</i> Type C Beta Antitoxins (217.37 KB)	SAM 202	October 4, 2024	February 07, 2025
Potency Testing <i>Clostridium novyi</i> Type B Alpha Antigen (268.06 KB)	SAM 207	October 4, 2024	February 07, 2025
Potency Testing Products Containing <i>Clostridium haemolyticum</i> Antigen (232.32 KB)	SAM 209	March 23, 2024	February 07, 2025
Potency Testing of Erysipelas Bacterins in Mice (266.91 KB)	SAM 611	March 26, 2024	February 07, 2025

Title	ID	Document Date	Posted Date
Potency Testing of <i>Pasteurella multocida</i> Bacterins of Bovine Origin (230.42 KB)	SAM 634	March 26, 2024	February 07, 2025
Potency Testing of <i>Pasteurella multocida</i> Bacterins of Porcine Origin (258.13 KB)	SAM 635	March 26, 2024	February 07, 2025
Titration of Infectious Canine Hepatitis Virus in Primary Canine Kidney Cell Culture (191.86 KB)	SAM 304	August 22, 2023	January 15, 2025
Titration of Feline Calicivirus in Cell Culture (216.98 KB)	SAM 306	August 23, 2023	January 15, 2025
Titration of Feline Rhinotracheitis Virus in Cell Culture (203.26 KB)	SAM 307	August 23, 2023	January 15, 2025
Titration of Canine Parainfluenza Virus in Vero Cell Culture (196.24 KB)	SAM 309	August 23, 2023	January 15, 2025
Fluorescent Antibody Staining Procedure for Detection of Extraneous Agents in Master Seeds (194.99 KB)	SAM 314	August 24, 2023	January 15, 2025
Detection of Serum Neutralizing Antibodies to Rabies Virus using the Rapid Fluorescent Focus Inhibition Test (RFFIT) (229.57 KB)	SAM 315	August 24, 2023	January 15, 2025
Titration of Canine Parvovirus in Cell Culture (194.6 KB)	SAM 316	August 24, 2023	January 15, 2025
Titration of <i>Chlamydomphila felis</i> (formerly Feline <i>Chlamydia psittaci</i>) in Cell Culture (284.93 KB)	SAM 319	August 25, 2023	January 15, 2025

Testing Protocols

Title	ID	Document Date	Posted Date
Potency Testing of <i>Clostridium chauvoei</i> Bacterins using an ELISA Procedure (202.09 KB)	CVB-PRO-0005	January 21, 2025	February 14, 2025
Polymerase Chain Reaction for the Detection of <i>Mycoplasma</i> Contamination (218.91 KB)	CVB-PRO-0006	January 21, 2025	February 14, 2025

Reagent Data Sheets

Title	Lot ID	Publication Date	Posted Date
Secondary Reference Serum-Bovine IgG; Stock for Bovine IgG Species Standard (98.93 KB)	10848	March 24, 2025	April 02, 2025
Rabies challenge, fox salivary gland origin (103.16 KB)	92-5	February 13, 2025	March 24, 2025
Chicken Anemia Virus DNA Positive Control (117.03 KB)	15-07	March 19, 2025	March 24, 2025
Leptospira pomona Master Reference Bacterin (95.31 KB)	IRP 524 (05)	February 13, 2025	March 24, 2025
Standard Reference Mycobacterium Tuberculosis Tuberculin (Old Tuberculin) (96.73 KB)	IRP 115B	February 13, 2025	March 24, 2025
Leptospira icterohaemorrhagiae Challenge Culture (97.67 KB)	IRP 655	February 13, 2025	March 24, 2025
Clostridium perfringens type D (epsilon) toxin (127.79 KB)	IRP 632	March 18, 2025	March 24, 2025
Veterinary Rabies Reference Vaccine, killed virus (99.46 KB)	17-06	March 20, 2025	March 24, 2025
Clostridium chauvoei Spore Preparation (100.05 KB)	IRP 631	March 11, 2025	March 24, 2025
Clostridium perfringens type C (beta) toxin (109.37 KB)	IRP 624	March 11, 2025	March 24, 2025
Escherichia coli Anti-F41 Pilus Polyclonal Antibody (F41 PAb) (93.74 KB)	IRP 693	March 11, 2025	March 24, 2025
Clostridium haemolyticum spore preparation (100.57 KB)	IRP 647	March 11, 2025	March 24, 2025
Clostridium novyi type B (alpha) Antitoxin (106.6 KB)	IRP 507 (04)	March 7, 2025	March 24, 2025
Acholeplasma laidlawii (96.33 KB)	17Apr12-AL	March 7, 2025	March 24, 2025
Clostridium tetani Toxin (116.98 KB)	IRP 664	March 7, 2025	March 24, 2025

Title	Lot ID	Publication Date	Posted Date
<u>Escherichia coli Anti-K99 Pilus Horseradish Peroxidase (HRP)-Labeled Monoclonal Antibody (K99-HRP Conjugate) (121.64 KB)</u>	IRP 680	March 10, 2025	March 24, 2025
<u>Clostridium perfringens Type C (beta) Antitoxin (103.83 KB)</u>	IRP 637	March 10, 2025	March 24, 2025
<u>Clostridium novyi Type B Toxin (103.7 KB)</u>	IRP 636	March 10, 2025	March 24, 2025
<u>Clostridium perfringens Type C (beta) Antitoxin (101.02 KB)</u>	IRP 645	March 10, 2025	March 24, 2025
<u>Secondary Reference Serum-Equine IgG; Stock for Equine IgG Species Standard (98.51 KB)</u>	10849	March 10, 2025	March 24, 2025
<u>Clostridium perfringens Type A (alpha) toxin (111.72 KB)</u>	IRP 612	February 27, 2025	March 20, 2025
<u>Negative Guinea Pig Serum (101.53 KB)</u>	IRP 550 (07)	February 27, 2025	March 20, 2025
<u>Clostridium perfringens Type D (epsilon) Antitoxin (106.08 KB)</u>	IRP 249	February 27, 2025	March 20, 2025
<u>Clostridium tetani Antitoxin 5.0 AU/mL (guinea pig origin) (95.19 KB)</u>	IRP 466	March 6, 2025	March 20, 2025
<u>Clostridium septicum (alpha) Toxin (105.58 KB)</u>	IRP 688	March 6, 2025	March 20, 2025
<u>Clostridium novyi Type B Toxin (101.27 KB)</u>	IRP 698	March 6, 2025	March 20, 2025
<u>Clostridium perfringens type A recombinant-alpha antitoxin (99.84 KB)</u>	IRP 564 (08)	March 6, 2025	March 20, 2025
<u>Clostridium chauvoei Flagella-specific (7D11/YD7) Monoclonal Antibody (MAb) (125.91 KB)</u>	IRP 608	March 6, 2025	March 20, 2025
<u>Clostridium septicum Antitoxin (112.47 KB)</u>	IRP 600	March 6, 2025	March 20, 2025
<u>Salmonella pullorum Stained K Polyvalent Plate Antigen (168.69 KB)</u>	16-301	February 27, 2025	March 20, 2025

Title	Lot ID	Publication Date	Posted Date
<u>Clostridium sordellii Toxin</u> (150.85 KB)	IRP 675	February 27, 2025	March 20, 2025
<u>Clostridium sordellii antitoxin</u> (131.52 KB)	IRP 501 (04)	February 27, 2025	March 20, 2025
<u>Leptospira canicola Master Reference Bacterin</u> (98.26 KB)	IRP 699	March 6, 2025	March 20, 2025
<u>Mycoplasma hyorhinis</u> (99.32 KB)	16Apr12	March 6, 2025	March 20, 2025
<u>Mycoplasma fermentans</u> (129.79 KB)	17Apr12-MF	February 27, 2025	March 20, 2025
<u>Mycoplasma orale</u> (128.42 KB)	18Apr12	February 27, 2025	March 20, 2025
<u>Mycoplasma synoviae</u> (129.7 KB)	17Apr12-MS	February 27, 2025	March 20, 2025
<u>Leptospira icterohaemorrhagiae Reference Bacterin</u> (103.53 KB)	IRP 542 (06)	February 19, 2025	March 19, 2025
<u>Escherichia coli harboring the pMyco plasmid (E. coli/pMyco)</u> (101.42 KB)	091510B	February 12, 2025	March 17, 2025
<u>Pasteurella multocida Challenge Culture (bovine)</u> (96.58 KB)	IRP 690	February 12, 2025	March 17, 2025
<u>Leptospira grippotyphosa Polyclonal Antibody (LG PAb)</u> (102.66 KB)	IRP 511-04	February 12, 2025	March 17, 2025
<u>Secondary Reference Serum-Equine IgG; Stock for Equine IgG Species Standard</u> (98.51 KB)	10849	February 4, 2025	February 20, 2025
<u>Leptospira canicola Challenge Culture</u> (96.98 KB)	IRP 653	February 5, 2025	February 20, 2025
<u>Leptospira icterohaemorrhagiae Polyclonal Antibody (LI PAb)</u> (102.86 KB)	IRP 04-481	February 5, 2025	February 20, 2025
<u>Escherichia coli Anti-K99 Pilus Monoclonal Antibody (K99 MAb)</u> (92.84 KB)	IRP 629	February 6, 2025	February 20, 2025

Title	Lot ID	Publication Date	Posted Date
<u><i>Clostridium chauvoei</i> Flagella-specific Rabbit Polyclonal Antibody (detection antibody)</u> (111.74 KB)	IRP 440	February 6, 2025	February 20, 2025
<u><i>Leptospira grippotyphosa</i> Reference Bacterin</u> (98.12 KB)	IRP 523 (05)	February 6, 2025	February 20, 2025
<u><i>Pasteurella multocida</i>, 169 (Swine) Challenge Culture</u> (97.97 KB)	IRP 490	February 6, 2025	February 20, 2025
<u><i>Clostridium tetani</i> Antitoxin, 1.3 AU/mL</u> (95.14 KB)	IRP 528	February 6, 2025	February 20, 2025
<u><i>Clostridium botulinum</i> Type C Toxin</u> (105.21 KB)	IRP 583	February 6, 2025	February 20, 2025
<u><i>Salmonella typhimurium</i> Challenge Culture</u> (105.19 KB)	IRP 596	January 30, 2025	February 19, 2025
<u><i>Clostridium septicum</i> Cell Assay Proficiency Panel</u> (109.56 KB)	IRP 639	January 31, 2025	February 19, 2025
<u><i>Clostridium botulinum</i> Type B Toxin</u> (112.25 KB)	IRP 430	January 31, 2025	February 19, 2025
<u><i>Leptospira grippotyphosa</i> Monoclonal Antibody (LG MAb)</u> (96.4 KB)	IRP 04-505	January 30, 2025	February 19, 2025
<u><i>Leptospira canicola</i> Monoclonal Antibody (LC MAb)</u> (94.41 KB)	IRP 04-500	January 28, 2025	February 19, 2025
<u><i>Clostridium perfringens</i> Type D (epsilon) Cell Assay Proficiency Panel</u> (129.01 KB)	IRP 638	January 28, 2025	February 19, 2025
<u><i>Escherichia coli</i> Anti-987P Pilus Monoclonal Antibody (987P MAb)</u> (94.36 KB)	IRP 475	January 28, 2025	February 19, 2025
<u>Avian Lymphoid Leukosis Virus Type A Positive Control (PC)</u> (103.95 KB)	12-02	January 31, 2025	February 19, 2025
<u><i>Erysipelothrix rhusiopathiae</i> Anti-65 kD Protein Monoclonal Antibody (ERHU MAb)</u> (96.74 KB)	IRP 569-08	January 21, 2025	February 06, 2025
<u><i>Escherichia coli</i> Anti-K99 Pilus Horseradish Peroxidase (HRP)-Labeled Monoclonal Antibody (K99-HRP Conjugate)</u> (121.64 KB)	IRP 680	January 21, 2025	February 06, 2025

Title	Lot ID	Publication Date	Posted Date
Erysipelothrix rhusiopathiae Challenge Culture (96.08 KB)	IRP 592	January 21, 2025	February 06, 2025
Fowl Laryngotracheitis Challenge Virus (96.68 KB)	07-3	January 21, 2025	February 06, 2025
Rabies challenge, fox salivary gland origin (96.52 KB)	92-5A	January 21, 2025	February 06, 2025
Veterinary Rabies Reference Vaccine, killed virus (153.16 KB)	08-14	January 17, 2025	January 31, 2025
Leptospira pomona Polyclonal Antibody (LP PAb) (171.24 KB)	IRP 04-482	December 19, 2024	January 30, 2025
Leptospira canicola Polyclonal Antibody (LC PAb) (152.41 KB)	IRP 491	December 19, 2024	January 30, 2025
Clostridium botulinum type B antitoxin (102.7 KB)	IRP 435	January 3, 2025	January 30, 2025
Leptospira pomona Challenge Culture (97.81 KB)	IRP 654	January 3, 2025	January 30, 2025
Pasteurella multocida Type A Bacterin (Bovine Isolate) (98.66 KB)	IRP 591	January 6, 2025	January 30, 2025
Clostridium tetani Toxin (116.98 KB)	IRP 664	March 15, 2024	January 06, 2025

Other

Title	ID	Publication Date	Posted Date
Current Veterinary Biologics Product Catalog (375.54 KB)		April 3, 2025	April 24, 2025
NCAH Portal User Guide: Qualifications of Veterinary Biologics Personnel (632.84 KB)	4	March 31, 2025	April 4, 2025
NCAH Portal User Guide: Creating and Revising Electronic Outlines (495.34 KB)	18	March 31, 2025	April 4, 2025

Title	ID	Publication Date	Posted Date
Organization Chart: Policy, Evaluation, and Licensing Unit (179.97 KB)	DB-9	February 10, 2025	March 14, 2025
Organization Chart: Inspection and Compliance Unit (116.39 KB)	DB-6	January 12, 2025	February 14, 2025
Organization Chart: Safety and Security Unit (183.38 KB)	DB-8	January 9, 2025	January 31, 2025
NCAH Portal User Guide: General Guide for Veterinary Biologics Production and Test Report (836.08 KB)	5	January 7, 2025	January 28, 2025
NCAH Portal User Guide: Submitting Outlines to Policy, Evaluation and Licensing (PEL) (309.18 KB)	20	January 7, 2025	January 28, 2025
Organization Chart: CVB Management (99.24 KB)	DB-3	December 27, 2024	January 23, 2025
Inspection and Compliance Manual Chapter: Rebottling/Reprocessing - Process (114.57 KB)	CVB-WI-0106	September 13, 2024	January 23, 2025
Inspection and Compliance Manual Chapter: Items to Consider in Evaluating Electronic Records and Digital Data (134.55 KB)	CVB-WI-0135	October 22, 2024	January 03, 2025

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