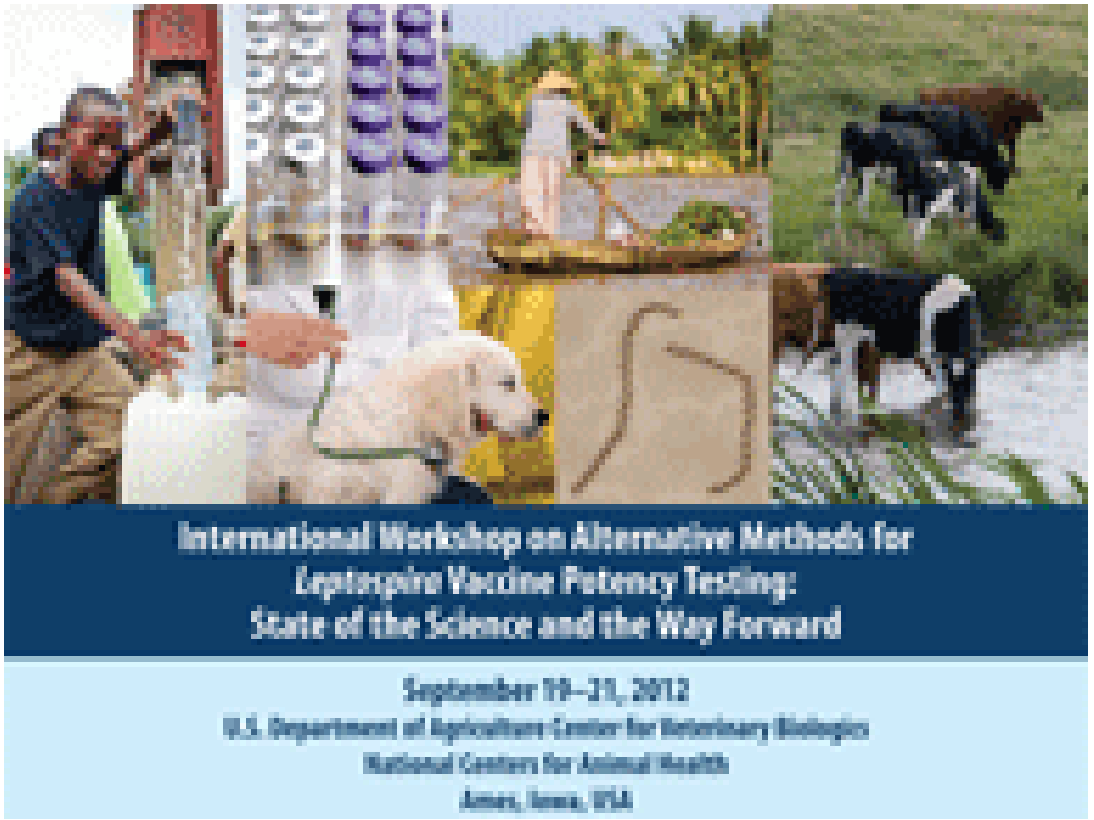
USDA

NCAH
National Centers for Animal Health

Welcome to the National Centers for Animal Health



APHIS

Safeguarding Animal Health

VS Veterinary Services


NCAH
National Centers for Animal Health

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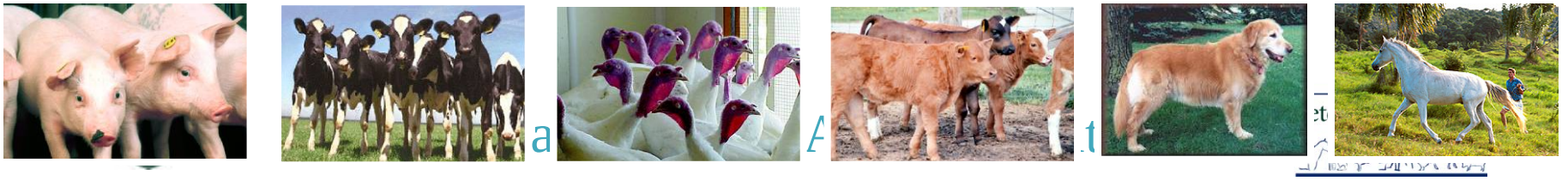
Center for Veterinary Biologics (CVB), APHIS

National Animal Disease Center (NADC), ARS

National Veterinary Services Laboratories (NVSL), APHIS

Together we meet the national needs for animal health research, diagnosis, and product evaluation.



Organizational Structure

- USDA  ➡ United States Department of Agriculture
- APHIS ➡ Animal and Plant Health Inspection Service
- VS ➡ Veterinary Services
- CVB  ➡ Center for Veterinary Biologics

Safeguarding Animal Health

Mission

The Veterinary Biologics Program implements the provisions of the Virus-Serum-Toxin Act to ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective.

Center for Veterinary Biologics Strategic Goals

- Reduce animal testing
- Maximize use of technologies
- Provide additional Standard Requirements
- Document more policies and procedures
- Common facility for CVB staff
- Review and validate current standards
- Improve pharmacovigilance

Goals

- Common goal – fewer animals
- Collaborative effort
- Foundation in science
- Flexible/practical regulatory approach
- Use available tools
- Incentives
- Harmonized Standards & International Collaboration

Example Guidance Documents Related to *In vitro* & Reduce, Refine, Replace Initiatives

Document	Title/Topic	Date of change*
9 CFR 113.8	*In vitro* tests for Serial Release	May 21, 1984
SAM 318	Relative Potency Method for Enzyme Immunoassays	July 17,1992
9 CFR 117.4	Test Animals (allow for humane removal)	August 21, 1995
VS Memo 800.90	Guidelines for Veterinary Biologics Relative Potency Assays and Reference Preparations Based on ELISA Antigen Quantification	August 5, 1998
SAM 624-627	*In vitro* Potency Testing for Leptospira Bacterins	August 30, 2000
VS Memo 800.102	Exemption from Leptospira Bacterin Testing Under 9 CFR 113.101(c), 113.102(c), 113.103(c), and 113.104(c)	May 23, 2002
VS Memo 800.104	*In Vitro* Serial Release Potency Test for Completed Product Containing *Clostridium chauvoei*	May 29, 2003
CVB Notice 04-09	Use of Humane Endpoints in Animal Testing of Biological Products	April 1, 2004
CVB Notice 04-17	Exemption to 3-year Master Seed Immunogenicity Retesting	November 4, 2004,
Draft VS Memo	Qualification and Requalification of References by Serology	October 2, 2006
CVB Notice 07-02	Subject: Qualification of *Leptospira grippotyphosa* and *icterohaemorrhagiae* Reference Bacterins for products intended for Use in Dogs	March 1, 2007
CVB Notice 07-12	Qualification of *Leptospira pomona* and *Leptospira canicola* Reference Bacterins for Products Intended for Use in Dogs	July 13, 2007
VS Memo 800.112	Guidelines for Validation of *In Vitro* Potency Assays	June 25, 2008
CVB Notice 09-16	Qualification of Leptospira Canicola, Leptospira Grippotyphosa, Leptospira Icterohaemorrhagiae, and Leptospira Pomona Reference Bacterins for Products Intended for Use in Swine and/or Cattle	August 3, 2009

** Date may vary slightly based on version control of documents*

CVB Organizers

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Thanks also to:

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