Welcome to the National Centers for Animal Health
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
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

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

Geetha Srinivas
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Thanks also to:

Jim Fosse
Scott Gayer
Charles Lewis
Dee McVey
Renee Olsen
Kevin Ruby
Wayne Sturtz

Safeguarding Animal Health