

Overview and Expectations

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- Impetus for this meeting
- Expectations of meeting
- Quick review of potency testing of Veterinary Biological Products

Impetus for meeting

- Commitment to IAB's to have meet on 3R's
- Commitment by the Center for Veterinary Biologics (CVB) to reducing animal testing
- Provide forum for discussion of issues concerning animal testing
- Provide information on technology used for *in vitro* potency testing of Veterinary Biologics

Impetus for meeting

- Provide information on new technology with potential for:
 - Potency testing of Veterinary Biologicals
 - Characterizing Veterinary Biologicals
 - Search and evaluating targets for development of new and improved Veterinary Biologicals
 - All of the above

Impetus for meeting

- Provide opportunity for the Center for Veterinary Biologics to propose for discussion changes in regulations being considered
- Provide for discussion purposes the direction the Center for Veterinary Biologics is considering in order to decrease animal testing by:
 - Changes in regulations
 - Encouragement of developmental work at the Center

Expectations

- Clear idea of the issues involved in animal testing of Veterinary Biologics
- Understanding of the tools and types of methods currently used for potency of Veterinary Biologics and their advantages and disadvantages

Expectations

- An understanding of the alternatives to animal testing
- Appreciation for how the technologies discussed could be applied to testing and potency testing of Veterinary Biologics
- An understanding of how the proposed changes to the regulations governing potency testing of Veterinary Biologics will induce movement away from potency testing animals toward in vitro testing.

Veterinary Biologics

- Vaccines and bacterins
 - Live and inactivated
 - Virus, bacteria and other
- Immunomodulators
- Anti-toxins
- Toxoids
- Diagnostic kits
- Allergenic extracts

Veterinary Biologics requirements

- Must demonstrate efficacy in target species in order to be licensed
- Each serial (lot) of Licensed Biological Product must be tested for potency in order to be released for marketing

Veterinary Biologics requirements

- The potency test provides assurance the Licensed Veterinary Biological product will perform in a satisfactory manner for the purpose intended.
- The potency test measures some parameter correlated to efficacy
- Potency tests
 - Vaccination-challenge in target or surrogate species
 - Vaccination-serology or other in target or surrogate species
 - *in vitro* tests-An assay which measures some entity in the serial correlated to efficacy (frequently an ELISA method)
 - Quantification of live agent in live vaccines

Veterinary Biologics requirements

- Potency tests are performed on final product (bulk or final container)
- Approximately ½ of Licensed Veterinary Biologic Products are live vaccines and therefore are not potency tested in animals
- Our goal is to increase the fraction of products potency tested by *in vitro* methods.