Column E Explanations Referencing APHIS Form 7023

2014 Annual Report of Research Facility
18 November 2014

1. **Registration Number 42-R-0020**

2. **Number of Animals Used in the Study:**

   Six (6) used in Tetanus Toxoid potency testing

3. **Species (common name) of Animals Used in the Study:**

   Guinea Pig

4. **Explanation of Procedure Producing Pain and/or Distress:**

   Tetanus Toxoid Potency test: These tests are mandated by APHIS-Center for Veterinary Biologics (CVB) in the licensing of vaccines to protect animals from the effects of disease caused by infection with Tetanus Toxoids. These tests are prescribed in Title 9 of the Code of Federal Regulations.

5. **Scientific Justification as to Why Pain and /or Distress Could Not Be Relieved:**

   This test is codified in the Title 9 Code of Federal Regulations. This codified test method has been promulgated by APHIS-CVB.

   To prevent interference with the test objectives, while at the same time promote the most humane treatment/endpoints of test animals permissible, the 9CFR allows the humane euthanasia of moribund animals exhibiting clinical signs consistent with disease pathogenesis that are unable to rise or move under their own power.

6. **Identification of Federal Regulations Requiring This Procedure:**

   - USDA (APHIS-CVB): 9 CFR 113.106 (c).

Initials (b) (6), (b) (7)(C) Date: 18 Nov 2014

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1. **Registration Number 42-R-0020**

2. **Number of Animals Used in the Study:**

   Two thousand three hundred and thirty (2330) used in *Leptospira* species potency assay for release of serials of USDA regulated biological product (i.e. vaccine).

   Five hundred and sixty-nine (569) used in *Leptospira* species passage process to maintain virulent strains of Leptospira organisms for use in challenge culture preparation for potency assays.

3. **Species (common name) of Animals Used in the Study:**

   Hamster

4. **Explanation of Procedure Producing Pain and/or Distress:**

   Leptospira species Potency Assay: These tests are mandated by APHIS-Center for Veterinary Biologics (CVB) in the licensing of vaccines to protect animals from the effects of disease caused by infection with multiple *Leptospira* species. These tests are prescribed in Title 9 of the Code of Federal Regulations.

   As per 9 CFR 117.4 (e), and In accordance with APHIS-CVB communication of April 1, 2004 (RE: VBN 04-09), APHIS-CVB has approved a "non-death" endpoint in our production outlines that allows humane methods of euthanasia.

   Leptospira species Passage Process: This process is necessary to maintain virulent *Leptospira* organisms for challenge preparation for use in the above mandated potency assay.

5. **Scientific Justification as to Why Pain and /or Distress Could Not Be Relieved:**

   The potency test is codified in the Title 9 Code of Federal Regulations. The codified test methods have been promulgated by APHIS-CVB and to date; APHIS-CVB has not published guidance to licensed biological manufacturers that would allow for the use of drugs such as pain relievers to reduce pain and suffering prior to attaining the study endpoint.

   To our knowledge, APHIS-CVB has not determined, nor communicated, what impact, use of drugs such as pain relievers would have on the validity of these assays.

   In some species of animals, clinical signs indicative of an inevitable progression to death are difficult to assess. To prevent interference with the test objectives, while at the same time promote the most humane treatment/endpoints of test animals permissible, production outlines have been modified to include the humane euthanasia of moribund animals exhibiting clinical signs consistent with disease pathogenesis that are unable to rise or move under their own power.

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6. Identification of Federal Regulations Requiring This Procedure:

- USDA (APHIS-CVB): 9 CFR 113.101(c).
- USDA (APHIS-CVB): 9 CFR 113.102(c).
- USDA (APHIS-CVB): 9 CFR 113.103(c).
- USDA (APHIS-CVB): 9 CFR 113.104(c).

Initials (b) (6), (b) (7)(C) [redacted] Date: 18Nov2014