Column E Explanations Referencing APHIS Form 7023

2016 Annual Report of Research Facility
11 November 2016

1. **Registration Number 32-R-0053**

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

   Two thousand six hundred one (2601) hamsters used in *Leptospira* potency assay for release of serials of USDA regulated biological product (i.e. vaccine).

   Four hundred twenty-seven (427) hamsters used in *Leptospira* 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 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 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. 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.

   Earlier humane endpoints have been adopted to reduce pain and suffering. 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.

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).

1. Registration Number 32-R-0053

2. Number of Animals Used in the Study:

Nineteen (19) guinea pigs used in *Clostridium chauvoei* potency assay for release of serials of USDA regulated biological product (i.e. vaccine).

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

Guinea pig

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

Clostridium chauvoei Potency Assay: This test is 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 *Clostridium chauveoi*. This test is prescribed in Title 9 of the Code of Federal Regulations.

The test procedure involves a vaccination/challenge model, which requires that control animals (guinea pigs) succumb to the test challenge, become recumbent and are unable to rise.

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.

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. 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.

Earlier humane endpoints have been adopted to reduce pain and suffering. 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.

6. Identification of Federal Regulations Requiring This Procedure:

- USDA (APHIS-CVB): 9 CFR 113.06 (c).