Category E Explanations

Registration Number: 22-R-0144

Number of hamsters: 959

Species (common name): Hamsters of animals used in the study.

Explain the procedure producing pain and/or distress

The 959 hamsters listed in column E were used in the regulatory required potency testing of bacterial vaccines and for the development of an in vitro testing validation to reduce animal use. The potency testing, conducted as required by Federal regulations, caused depression and discomfort in the hamsters.

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

The effects of analgesic medication on the length and severity of the disease are not known; thus, use of analgesic medications would invalidate the scientific value of the potency tests. For this reason, neither the USDA/CVB nor our company uses any medications to relieve pain and distress. The USDA/CVB regulations do not allow the use of any other standard potency test for the release of these vaccine serials, as no alternative potency test has been validated and accepted by the USDA/CVB. Distress/discomfort caused by these tests has been substantially reduced by the use of sensitive endpoints determined in previous studies and successfully applied to these tests, as allowed by USDA notice 04-09. All of the studies were reviewed and approved by the IACUC.

What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number:

APHIS 9 CFR 113.101
APHIS 9 CFR 113.102
APHIS 9 CFR 113.103
APHIS 9 CFR 113.104
Category E Explanations

Registration Number: 22-R-0144

Number of Dogs: 2

Species (common name) dog of animals used in the study.

Explain the procedure producing pain and/or distress

Dogs listed in column E were used in a study required to optimize the challenge dose of a virus for a canine vaccine. The regulations require that the study be allowed to proceed until the dogs develop significant clinical signs of the disease.

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results.

The dogs were observed carefully every day for clinical signs of the disease after challenge to allow humane intervention and euthanasia if dogs developed severe clinical signs of the disease. The disease progressed rapidly, and two dogs developed acute terminal complications. This study was reviewed and approved by the IACUC.

What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number:

The study was required to support requirements of 9CFR 113.306.
Category E Explanations

Registration Number: 22-R-0144

Number of 3

Species (common name): Dogs used in the study.

Explain the procedure producing pain and/or distress

The three dogs were involved in Antigen Dose-finding of 6-month Duration of Immunity for Rabies ORA-DPC Vaccine in dogs by serology.

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

The animals develop acute terminal complications related to testing before any veterinary intervention was possible.

What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number:

APHIS 9 CFR 113.209
Category E Explanations

Registration Number: 22-R-0144

Number of Guinea Pigs: 752

Species (common name). *Guinea Pig* of animals used in the study.

Explain the procedure producing pain and/or distress

Guinea Pigs (n = 752) listed in column E were used in the regulatory required potency testing of commercial bacterins. The potency tests were conducted as required by Federal regulations. Guinea pigs became sick and developed signs and/or local irritation due to the bacterial challenge.

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

The effects of analgesic or anti-inflammatory medication on the length and severity of the disease has not been known; thus, use of medications would invalidate the scientific value of the potency test. For this reason, neither the USDA/CVB nor our company have used any medications to reduce pain and distress. USDA/CVB regulations do not allow the use of any other standard potency test for the quality control release of these bacterin products as no alternative potency test has been validated and accepted by the USDA/CVB. In April 2011, we validated the use of an analgesic in the potency test for one product and implemented drug in use in June 2011 after USDA approval. We are in the process of developing regulatory acceptable in vitro testing that will reduce or eliminate the use of guinea pigs. All studies were reviewed and approved by the IACUC.

What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number:

APHIS 9 CFR 113.106
APHIS 9 CFR 113.107