

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 48-R-0109/35029
2. Number 374 of animals used in this study.
3. Species (common name) Hamster of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Potency Testing of EHV-1 Vaccines in hamsters for the purpose of obtaining a USDA/APHIS license for EHV-1 containing veterinary products.

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

Death as an End Point Scientific Rational Principle Investigator:

(b)(6), (b)(7)c

Project Title or Course Number: Equine Herpes Virus Vaccine Potency Testing

Species/Strain: Hamster, Golden Syrian

A total of 374 hamsters were used during this reporting period for potency testing of production lots, in order to correlate host animal protection with laboratory animal protection and to determine EHV-1 potency of production lots as required by APHIS-CVB. These activities were covered by Hennessy Research IACUC protocols HRA 0004 and HRA 0011.

Hamsters are the laboratory animal that has been used and accepted by USDA-APHIS-CVB for the past 20+ years as a correlate to protection in horses for immunogenicity studies. The number of hamsters requested for this protocol takes into account testing necessary to evaluate multiple vaccine lots in comparison with data established in host animal immunogenicity studies.

Death as an end point is required by USDA-APHIS-CVB for all LD₅₀ and PD₅₀ calculations. In hamsters the interval between moribundity and death is very short for this disease. It is difficult to predict death without jeopardizing the end point result.

There are no analgesics available which will relieve pain and distress and not bias the PD₅₀ end result.

This is currently the only laboratory animal procedure accepted by the USDA-APHIS-CVB for correlation to horse vaccination/challenge for vaccine efficacy evaluation.

There are currently no acceptable animal model alternatives recognized by USDA-APHIS-CVB for evaluating EHV-1 containing veterinary vaccines. In-vitro methods, such as the ELISA test, are currently under development; however, it will be necessary to use the hamster model for EHV-1 vaccine testing until the in-vitro method is perfected and accepted.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

USDA-APHIS-CVB approved production outlines describing the accepted hamster vaccination/challenge potency test for batch release.

Agency USDA-APHIS-CVB CFR 9CFR 113.200

29

Obtained by Rise for Animals.