

Attachment A: Category E Explanation, USDA, APHIS Form 7023 (FY17)
BIOQUAL, Inc.
Registration number 51-R-0036

NOV 03 2017

Protocol: 17-052P

Species (Common name): Guinea Pig

Number: 12

Explanation of the procedure producing pain and/or distress:

The pain and distress resulted from the actual progression of the HSV infection.

Justification why pain and/or distress could not be relieved:

The Guinea pig model is a widely accepted model for the evaluation of experimental HSV vaccines. This is the only model that shares many of the features of herpes infection in humans, including primary, latent, and recurrent HSV infection. Many humoral, cellular, and cytokine responses to HSV infection in the guinea pig have been characterized. The guinea pig model is ideally suited for examining immunogenicity and efficacy. It is anticipated that some animals may experience signs of distress related to viral infection. The pain and distress observed in this model will be directly related to the viral infection and therefore cannot be eliminated. Acyclovir has the potential to interfere with the viral infection and therefore cannot be used to alleviate this pain and distress. Pain-relieving medicines can alter the immune response and can interfere with the outcome and interpretation of the virus modulated immune response in the context of the vaccine.