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ATTACHMENT FOR COLUMN E EXPLANATION

The animals were used in the challenge protection tests conducted to demonstrate host animal immunogenicity for Pasteurella Haemolytica-Pasteurella Multocida Bacterin Toxoid Codes #7935.03. All 15 animals were challenged including 5 placebos, and 10 vaccinates 21 days post vaccination. Since the USDA requires observation for clinical signs post challenge, we knew that this requirement would produce some degree of pain and distress for the 5 placebos and for the 10 vaccinates depending on the degree of protection conferred by the vaccination. The 15 animals were suffered throughout the post-challenge period of observation.

The above-mentioned Host Animal Immunogenicity work involved pneumonia protection. Although the pivotal analysis was based on lung lesion scores, the USDA required observation as to whether the products help mitigating clinical signs. Therefore, pain and/or distress could not be relieved.

Principal Investigators:

(b) (6), (b) (7)(C)



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