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Attachment to APHIS Form 7023
Column E Explanation for USDA Reporting Year
October 1, 2009 through October 16, 2009

Registration Number: 23-R-0018

(b)(7)f

Three (3) dogs were used in tests to assess the safety of new pharmaceuticals wherein unanticipated signs of one or more signs of organ system involvement (b)(4) were observed following dosing. All animals showing signs of pain or distress were attended by specially-qualified veterinary staff; and any animals with severe or chronic signs of pain or distress were provided appropriate veterinary medical care. Safety assessment studies are required for the approval of human pharmaceuticals by international drug regulatory authorities and the FDA (Food, Drug and Cosmetics Act, CFR Title 21). Prior to the conduct of these studies, the IACUC determined that no alternatives were available and that the minimum numbers of animals of the appropriate species were used, consistent with obtaining valid results. The IACUC approved the withholding of treatment to ensure that unexpected interactions of the treatment with the test compound or the masking of clinical signs required for safety assessment did not occur. Either would interfere with the interpretation of results and possibly invalidate the study. Invalid studies would need to be repeated, requiring the use of additional animals.

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