Attachment to APHIS Form 7023
Column E Explanation for USDA Reporting Year
October 1, 2020 through September 30, 2021

Registration Number: 23-R-0016

For all studies below, the IACUC determined that no alternatives were available and that the minimum number of animals of the appropriate species were used consistent with obtaining valid results prior to study initiation.

One hundred thirteen (113) hamsters were used for studies to determine the efficacy of antibody preparations from transchromosomic cows in preventing or treating COVID-19. Continuation is required until clinical symptoms are evident. The IACUC approved withholding the use of analgesics and other pharmacological intervention to alleviate pain and distress because these substances would interfere with the characterization of the disease process and effectiveness of investigational therapeutics. The animals were monitored and euthanized at protocol defined endpoints.

Forty (40) hamsters were used for studies to determine the efficacy of alphavirus-based nucleic acid replicon vaccines and licensed 17D yellow fever virus vaccine in preventing COVID-19. Continuation is required until clinical symptoms are evident. The IACUC approved withholding the use of analgesics and other pharmacological intervention to alleviate pain and distress because these substances would interfere with the characterization of the disease process and effectiveness of investigational therapeutics. The animals were monitored and euthanized at protocol defined endpoints.

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Fifty-five (55) rabbits were infected via aerosol exposure to a virulent strain of *Francisella tularensis*, the causative agent of tularemia, to evaluate efficacy of candidate vaccines. The IACUC approved withholding the use of analgesics and other pharmacological intervention to alleviate pain and distress due to bacterial challenge because these substances would interfere with the assessment of the vaccines studied and adversely affect the interpretation of test results. The animals were monitored and euthanized at protocol defined endpoints.

Forty-one (41) rabbits were used in studies to investigate novel treatments for orthopedic infections. Animals received anesthesia and analgesia post-operatively and throughout the study duration according to an established pain assessment scale. Despite the use of poly-pharmacy analgesia, breakthrough pain due to infection and osteomyelitis is expected therefore all animals in this study are classified as Category E. The animals were monitored and euthanized at protocol defined endpoints.

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Fifty-one (51) cynomolgus macaques were infected with influenza A (H5N1) by aerosolization, which produces acute respiratory distress syndrome in a dose-dependent manner. The study evaluates the protective efficacy of candidate universal influenza vaccines in preventing severe respiratory disease caused by H5N1 influenza. The IACUC approved withholding the use of pharmacological intervention to alleviate pain and distress because these substances would interfere with the characterization of vaccine effectiveness. The animals were monitored and euthanized at protocol defined endpoints.

Eighteen (18) African green monkeys were used in studies that involved the development of a nonhuman primate model of COVID-19 (SARS-CoV-2) for vaccine efficacy testing. The NHPs were infected with SARS-CoV-2 to characterize the clinical signs, immunological and inflammatory response, and progression of disease for animal model development and vaccine efficacy testing. The IACUC approved withholding the use of analgesics and other pharmacological intervention to alleviate pain and distress because these substances would interfere with the characterization of the disease process and vaccine effectiveness. The animals were monitored and euthanized at protocol defined endpoints.

Twenty-nine (29) cynomolgus macaques were used in studies that involved the development of a nonhuman primate model of alphaviruses for monovalent and trivalent vaccine efficacy testing. The NHPs were infected with alphaviruses to induce clinical symptoms. The IACUC approved withholding the use of analgesics and other pharmacological intervention to alleviate pain and distress because these substances mask clinical signs of disease, alter immune responses, and influence the outcome of infection. The animals were monitored and euthanized at protocol defined endpoints.

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Twenty-four (24) ferrets experienced nausea, emesis, and altered gastrointestinal physiology following a vagal nerve stimulation study. Ferrets underwent a surgical procedure with the appropriate use of anesthetics and post-operative analgesics. Emesis was induced post-operatively. The IACUC approved withholding the use of antiemetics and other pharmacological intervention after emesis induction because these substances would adversely affect the interpretation of test results. The animals were monitored and euthanized at protocol defined endpoints.

Ninety-seven (97) ferrets were used to study influenza A resulting in clinical symptoms of respiratory disease. These studies explore the molecular determinants of influenza virus transmission and characterize the epidemiology of viral pandemics with the goal to determine potential intervention strategies. Clinical symptoms were expected and observed secondary to influenza infection. The IACUC approved withholding the use of pharmacological intervention to alleviate pain and distress because these substances would interfere with the characterization of influenza virus transmission and the effectiveness of investigational antiviral therapies. The animals were monitored and euthanized at protocol defined endpoints.

Forty-eight (48) ferrets were used to develop a model alphavirus encephalitis via aerosolization. Animals received anesthesia and analgesia for the surgical placement of telemeters according to the approved protocol. The IACUC approved withholding the use of analgesics and other pharmacological intervention to alleviate pain and distress due to disease progression because these substances would interfere with the characterization of the disease process. The animals were monitored and euthanized at protocol defined endpoints.

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Four (4) cats received intragastric copper sulfate as a model to understand neural pathways involved in nausea and vomiting. The IACUC approved withholding the use of antiemetics and other pharmacological intervention after emesis induction because these substances would adversely affect the interpretation of test results. The animals were monitored and euthanized at protocol defined endpoints.