Explanation for Animals Listed in Category E-APHIS Form 7023: FY 1 Oct 2017 - 30 Sep 2018

Registration Number 22-R-0155

Customer number 334734

Horses

In sixty (60) horses, the work (b) (4) (b) (4) does not permit any deviation from the outline of production during the course of the protocol, including the administration of analgesics, systemic symptomatic or therapeutic treatment due to the possible residual contamination of the final blood product, which is used as a human therapeutic.

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Dogs

Fifty-three (53) dogs were used in (b) (4) to evaluate safety and efficacy of novel therapeutic compounds. Post compound reactions were signs that would be expected (b) (4) (b) (4). Pain relieving drugs were not used as they would have adversely affected the scientific validity of the studies. One dog deceased prior to euthanasia, fifteen reached IACUC determined humane endpoints and were euthanized, while the rest remained on study under veterinary oversight.

Thirty-one (31) dogs experienced short-term lameness in a model (b) (4) (b) (4). Administration of analgesics (b) (4) is not possible during the testing regimen, as they may alter the animal's response to the test compound and adversely affect the scientific validity of the study. Nursing and supportive care, are provided, and post-procedural analgesics are provided by the veterinary staff, as indicated.

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Hamsters

The study objectives were (b) (4) [redacted] (b) (4) [redacted] Four thousand two hundred eighty-three (4,283) experienced acute systemic toxic effects and died during the conduct of the study. Use of drugs may invalidate the scientific validity of the results per CFR regulations.

Another study objective was to determine the potency of vaccines in hamsters as required by outlines of production for certain vaccines. The tests are required by regulation as proof of vaccine potency in each serial of vaccine produced. One hundred thirty-four (134) experienced acute systemic toxic effects and died during the conduct of the study. Use of drugs may invalidate the scientific validity of the results per CFR regulations.

Twenty-seven (27) animals were used to evaluate experimental vaccines for (b) (4) [redacted]. Post vaccination/challenge reactions were signs expected from the infectous disease agent. All twenty seven animals died prior to euthanasia.

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Guinea pigs

The study objective was (b) (4) [redacted] Two thousand four hundred forty-two (2,442) animals experienced acute lameness due to localized muscle or tissue damage from the administration of challenge material. Within this group of animals, four hundred seventeen (417) also experienced acute systemic toxic effects and died during the study. Use of drugs may invalidate the scientific validity of the results as per CFR regulations.

Another study objective was to evaluate the toxicity limit of vaccines in guinea pigs as required by international markets. One animal experienced acute systemic effects and died during the study.