

Attachment 1

Explanation for Animals Listed in Category E-APHIS Form 7023: FY 2017

Registration Number 22-R-0155

Customer number 334734

Dogs

One hundred forty four (144) dogs were used (b) (4) to evaluate safety and efficacy of novel therapeutic compounds. Post compound reactions were transient fever with lethargy, anorexia and ascites. Pain relieving drugs were not used as they would have adversely affected the scientific validity of the studies. Within this group, ten (10) dogs were removed from the study and euthanized, and one dog was found dead.

Guinea pigs

The study objective was to determine (b) (4)

(b) (4)

One thousand eight hundred ninety nine (1899) animals experienced acute lameness due to localized muscle or tissue damage from the administration of challenge material. Within this group of animals, four hundred fifty (450) also experienced acute systemic toxic effects and were euthanized or died during the study. Use of drugs may invalidate the scientific validity of the results as per CFR regulations.

Hamsters

The study objective was to determine the potency of vaccines in hamsters as (b) (4)

(b) (4)

(b) (4) Four thousand one hundred ten (4110) 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.

Horses

In forty eight (48) horses, the work conducted (b) (4)

(b) (4)

does not permit any deviation (b) (4) 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.

Summary of IACUC Approved Exceptions to the Standards and Regulations for APHIS Form 7023: FY 2017

The IACUC approved exceptions to the sanitation period such that primary enclosures were not cleaned and sanitized every two weeks to minimize the potential for cross contamination

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(b) (4) [REDACTED] which could invalidate the study. This exception included 104 dogs for intervals up to 53 days, and 244 cats for intervals up to 29 weeks. Pens were washed down each day. The veterinary staff monitored the living conditions, and felt there was minimal impact on overall animal health. Additionally, an IACUC exception was approved for a behavioral study involving 14 cats for 1 week to prevent an impact on study data. Pens were washed down every day, and the veterinary staff felt there was minimal impact on animal health.