

**Explanation for Animals Listed in Category E-APHIS Form 7023: FY 1 Oct 2018 -30 Sep 2019**

Registration Number 22-R-0155

Customer number 334734

**Species: Hamsters**

The study objective (b) (4)

The tests are required by regulation as proof of vaccine potency in each serial of vaccine produced. During the conduct of the study, four thousand four hundred ninety-six (4,496) animals experienced acute systemic toxic effects and died. Use of analgesics may invalidate the scientific validity of the results.

Six (6) animals were used to evaluate (b) (4)

Post vaccination/challenge reactions were signs expected from the (b) (4) agent. All six animals died prior to euthanasia.

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**Species: Horse**

In ninety-six (96) horses, (b) (4) [REDACTED]  
(b) (4) [REDACTED] which 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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**Species: Rabbit**

Two (2) rabbits (b) (4). Both experienced short-term lameness which was not relieved with analgesics. Pain-relieving compounds would have adversely affected the scientific validity of the study.

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**Species: Guinea Pigs**

The study objective (b) (4)

. The tests are required as proof of vaccine potency in each serial of vaccine produced. Two thousand six hundred twenty-seven (2,627) animals experienced acute systemic toxic effects or lameness from the administration of challenge material. Use of pain-relieving drugs may invalidate the scientific validity of the results as per 9CFR regulations.

## Summary of IACUC Approved Exceptions to the Standards and Regulations for APHIS Form 7023: FY 2019

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The IACUC approved AUP exceptions to the sanitation period such that the primary enclosure was not cleaned and sanitized every two weeks. This was to ensure that no cross-contamination occurred (b) (4) as well as to minimize stress involved in moving animals that had been recently vaccinated or challenged. If cross contamination occurred, study integrity could be compromised, which could require the study to be repeated. Pens were washed daily, the veterinary staff monitored the living conditions, and there was felt to be minimal impact on animal health. This exception was IACUC approved for two hundred twenty-nine (229) dogs for up to 25 days and one hundred twenty-eight (128) dogs for up to 57 days.

The IACUC approved AUP exceptions to space requirements of primary enclosures [AWA§3.53(c)(2)] such that rabbits with weight ranges between 4.4 – 8.8 lbs. were allowed 2.5 ft<sup>2</sup> not 3.0 ft<sup>2</sup>. The exemption was required following a change in the primary enclosure. The veterinary staff monitored the living conditions, and there was felt to be minimal impact on animal health. The IACUC approved exception was approved for two hundred seventy-six (276) rabbits for 10 – 40 days.

The IACUC approved AUP exception to feeding [AWA §3.54(b)] period such that food receptacles were not sanitized every 2 weeks. The exemption was approved for a delay in sanitization up to Day 17 only if rabbits are scheduled to be euthanized. The veterinary staff monitored the living conditions, and there was felt to be minimal impact on animal health. The exception impacted one hundred twenty (120) rabbits for 1 day.

An exception from the AWA sanitation requirement for guinea pig water receptacle (§3.30) and primary enclosure (§3.31) occurred. There were five (5) instances in which the racking system, which includes the lixit and is the ceiling of the bin, was sanitized on day 15 instead of day 14. The veterinary staff monitored the living conditions, and there was felt to be minimal impact on animal health. A total of two hundred seventy-eight (278) guinea pigs were impacted.

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**Species: Dog**

Seven (7) dogs used in (b) (4) experienced short-term clinical disease. The clinical signs were consistent with (b) (4). Pain relieving drugs were not used as they would have adversely affected the scientific validity of the study.

Sixty-three (63) 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). Pain relieving drugs were not used as they would have adversely affected the scientific validity of the studies. Seven (7) dogs deceased prior to euthanasia, twenty-five (25) reached IACUC determined humane endpoints and were euthanized, while the rest remained on study under veterinary oversight.