OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2021-2022

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER

21-R-0248

2. Research Facility Headquarters address

Clinvet USA LLC
1479 Talmadge HIll Rd So
Waverly, NY 14892

3. Number of animals used in the study.

42

4. Species (common name) of animals used in the study.

Feline

5. Explain the procedure producing pain and distress.

Development of a feline combination vaccine that contains modified live feline panleukopenia virus (FPL). As part of licensing and registration requirements, the demonstration of duration of immunity for FPL must be conducted by vaccination and challenge in the target species. The USDA requires that at least 80% of the unvaccinated control cats develop leukopenia as defined by a white cell count of < 4000 leukocytes per mm3 or < 25% of the baseline value, on at least one occasion, established prior to challenge (9 CFR 113.304). The purpose of this study is to confirm the dose of FPL challenge necessary to meet the control group requirements

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The 9 CFR 113.304 requires feline panleukopenia susceptible cats to be used as test animals therefore animals may experience more than slight or momentary pain/distress before euthanasia. Animals were monitored at least twice daily throughout the study including weekends and holidays. The Veterinarian in consultation with the PI determined if increased monitoring frequency wasneeded based on the presentation of clinical signs. Once endpoint criteria were met, the animal(s) were euthanized as per study protocol, however, no intervention was allowed prior.

- The activity in this protocol and Column E was approved by IACUC.

7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102):

Agency	CFR
APHIS	113.304 (c) (1)

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21-R-0248

2. Research Facility Headquarters address

Clinvet USA LLC
1479 Talmadge Hill Rd So
Waverly, NY 14892

3. Number of animals used in the study.

38

4. Species (common name) of animals used in the study.

Canine

5. Explain the procedure producing pain and distress.

The objective of this study is to demonstrate the efficacy of a single dose of a new vaccine containing A72 CPV MLV (modified live virus) and CPV-VLP in the presence of residual levels of CPV maternal antibodies (MDA) by a CPV2b virulent challenge in dogs.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The 9 CFR 113.317 requires 3 of 4 criteria are met for diagnosis of CPV therefore, animals may experience more than slight or momentary pain/distress before euthanasia.
Animals were monitored at least twice daily throughout the study including weekends and holidays. The Veterinarian in consultation with the PI determined if increased monitoring frequency was needed based on the presentation of clinical signs. Once endpoint criteria were met, the animal(s) were euthanized as per study protocol, however, no intervention was allowed prior.
• The activity in this protocol and Column E was approved by IACUC.

7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102):

Agency	**CFR**
APHIS	9 CFR 113.317 (c)(3) (i)