OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2020-2021

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	2. Research Facility Headquarters address
32-R-0053	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140
3. Number of animals used in the study.	**4. Species (common name) of animals used in the study.**
2	Dogs

5. Explain the procedure producing pain and distress.

(b) (4)
(b) (4) These two dogs exhibited several days of vomiting, diarrhea and dehydration and due to the duration of signs, potentially experienced pain/distress, despite that they both started to recover before study end.

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.

Both the USDA and the European Union require efficacy of (b) (4) to be demonstrated in the host animal. Therefore, clinical signs are assessed over time to prevent disease.

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

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1	Rabbit

5. Explain the procedure producing pain and distress.

This tests requires anesthesia of the rabbit, in which it exhibited self-injurious behavior resulting in ulceration of the skin, likely caused by the anethetic injection.

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.

Systemic analgesics have not been assessed and could impact test outcomes.

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):

Procedure described in section (d) (2) Safety test (i)

Agency	CFR
APHIS - CVB and Notice 11-18	9CFR113.209

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2381	Hamsters

5. Explain the procedure producing pain and distress.

These hamsters were used for an in-vivo potency test, which included passage of the organism and subsequent potency testing for serial release (n=2337), with the remaining animals used for an assessment of vaccine effficacy (n=44), in which all these hamsters were found dead despite additional daily welfare checks.

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.

Additional welfare checks are part of the oversight of these animals in order to identify moribund animals for humane euthanasia, however due to the rapid progression of disease, these animals were still found dead.

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):

Testing in accordance with section (c) Potency for QC testing.

Agency	CFR
AHIS: CVB	9CFR-101 thru -104

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140	Rabbit

5. Explain the procedure producing pain and distress.

These rabbits evaluate the serological response to (b) (4) for vaccine test release. These animals receive a large volume of vaccine with adjuvant as an intramuscular injection which resulted in reluctance to move and lameness in the limb, which are clinical signs suggesting pain.

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.

Systemic analgesics have not been assessed and could impact test outcomes.

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):

Volumes given are in accordance with the regulatory requirements described below.

Agency	CFR
APHIS - CVB Special outline 8-020	9CFR113.105

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4	Rabbits

5. Explain the procedure producing pain and distress.

The potency test release for this serial results in localized swellings at the injection site, in which these rabbits progressed to skin ulcerations, which were treated with topical antibiotic ointment to prevent secondary infection, however systemic analgesics were not provided.

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.

Systemic analgesics have not been assessed for impact to titers, and potential results.

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):

Code of Federal Reguations: 9CFR113.9 with Standard Outline SO-098

Agency	CFR
APHIS: CVB	9CFR113.9

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4	Rabbits

5. Explain the procedure producing pain and distress.

The potency test release for this serial results in localized swellings at the injection site, in which these rabbits progressed to skin ulcerations, which were treated with topical antibiotic ointment to prevent secondary infection, however systemic analgesics were not provided.

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.

Systemic analgesics have not been assessed for impact to titers, and potential results.

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Code of Federal Reguations: 9CFR113.9 with Standard Outline SO-098

Agency	CFR
APHIS: CVB	9CFR113.9

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1	Dog

5. Explain the procedure producing pain and distress.

To determine the efficacy [redacted] in dogs when challenged.
Despite humane euthanasia of this dog, it exhibited several days of diarrhea, vomiting, and then jaundice in order to meet the case definition for disease. Due to duration of clinical signs, this dog was deemed to have experienced pain/distress.

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.

Dogs had defined criteria to meet the case definition [redacted] for humane euthanasia. This dog exhibited non-specific clinical signs and intervention would obscure symptoms of disease, thus confounding the study.

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