OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2019-2020

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

32-R-0053

2. Research Facility Headquarters address

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

3. Number of animals used in the study.

3421

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

Hamsters

5. Explain the procedure producing pain and distress.

These animals were for the (b) (4) (n=1201) in order to maintain virulence of organisms for use in the codified potency tests to support vaccine efficacy (n=2220).
Despite the additional welfare checks to identify moribund animals for humane euthanasia, these hamsters experienced rapid progression of disease in which animals were found dead.

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.

These animals had additional welfare checks in order to intervene with humane euthanasia if moribund, however due to rapid progression of disease, 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): These animals support vaccine efficacy in compliance with the described regulations listed below.

Agency	APHIS – CVB	**CFR**	(b) (4)

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JUL 2020

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2. Research Facility Headquarters address

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

3. Number of animals used in the study.

28

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

Hamsters

5. Explain the procedure producing pain and distress.

These animals were for the assessment of virulence of (b) (4) [redacted]. Despite the additional welfare checks to identify moribund animals for humane euthanasia, these hamsters experienced rapid progression of disease in which animals were found dead.

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.

These animals have additional welfare checks in order to intervene with humane euthanasia if moribund, however due to rapid progression of disease, animals were 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):

This animals were used to evaluate virulence of (b) (4) [redacted] for support of challenge model development.

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Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

3. Number of animals used in the study.

12

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

Hamsters

5. Explain the procedure producing pain and distress.

These animals were for the assessment efficacy of a vaccine construct of (b) (4) [redacted] using the standard potency hamster test.
Despite the additional welfare checks to identify moribund animals for humane euthanasia, these hamsters experienced rapid progression of disease in which animals were found dead.

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.

These animals have additional welfare checks in order to intervene with humane euthanasia, however due to rapid progression of disease, animals were 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):

NA

Agency	CFR

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2. Research Facility Headquarters address

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

3. Number of animals used in the study.

173

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

Rabbits

5. Explain the procedure producing pain and distress.

These rabbits evaluate the serological response to (b) (4) [redacted] for vaccine test release. These animals receive a large volume of vaccine with adjuvant 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 could confound study outcome.

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 (b) (4) [redacted]	[redacted]

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32-R-0053

2. Research Facility Headquarters address

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

3. Number of animals used in the study.

18

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

Rabbits

5. Explain the procedure producing pain and distress.

These rabbits evaluate the serological response for (b) (4) for vaccine test release. These animals had individual reactions resulting in skin ulceration and/or swelling of a limb, both deemed to be potentially painful to the animals. Otherwise, animals remained on feed and clinically normal.

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.

Animals are not provided systemic medications that might confound the test results. Topical treatments were applied to skin ulcerations, however it does not provide analgesic relief, but rather prevents infection and improve healing time.

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 – CVB (b) (4)	(b) (4)

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2. Research Facility Headquarters address

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

3. Number of animals used in the study.

1

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

Rabbits

5. Explain the procedure producing pain and distress.

This rabbit exhibited overgrooming to the extent it ulcerated the skin, considered to be painful, most likely secondary to the anesthetic injection required to conduct the procedure per the protocol. The lesion healed with topical ointment. All other rabbits did not exhibit a complication.

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.

This was not an expected outcome from the study, in which only one rabbit exhibited complications secondary to the anesthetic.

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**
CVB	(b) (4) [redacted]

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32-R-0053

2. Research Facility Headquarters address

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

3. Number of animals used in the study.

22

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

Dogs

5. Explain the procedure producing pain and distress.

This study was to assess virulence and optimal challenge dose of an infectious agent (b) (4), in which animals exhibit clinical signs of disease and severity was determined by duration of such signs. These dog (n=22) exhibited clinical signs that included vomiting, diarrhea, dehydration, which were considered to have experienced pain/distress due to the duration of the clinical signs exhibited. Some dogs deteriorated and were humanely euthanized (n=9) while the remaining dogs (n=13) recovered or resolved in severity of signs.

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 scientific objective is to produce clinical signs of disease and assess these signs over time to determine virulence, thus intervention would confound this assessment. Eventually the information would be used for vaccine test release and comply with the 9CFR.

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): NA

Agency	CFR

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2. Research Facility Headquarters address

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Greenfield, IN 46140

3. Number of animals used in the study.

30

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

Dogs

5. Explain the procedure producing pain and distress.

This study was to assess various delivery routes of an infectious agent (b) (4) and their subsequent clinical presentation to find the optimal and less invasive route. Dogs experienced a range of symptoms, including vomiting, diarrhea, bloody stool, dehydration, and neuromuscular tics. Despite the additional welfare checks and humane euthanasia, due to the duration of clinical signs, dogs were considered to have experienced pain and/or 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.

This study was to assess severity of disease by the various routes of delivery, therefore clinical signs and duration were required to determine optimal route with the least invasive method.

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):

The (b) (4)

Agency	CFR

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Greenfield, IN 46140

3. Number of animals used in the study.

3

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

Dogs

5. Explain the procedure producing pain and distress.

These dogs were challenged IV with an infectious agent (b) (4) and exhibited clinical signs expected for the disease, which included bloody diarrhea, tenesmus, dehydration that progressed that dogs were euthanized. Due to the duration of the signs exhibited and continued deterioration of these three dogs to the study endpoint, these dogs were considered to have experienced pain and/or 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.

The justification was to establish a model that would be accepted for registration by the European authorities.

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**
NA	

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2. Research Facility Headquarters address

Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

3. Number of animals used in the study.

2

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

Dogs

5. Explain the procedure producing pain and distress.

Dogs on this study, which was a (b) efficacy assessment using a challenge model, exhibited higher than expected clinical signs, in which additional welfare checks were implemented to allow for prompt euthanasia. Despite these extra checks, these two dogs were found dead.

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 severity of disease was not expected, and due to the two dogs found dead, and other dogs that had been humanely euthanized, the study was terminated early.

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):

NA

Agency	CFR