This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21:

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 47-R-0010
CUSTOMER NUMBER: 1550

FORM APPROVED
OMB NO. 0579-0036

Schering-Plough Animal Health, Corp
P O Box 3113
Omaha, NE 68103

Telephone: (b)(6), (b)(7)(c)

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	12	649	58	1	708
5. Cats	41	316	32	1	349
6. Guinea Pigs	72	386	722	20	1,128
7. Hamsters	710	3,824	1,593	977	6,394
8. Rabbits	0	24	910	0	934
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Ferrets	0	0	70	0	70
Mink	14	369	0	36	405

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rest teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATU (b)(6), (b)(7)(c)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (b)(6), (b)(7)(c)

DATE SIGNED 11/14/08

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(AUG 98), which is obsolete.)

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Category E Explanations

Registration Number: 47-R-0010 / 1550

Number of dogs used: 708

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

Explain the procedure producing pain and/or distress:

The dog (n = 1) listed in column E became sick following a [redacted] required to test the [redacted] The rapid progression of the disease prevented humane intervention before the dog became moribund.

Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below).

The study was required to demonstrate the efficacy of a [redacted] fraction added to a [redacted] The study required an evaluation and comparison of the clinical signs of disease in the [redacted] and placebo [redacted] groups. Medications to relieve pain and distress were not used as they would have masked the clinical signs caused by the [redacted] That would have invalidated the study for purposes of determining [redacted] Sensitive endpoints were defined and applied in this study. The dogs were observed twice daily after the [redacted] to allow prompt and timely intervention to prevent needless suffering. The progression of the disease in this dog was unusually rapid and intervention was not possible.

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):

9CFR 102.3

[redacted]
(b)(4)

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All redactions on this page are pursuant to (b)(4).

Category E Explanations

Registration Number: 47-R-0010 / 1550

Number of cats used: 349

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

Explain the procedure producing pain and/or distress

The cat (n = 1) listed in column E was enrolled in a multi-vear [redacted] of [redacted] meant to [redacted]

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

[redacted] The cat was observed daily for clinical signs of pain or distress and had always appeared to be normal. The protocol allows symptomatic treatment of cats with mild clinical signs of the disease and euthanasia of cats with [redacted] and clinical signs typical of the disease. Clinical signs of disease, distress, or pain were not observed in this cat prior to death. Pain relieving medication was not provided because there was no indication or expectation that the cat was, or would soon be, in pain or distress.

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):

[redacted]

NOV 2 0 2008 ✓

Category E Explanations

Registration Number: 47-R-0010 / 1550

Number of Guinea Pigs used: 1,128

Species (common name) . Guinea Pig **of animals used in the study.**

Explain the procedure producing pain and/or distress

Guinea Pigs (n = 20) listed in column E were used in the [redacted] The [redacted] were conducted as required by Federal regulations. Guinea pigs became sick and developed [redacted] due to the [redacted]

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below).

The effects of analgesic medication on the length and severity of the disease is not known; thus, use of analgesic medications would invalidate the scientific value of the [redacted] The use of anti-inflammatory medication would also be likely to affect the normal progression of the disease. For this reason, neither the USDA/CVB nor our company uses any medications to reduce pain and distress. The current test is the only acceptable [redacted] for use in the release of [redacted] as no alternative [redacted] has been validated and accepted by the USDA/CVB.

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):

[redacted]

NOV 2 0 2008 ✓

Category E Explanations

Registration Number: 47-R-0010 / 1550

Number of hamsters used: 6,394

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

Explain the procedure producing pain and/or distress

Hamsters (n = 977) are listed in column E The hamsters were used in the [redacted] of [redacted] The [redacted] conducted as required by Federal regulations, caused [redacted] in the hamsters.

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below).

The effects of analgesic medication on the length and severity of the disease is not known; thus, use of analgesic medications would invalidate the scientific value of the [redacted] For this reason, neither the USDA/CVB nor our company uses any medications to relieve pain and distress. No alternative [redacted] has yet been validated and accepted by the USDA/CVB, leaving only this standard test as acceptable for use in the release of [redacted] Suffering caused by these tests has been substantially reduced by the use of sensitive endpoints determined in previous studies and successfully applied to these tests, as allowed by USDA notice 04-09.

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):

[redacted]

NOV 2 0 2008

All redactions on this page are pursuant to (b)(4).

Category E Explanations

Registration Number: 47-R-0010 / 1550

Number of mink used: 405

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

Explain the procedure producing pain and/or distress

Mink that are listed in column E (n = 36) were used in a serial release [redacted] for a [redacted] The animals experienced [redacted]

Provide scientific justification why pain and/or distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below).

The disease progresses rapidly through [redacted] The normal progression of the disease is likely to be altered by the use of analgesic medication. For this reason, neither the USDA/CVB nor our company uses any substance to reduce pain and distress in this test, as use of pain-relieving medication would invalidate the scientific value of the [redacted] required for assessing [redacted] The current test is the only acceptable [redacted] for use in the release of this [redacted] as no alternative test has been validated and accepted by USDA/CVB.

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, 9CFR 113.102):

Federal regulations: [redacted]

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All redactions on this page are pursuant to (b)(4).

Exceptions to Regulations:

Registration Number: 47-R-0010 / 1550

Exceptions to the regulations and standards, specified and explained by the principal investigator and approved by the IACUC.

Dogs in 2 studies (n = 24 dogs/study) were not removed from their cages for exercise during the 21 observation period because was a The BioSafety Committee at this site noted that repeatedly lifting the dogs out of and back into their cages to allow them to exercise would have The IACUC was aware of the exception when it approved the studies.

What, if any, federal regulations require this procedure?

The studies were required by support licensure of a new product. That requirement was confirmed by the USDA/CVB by letter on 08 Dec 2005.

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