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 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 22-R-0036 CUSTOMER NO. 181

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Schering Corporation, Schering-Plough Research Inst.
2015 Galloping Hill Road, Kenilworth NJ 07033
(b)(2)High, (b)(7)f

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

FACILITY LOCATIONS *(sites)*

See Attached 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 animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of 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 and 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 which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	1	461	60	12	533
5. Cats	0	0	29	0	29
6. Guinea Pigs	0	344	371	5	720
7. Hamsters	0	0	882	25	907
8. Rabbits	0	221	9	4	234
9. Non-Human Primates	78	410	193	28	631
10. Sheep	0	0	0	0	0
11. Pigs	0	0	74	0	74
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, 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 approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a 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)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)c	(b)(6), (b)(7)c	20nov2008

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

NOV 25 2008

NP

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

USDA ANNUAL REPORT: REGISTRATION NUMBER 22-R-0036
COLUMN E EXPLANATIONS, EXEMPTIONS AND EXCEPTIONS

COLUMN E EXPLANATIONS

SITE 1:

Two Guinea Pigs unexpectedly died and three were euthanized due to clinical signs of depression and weakness during a study to evaluate [redacted] of an investigational compound. Treatment would have interfered with the evaluation of the compound being studied. Adverse effects were not expected based on the history and previous studies in other species using this compound. The study design, criteria to evaluate the animals and frequency of observation were described in the protocol and approved by the IACUC.

Twenty-five hamsters were euthanized due to signs of infection during studies to investigate compounds to treat [redacted] Treatment would have interfered with the evaluation of the compounds being studied to [redacted] The study design, criteria to evaluate the animals and frequency of observation were described in the protocol and approved by the IACUC.

SITE 2:

Four nonhuman primates experienced emesis of more than 3 consecutive days following test compound administration. The study was designed to evaluate [redacted] of the test article and antiemetic treatment would have interfered with the evaluation of the compound being studied. The study was conducted under a protocol reviewed and approved by the IACUC and in accord with FDA requirements [redacted]

One nonhuman primate was euthanized after 5 consecutive days of emesis, leading to dehydration, ataxia and hypoactivity. Treatment would have interfered with the evaluation of the compound being studied. The study was conducted under protocols reviewed and approved by the IACUC and was in accord with FDA requirements [redacted]).

One nonhuman primate was euthanized during a study designed to evaluate [redacted] of a test compound after the veterinarian diagnosed a leg fracture. The injury likely occurred during handling for a study-related activity and was diagnosed after the activity was completed. The study was conducted under a protocol reviewed and approved by the IACUC and was in accord with FDA requirements [redacted]

One non-human primate experienced a seizure and recovered prior to administration of any anti-seizure treatment. The study was conducted under a protocol reviewed and approved by the IACUC, and designed to determine [redacted]

A total of four nonhuman primates were used in a study designed to assess the potential for [redacted] after repeat dosing. The study was conducted under a protocol reviewed and approved by the IACUC. The animals exhibited hunched posture, hypoactivity and

decreased food consumption. Treatment would have interfered with the evaluation of the compound being studied. The study was ended prematurely due to the effects of the test article.

A total of three nonhuman primates were used to validate an animal model measuring [redacted] The study was conducted under a protocol reviewed and approved by the IACUC. The three primates repeatedly assumed a hunched posture and exhibited periods of hypoactivity or inactivity which increased in frequency until the cessation of dosing on day 7. Drugs could not be used to relieve the distress since the purpose of the study was to evaluate [redacted] following repeated dosing and any additional drugs would confound the interpretation of the study. The study was ended prematurely due to the effects of the test article.

SITE 3:

Three rabbits were found dead in studies designed to determine [redacted] for subsequent [redacted] There were no opportunities to provide treatment to these animals. The study was conducted under a protocol reviewed and approved by the IACUC and in accord with the [redacted]

One rabbit had poor food consumption and scant stool for 4 days in a study of [redacted] Treatment would have interfered with the evaluation of the compound being studied. The animal was euthanized. The study was conducted under a protocol reviewed and approved by the IACUC and in accord with the [redacted]

Ten dogs experienced 3 or more consecutive days of emesis while on studies designed to assess [redacted] of the test article. Antiemetic treatment would have interfered with the evaluation of the compound being studied. Studies were conducted under protocols reviewed and approved by the IACUC and were in accord with FDA requirements [redacted]

Two dogs were found dead after test article was inadvertently administered into the lung. Staff performing this procedure were retrained. Animals were on studies to assess [redacted] of test article. Studies were conducted under protocols reviewed and approved by the IACUC and were in accord with FDA requirements [redacted]

Fourteen nonhuman primates experienced repeated emesis of more than 3 days duration. Antiemetic treatment would have interfered with the evaluation of the compound being studied. Studies were conducted under protocols reviewed and approved by the IACUC and were in accord with FDA requirements [redacted]

NONHUMAN PRIMATE EXEMPTION FROM PAIRED HOUSING

SITE 1:

56 Single housed due to aggression with cage mates
15 Single housed for varied duration because of unavailable partner

SITE 2:

22 Single housed due to aggression with cage mate
73 Single housed for study period due to requirements of the IACUC-approved protocol
11 Single housed for varied duration due to medical issues that would not allow treatment when pair housed
6 Single housed for varied duration because of unavailable partner

Site 3:

1 Single housed due to aggression with cage mate
40 Single housed for study period because of protocol
121 Single housed for varied duration for medical issues that would not allow treatment when pair housed
7 Single housed for varied duration because of unavailable partner

CANINES EXEMPTED FROM EXERCISE

SITE 1:

No exemptions

SITE 2:

14 Canines exempt from exercise for 2 weeks postoperatively during recovery

5 Canines exempt from exercise for two week period due to study protocol

SITE 3:

No exemptions