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OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 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.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year: 2009

**UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

REGISTRATION NUMBER: 22-R-0040

Customer Number: 689

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

Huntingdon Life Sciences Inc
P.O. Box 2360
East Millstone, NJ 08875

Telephone: (732) 873 2550

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 on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs	13	659	48	35	742
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	440	0	18	458
9. Non-human Primates	112	448	96	30	574
10. Sheep					
11. Pigs	0	114	3	1	118
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 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.
- Each principal investigator has considered alternatives to painful procedures.
- 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 such 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.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions 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 (C.E.O.) or Legally Responsible Institutional Official (L.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

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

DATE SIGNED

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A) Explanation of Category E Studies

All studies listed were conducted to conform to federally mandated requirements, promulgated by the US Food and Drug Administration (FDA). These regulations specify pre-clinical testing requirements necessary for approval of new drugs. Specific regulations and/or guidelines include the following:

- ICH Harmonized Tripartite Guideline for the Detection of Toxicity to Reproduction for Medicinal Products, and Toxicity to Male Fertility ICH S5 (R2).
- Redbook 2000 - Toxicological Principles for the Safety Assessment of Food Ingredients: Section IV.C.9.b Guidelines for Developmental Toxicity Studies, *III*. Guideline for Developmental Toxicity Studies, *B*. Dose Range-Finding Study (and as updated in 2003 and July 2007).
- ICH S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Non-Rodent Toxicity Testing).
- Guidance on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals. ICH guideline M3 (R2). CPMP/ICH/286/95
- Test No 409 Repeated Dose 90-Day Oral Toxicity Study in Non-Rodents (OECD Guidelines for the Testing of Chemicals)
- ICH Harmonized Tripartite Guideline S3A Note for Guidance on Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies

Species	Number of Category E Animals	Description
Dogs	1	Animals were exposed to test article for 3 months. One dog exhibited test article effects, and was humanely euthanized.
Dogs	5	Animals were exposed to test compound for 14 days. Test article effects were evident in 5 dogs. Affected dogs were humanely euthanized.
Dogs	13	Animals were exposed to test compound for 28 days. Test article effects were evident in 13 dogs. All affected dogs received palliative treatment.
Dogs	4	Animals were exposed to test article for 3 months. Test article effects were evident in 4 dogs. Of these, effects were transient (self-limiting) in 2 dogs, and the remaining 2 affected dogs were humanely euthanized.
Dogs	7	Animals were exposed to test article for one day. Test article effects were evident in 7 dogs. Of these, effects were transient (self-limiting) in 3 dogs, and the remaining 4 affected dogs were humanely euthanized.

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Species	Number of Category E Animals	Description
Dogs	1	Animals were exposed to test article for 3 months. Transient self-limiting test article effects were evident in one dog.
Dogs	4	Animals were exposed to test article for 3 months. Transient self-limiting test article effects were evident in 4 dogs.
Pigs	1	Animals were exposed to test article for 14 days. One pig had signs that were attributable to test article. Dosing was suspended for this animal.
Rabbits	5	Animals were exposed to test compound for 12 days. Test article effects were evident in 5 rabbits. All affected rabbits received treatment, and 2 were humanely euthanized.
Rabbits	4	Animals were exposed to test compound for approximately 13 days. Test article effects were evident in 4 rabbits. All affected rabbits were humanely euthanized.
Rabbits	9	Animals were exposed to test compound for approximately 13 days. Test article effects were evident in 9 rabbits. As a result, the study was terminated.
Monkeys	17	Animals were exposed to test article for approximately 4 weeks. Test article effects were evident in 17 monkeys. Of these, 16 were treated, and one was humanely euthanized.
Monkeys	4	Animals were exposed to test article for approximately 6 days. Transient (self-limiting) test article effects were evident during dosing in 4 animals.
Monkeys	3	Animals were exposed to test compound for approximately 8 days. Transient (self-limiting) test article effects were evident in 3 animals.
Monkeys	1	Animals were exposed to test compound for approximately 28 days. One monkey had signs that were not attributable test article.
Monkeys	2	Animals were exposed to test compound intermittently for approximately 2 weeks. Test article effects were evident in 2 monkeys. Both monkeys were humanely euthanized.
Monkeys	3	Animals were exposed to test article for 14 days. Transient self-limiting test article effects were evident in 3 monkeys.

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B) Summary of IACUC-approved exceptions to the Standards and Regulations:

- 34 dogs were exempted from the exercise requirement for 14 days during recovery from a surgical procedure.
- 10 dogs were exempted from the exercise requirement for 6 days due to individual telemetric data collection.
- 4 dogs were exempted from the exercise requirement for 26 days during telemetric data collection.
- 12 dogs were exempted from the exercise requirement for 23 days, and 2 dogs for 5 days, due to individual telemetric data collection.

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