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: 22-R-0040
CUSTOMER NUMBER: 689

FORM APPROVED
OMB NO. 0579-0036

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, 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	3	719	109	77	905
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	6	146	3	7	156
9. Non-human Primates	128	258	76	10	344
10. Sheep					
11. Pigs	0	10	0	0	10
12. Other Farm Animals					
13. Other Animals					

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 rese 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)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL (b)(6), (b)(7)(c)

Type or Print)

DATE SIGNED 11/13/08

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

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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:

- M3 (R1): Maintenance of the ICH Guideline on Non-Clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals, 1997. Amended November 2000 (Maintenance Process), and M3 (R2) Final Concept Paper, September 2006.
- 21 CFR 312.22, Investigational New Drugs/Biologics
- International Conference on Harmonization 'Tripartite Guideline for the Detection of Toxicity to Reproduction for Medicinal Products (ICH S5A and 5SB(M))"
- International Conference on Harmonization S3A: Note for Guidance on Toxicokinetics: Assessment of Systemic Exposure in Toxicity Studies.
- International Conference on Harmonization S4: Duration of Chronic Toxicity Testing in Animals (Rodent and Non-Rodent)

Species	Number of Category E Animals	Description
Dogs	3	Animals were exposed to test article for one year. Three dogs exhibited transient test article effects consistent with a drug of this class.
Dogs	2	Animals were exposed to test compound for 6 months. Transient test article effects were evident in 2 dogs. Dose administration was suspended for affected dogs.
Dogs	1	Animals were exposed to test article for one week. One dog had signs that were not attributable to test article. This dog was humanely euthanized.
Dogs	6	Animals were exposed to test compound for 1 month. Test article effects were evident in 6 dogs. Of these, 1 dog was humanely euthanized, and dose levels were lowered for the remaining 5 dogs.
Dogs	1	Animals were exposed to test compound for 8 days. Test article effects were evident in 1 dog. This animal was initially treated, and then subsequently euthanized.
Dogs	26	Animals were exposed to test compound once every 3 days. Transient test article effects were evident in all 26 dogs. . Due to the fact that the test article had sedative properties, additional analgesia was contraindicated.
Dogs	1	Animals were exposed to test article for approximately 2 weeks. Test article effects were evident in 1 dog that was subsequently euthanized.

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Species	Number of Category E Animals	Description
Dogs	37	Animals were exposed to test article for approximately 2 weeks. Test article effects were evident in 37 dogs. Of these, 36 recovered, and 1 dog was euthanized.
Rabbits	4	Animals were exposed to test compound for approximately 14 days. Test article effects were evident in 4 animals. Affected animals were treated and recovered.
Rabbits	3	Animals were exposed to test compound for approximately 14 days. Test article effects were evident in 3 rabbits. Animals were initially treated and subsequently euthanized.
Monkeys	2	Animals were exposed to test compound intermittently for approximately 9 months. Two monkeys were euthanized due to test article effects.
Monkeys	4	Animals were exposed to test compound once every 4 days, for a maximum of four dosing cycles. Test article administration procedures were modified and dosing cycles were suspended for 4 monkeys exhibiting test article effects.
Monkeys	4	Animals were exposed to test compound intermittently for approximately 13 weeks. 4 animals were euthanized due to test article effects.

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

- 38 dogs were exempted from the exercise requirement for 14 days during recovery from a surgical procedure.
- 11 dogs were exempted from the exercise requirement for 10 days during recovery from a surgical procedure.
- 5 dogs were exempted from the exercise requirement for 5 days due to individual telemetric data collection.
- 4 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 9 days due to individual telemetric data collection.
- 4 dogs were exempted from the exercise requirement for 6 days, and 1 dog for 2 days, due to individual telemetric data collection.
- 10 dogs were exempted from the exercise requirement for 24 days during continuous infusion.
- 16 dogs were exempted from the exercise requirement for 2 days due to test article effect.
- 44 dogs were exempted from the exercise requirement for 40 days during continuous infusion.
- 14 dogs were exempted from the exercise requirement for 14 days due to individual telemetric data collection.
- 5 dogs were exempted from the exercise requirement for 7 days due to individual telemetric data collection.
- 4 dogs were exempted from the exercise requirement for 9 days, and 2 dogs for 7 days, due to individual telemetric data collection and continuous infusion.