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: 23-R-0107
CUSTOMER NUMBER: 366

FORM APPROVED
OMB NO. 0579-0036

Calvert Laboratories Inc
Scott Technology Park
100 Discovery Drive
Olyphant, PA 18447

Telephone: (570) -586-2411

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 reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	14	572	59	14	645
5. Cats	0	0	0	0	0
6. Guinea Pigs	103	729	0	2	731
7. Hamsters	0	0	0	0	0
8. Rabbits	166	784	24	22	830
9. Non-human Primates	0	253	2	0	255
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	0	0	0	0	0

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	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
(b)(6), (b)(7)(c)		20 NOV 08

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)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

NOV 21 2008

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Column E Explanation

Dogs – Two (2) animals in a subchronic toxicity test experienced emesis and decreased food consumption and were humanely euthanized. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested, thereby invalidating the data collected which would in turn require repeat testing and increase the number of animals utilized. The conduct of a subchronic toxicity study in a non-rodent species is a requirement of worldwide regulatory agencies. (1, 2, 3)
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 401)

Dogs – Four (4) animals in a subchronic toxicity test were found dead after experiencing emesis, decreased activity and lack of pupil response. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested, thereby invalidating the data collected which would in turn require repeat testing and increase the number of animals utilized. The conduct of a subchronic toxicity study in a non-rodent species is a requirement of worldwide regulatory agencies. (1, 2, 3)
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 401)

Dogs – Two (2) animals in a subchronic toxicity test experienced emesis, decreased activity and lack of pupil response and were humanely euthanized The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested thereby invalidating the data collected which in turn would require repeat testing and increase the number of animals utilized. The conduct of a subchronic toxicity study in a non-rodent species is a requirement of worldwide agencies. (1, 2, 3)
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 401)

Dogs – Two (2) animals in a subchronic toxicity test experienced hindlimb paralysis for three days. Dosing was terminated and the animals recovered. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested, thereby invalidating the data collected which would in turn require repeat testing and increase the number of animals utilized. The conduct of a subchronic toxicity study in a non-rodent species is a requirement of worldwide regulatory agencies. (1, 2, 3)
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 401)

Dogs- Two (2) animals in subchronic toxicity testing collapsed and died post dose. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested, thereby invalidating the data collected which would in turn require repeat testing and increase the number of animals utilized. The conduct of a subchronic toxicity study in a non-rodent species is a requirement of worldwide regulatory agencies. (1, 2, 3)
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 401)

Dogs – Two (2) animals a subchronic toxicity testing exhibited seizures and were humanely euthanized. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested thereby invalidating the data collected which in turn would require repeat testing and increase the number of animals utilized. The conduct of a subchronic toxicity study in a non-rodent species is a requirement of worldwide regulatory agencies. (1, 2, 3)
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 401)

Guinea Pig – One animal used in a skin toxicity test was found dead with discolored fur around facial area and teeth clinched to cage. .
(Per Organization for Economic Co-Operation and Development OECD) Guideline 404)

Guinea Pig – One animal used in a skin toxicity test experienced convulsions, prostration and was humanely euthanized. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested thereby invalidating the data collected which in turn would require repeat testing and increase the number of animals utilized.
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 404)

Rabbits – Thirteen (13) animals used in acute eye irritation/corrosion testing experienced corneal irritation. Dosing was terminated and the animals recovered. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested thereby invalidating the data collected which in turn would require repeat testing and increase the number of animals utilized.
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 405)

Rabbits – Eight (8) animals used in skin toxicity testing experienced skin irritation. Dosing was terminated and the animals recovered. The use of pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested, thereby invalidating the data collected which in turn would require repeat testing and increase the number of animals utilized.
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 404)

Rabbit – One (1) animal used in subchronic toxicity testing developed an open sore that the animal appeared to be grooming. The area was treated with "Chew Guard" and resolved. The use of Pharmaceuticals to alleviate pain or distress may have interfered with the compound being tested, thereby invalidating the data collected which in turn would require repeat testing and increase the number of animals utilized
(Per Organization for Economic Co-Operation and Development (OECD) Guideline 401

REFERENCES:

1. Gad, Shayne c. (ed.). (1995). *Safety Assessment for Pharmaceuticals*. Van Nostrand Reinhold, New York. Pp.111-128.
2) Speid, L.H., Lumley, C.E. and Walker, S.R. (1990). Harmonization of Guidelines for Toxicity Testing of Pharmaceuticals. *Regulatory Toxicology and Pharmacology*, 12: 179-211.
3) Study conducted under GLPs for FDA/OECD preclinical drug development and submission to regulatory agencies.

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Exercise Exemptions – Dog

Seven (7) dogs were exempted from exercise for 45 days each to allow for recovery from surgery to install telemetry implants.

Two (2) dogs were exempted from exercise for three days each due to hindlimb lameness.

One (1) dog was exempted from exercise for three days due to foreleg lameness.

Pair Housing Exemptions – Primate

Three (3) primates were exempted from pair housing for 365 days each due to their aggressive nature and resultant incompatibility.

Two (2) primates were exempted from pair housing for 99 days each due to their aggressive nature and resultant incompatibility.

One (1) primate was exempted from pair housing for 157 days due it its aggressive nature and resultant incompatibility.

Seven (7) primates were exempted from pair housing for 14 days each due to an uneven number of animals assigned to each dose group on study.

One (1) primate was exempted from pair housing for 35 days due to an uneven number of animals assigned to a study.