SH

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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: 23-R-0012

Customer Number: 286

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

Glaxo Smith Kline
709 Swedeland Road, P.O. Box 1539
King Of Prussia, PA 19406

Telephone: (610) 270 4800

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	0	354	497	10	861
5. Cats	0	0	0	0	0
6. Guinea Pigs	273	245	1775	0	2020
7. Hamsters	0	231	51	0	282
8. Rabbits	22	1405	333	0	1738
9. Non-human Primates	111	268	323	5	596
10. Sheep	0	0	0	0	
11. Pigs	0	0	0	0	
12. Other Farm Animals	0	0	0	0	
13. Other Animals					
Ferrets	2	0	0	170	170

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 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.

4.) 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 (I.O.))

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

DATE SIGNED
25 Nov-09

NF 12/18/2009

DEC 01 2009

APHIS Form 7023 Site List

The following sites have been reported by the facility.

Registration Number:	23-R-0012
Customer Number:	286
Facility:	GlaxoSmithKline 709 Swedeland Road P.O. Box 1539 King of Prussia, PA 19406-0939 (610)270-4800

(b)(2)High, (b)(7)f

TO:

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

SUBJECT: ***Animal Care Regulations and Standards***

DATE: *17-Nov-2009*

During the period from October 1, 2008 to September 30, 2009 there were no exceptions to the regulations or standards identified by the IACUC at our sites in (b)(2)High, (b)(7)f This includes having no exceptions to our exercise plan and all nonhuman primates participated in the environmental enrichment program.

TO:

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

SUBJECT: ***Animal Care Regulations and Standards***

DATE: ***18-Nov-2009***

During the period from October 1, 2008 to September 30, 2009 there were no exceptions to the regulations or standards identified by the IACUC at our site in (b)(2)High, (b)(7)f This includes having no exceptions to our exercise plan and all nonhuman primates participated in the environmental enrichment program.

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

Explanation of Animals Listed in Column E
2008-2009 USDA Annual Report for Registration Number 23-R-0012

Ferrets

One hundred one (170) ferrets are listed in Column E.

Studies for development of novel [redacted] compounds for the treatment of [redacted]

One hundred seventy (170) ferrets were involved in studies to evaluate novel [redacted] compounds. Animals were given a proposed new [redacted] compound then given a known agent that causes [redacted] and closely monitored. The ferrets exhibited [redacted] during a 6 or 72 hour period and were euthanized shortly after the end of the study. Known [redacted] analgesics were not given because of interference with study results.

Dogs

Ten (10) dogs are listed in Column E.

GLP Toxicology Study

Ten dogs exhibiting decreased food consumption, vomiting and/or abnormal feces were part of a Safety Assessment study that was conducted in accordance with US Food and Drug Administration Good Laboratory Practice for Non-clinical Laboratory Studies, 21 CRF Part 58. The animals were in the high dose group of a planned 28 day GLP toxicology study investigating a new anti-cancer agent and given adjunct treatment with canned food. One dog also showed additional clinical signs including lethargy, dehydration and a slightly elevated temperature. She was given fluid therapy. Although this animal showed some improvement initially, her condition regressed and she was euthanized. Subsequently, some of the other dogs showed progression of clinical signs and the decision was made to euthanize the other nine animals in the high dose group. Administration of analgesics or anti-inflammatory agents would have interfered with the documentation of the disease process for drug safety assessment.

Nonhuman primates

Five (5) nonhuman primates are listed in Column E.

GLP Toxicity Study

Five high dose animals showing abnormal clinical signs were part of a Safety Assessment study that was conducted in accordance with US Food and Drug Administration Good Laboratory Practice for Non-clinical Laboratory Studies, 21 CRF Part 58. One animal exhibited decreased food intake and intermittent unsteadiness. The animal was found dead unexpectedly. Another animal then began to exhibit decreased activity and subdued behavior. Clinical signs rapidly became more pronounced during serial blood collection needed for toxicokinetics and euthanasia was recommended. The animal died while it was being taken to be euthanized. Three other animals in the high dose group on this study showed slight trembling. Although the three animals were bright, active and alert, they were euthanized because of the progression of clinical signs seen in the other high dose animals. Administration of additional therapy with anesthetics, analgesics or sedatives would have interfered with the documentation of the disease process for drug safety assessment.