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-0012
CUSTOMER NUMBER: 286

FORM APPROVED
OMB NO. 0579-0036

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, 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	7	502	542	49	1093
5. Cats	2	0	19	0	19
6. Guinea Pigs	188	430	1438	0	1868
7. Hamsters	0	179	57	0	236
8. Rabbits	11	690	898	48	1636
9. Non-human Primates	117	271	514	0	785
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					
Ferrets	2	2	0	101	103

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)

[redacted]

DATE SIGNED
Nov 24, 2008

(AUG 91)

NP

NOV 25 2008

Explanation of Animals Listed in Column E
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Ferrets
One hundred one (101) ferrets are listed in Column E.

Studies for development of novel anti-emetic compounds for the treatment of chemotherapy induced emesis
One hundred one (101) ferrets were involved in studies to evaluate novel anti-emetic compounds. Animals were given a proposed new anti-emetic compound then given a known agent that causes vomiting and closely monitored. The ferrets exhibited intermittent emesis during a 6 or 72 hour period and were euthanized shortly after the end of the study. Known anti-emetic compounds or analgesics were not given because of interference with study results.

Dogs
Forty nine (49) dogs are listed in Column E.

Osteoarthritis Study
Twenty two (22) dogs were assigned to an osteoarthritis study. Dogs on study underwent intra-articular sampling and injection while under anesthesia. Some of the dogs exhibited lameness after the procedure but usually for only a few hours. No pain relieving drugs could be given because the drugs affect cytokine production and/or inflammation that would interfere with interpretation of data.

GLP Toxicology Study
One (1) dog was 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. This animal was part of a 28 day GLP toxicology study investigating a new anti-cancer agent. Near the end of the study the dog was reported to be lethargic. A physical exam revealed mild lameness of the left rear leg and a slightly elevated body temperature. Later in the day clinical signs progressed and the dog was euthanized. Administration of analgesics or anti-inflammatory agents would have interfered with the documentation of the disease process for drug safety assessment.

GLP Toxicity Study

Twenty (20) dogs 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 dogs were used in a 4 week toxicology study to evaluate toxicity of a novel anti-cancer drug. Dogs placed in the high and mid-dose groups developed intermittent emesis and abnormal fecal consistency. Some of these dogs had reduced food intake, weight loss and/or lethargy and were provided with alternative feeding regimens. A few dogs developed oral ulcers and/or became febrile and were euthanized prior to the scheduled end of the study. Administration of additional therapy such as anti-emetics or analgesics would have interfered with the documentation of the disease process for drug safety assessment.

GLP Toxicology Study

Three (3) dogs 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 dogs were used in a 14 day toxicology study to evaluate a new chemical entity. Three dogs in the high dose group developed clinical signs including emesis, decreased food intake, abnormal feces and/or dehydration. Some of the dogs were given supportive therapy. All the dogs were euthanized prior to the scheduled end of the study. Administration of additional therapy such as anti-emetics or analgesics would have interfered with the documentation of the disease process for drug safety assessment.

GLP Toxicology Study

Three (3) dogs 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 dogs were used in a 7 day dose range study for a new drug and developed clinical signs including emesis, dehydration and abnormal feces. They were given supportive treatment including supplemental feeding and/or fluids. All the dogs were euthanized prior to the scheduled end of the study. Administration of additional therapy such as anti-emetics or analgesics would have interfered with the documentation of the disease process for drug safety assessment.

Addendum to Explanation of Animals Listed in Column E
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Rabbits
Forty eight (48) rabbits are listed in Column E.

Osteoarthritis study
Forty eight (48) rabbits were assigned to an osteoarthritis study. Rabbits on study underwent intra-articular sampling and injection while under anesthesia. No lameness was noted in the rabbits at any time during the study. No pain relieving drugs could be given because the drugs affect cytokine production and/or inflammation that would interfere with interpretation of data.