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!

NOV 2 8 2008

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-0030
CUSTOMER NUMBER: 178

FORM APPROVED
OMB NO. 0579-0036

Merck & Company Inc
126 E Lincoln Avenue
Po Box 2000 Ry80m-101
Rahway, NJ 07065

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

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	175	970	1052	28	2050
5. Cats	0	0	0	0	0
6. Guinea Pigs	173	789	424	449	1662
7. Hamsters	177	14	521	190	725
8. Rabbits	372	1087	1993	18	3098
9. Non-human Primates	4573	278	1009	6	1293
10. Sheep	0	0	0	0	0
11. Pigs	0	17	0	0	17
12. Other Farm Animals Goats	10	0	0	0	0
Horses	17	2	0	0	2
13. Other Animals					
Cotton Rats	8	204	0	0	204
Ferrets	34	0	26	0	26
Gerbils	70	2	160	0	162

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 ~~CEO~~ OR INSTITUTIONAL OFFICIAL | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL | DATE SIGNED

(b)(6), (b)(7)(c) | (b)(6), (b)(7)(c) | 11/26/08

23 (OCT 88), which is obsolete.)

(AUG 91)

NP

Registration number 22-R-0030, December 1, 2008

A Summary of exceptions to the regulations and standards:

One exception to the canine exercise program is to be reported. Eight dogs used in radioisotope labeled drug metabolism studies have been housed in special canine metabolism kennels in order to ensure safe and accurate collection of excreta for metabolite analysis. The housing provides 100% of the required floor space, but less than the required space for exercise. The period of time in this housing varies with the test compound, study and excretion rates. The studies lasted between 4-18 days, with an average of a little over 7 days. Positive human interaction has been greatly increased during this period. The protocol for these studies, which includes this exception, was approved by the IACUC.

B) General Column 'E" Justification Statement

One hundred and ninety hamsters developed acute terminal complications or were humanely euthanized on IACUC approved study to determine the (b)(4) (b)(4) of novel (b)(4) against a specific (b)(4) The use of pain relief and supportive care alter the results of study so they can not be used. The animals are closely monitored and those animals with significant health issues were humanely euthanized.

Twenty-seven guinea pigs experienced lethargy, ruffled fur and decreased appetite for 24-72 hours after IP injection of a compound for an IACUC approved procedure (General Safety Test, as described in 21 CFR 610.11). This is a general safety test required for release of a biologic product and administration of analgesic agents would compromise evaluation of the test results. The guinea pigs were monitored closely to see if the clinical signs would resolve. The expected clinical signs resolved within the 24-72 hour time period.

Four hundred and eight guinea pigs are infected with a virus and develop clinical signs of infections. The studies are for the development of vaccines against this infectious agent. The signs can range from minor to severe. The animals are all closely monitored and those that develop severe complications are humanely euthanized. Analgesics are not used because they have a profound affect on the outcomes of the studies.

Fourteen guinea pigs were part of several studies examining (b)(4) to (b)(4) Blood was collected under general anesthesia using the (b)(4) (b)(4) The serum was examined to determine (b)(4) and in some cases, functional *in-vitro* assays. The technique is only performed by trained veterinary technicians. Subsequent to this procedure and after the effects of procedure-related anesthesia had worn off, sudden death appeared to have occurred in the absence of signs. Only a very small percentage of these

procedures were associated with this complication and the death is usually due to internal hemorrhage often inducing cardiac tamponade. Due to the lack of signs and sudden death, analgesics could not be administered.

Two rabbits developed acute terminal complications while on IACUC approved developmental toxicity study. The unexpectedly acute nature of the event made medical intervention not possible. The design of this study is based on requirements of worldwide regulatory agencies [ICH S5(R2) also published in Federal Register, Vol. 58, No. 183, Sept 22, 1994, pg 48746-48752]. All animals are observed frequently and animals that are moribund or that display physical signs indicating pain or significant medical issues are humanely euthanized.

Sixteen rabbits developed acute terminal complications while on IACUC approved (b)(4) is needed to induce an (b)(4) may lead to a significant medical condition. Animals that appear to be developing such medical conditions are humanely euthanized, however in some cases the only signs may be very acute. The adverse events were related to (b)(4) conditions and analgesics treatment was not medically appropriate.

Fourteen dogs and 4 Rhesus non-human primates on an IACUC approved study developed significant medical complications. The studies examine if there are toxicities associated with test compounds as well as their toxicokinetic profiles. The studies were conducted in accordance to FDA regulations as published in the Federal Register Vol. 59 No183, September 1994 pages 48746 to 48752 and ICH guidance documents S4A and S3A. The animals were closely monitored during the study by veterinary and research staff. Medical intervention would have confounded the study data so instead the eleven dogs were humanely euthanized based on predetermined end-points of weight loss. Three dogs and four Rhesus developed acute terminal complications. Extensive post mortem analysis was preformed to determine the effects of novel compounds.

Fourteen dogs on an IACUC approved (b)(4) (b)(4) minor gastro-intestinal tract disturbances (diarrhea and occasional vomiting). The dogs were examined by the veterinary staff and analgesics were not administered due to transitory nature of condition, which soon resolved. The unexpected side effects appear to be related to a class of study compounds and lowering the test doses addressed the condition for future studies.

Two cynomolgus non-human primates developed acute terminal complication while on an IACUC approved (b)(4) (b)(4) The acuteness of the event did not allow time for medical intervention. The studies were conducted to support preparation of Investigational New Drug applications as required by the United States Food and Drug Administration Regulations (21 CFR 312.33).