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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: 22-R-0030

Customer Number: 178

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

Merck & Company Inc
126 E Lincoln Avenue
Po Box 2000 [redacted] (b)(2)High, (b)(7)f
Rahway, NJ 07065

Telephone: (908) 423 1000

NOV 27 2009

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

See Attached

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	129	1294	1072	28	2,394
5. Cats	0	0	0	0	0
6. Guinea Pigs	37	595	1015	278	1888
7. Hamsters	123	635	556	298	1489
8. Rabbits	361	866	1011	36	1913
9. Non-human Primates	4789	937	442	2	1381
10. Sheep	0	0	0	0	0
11. Pigs	0	8	0	0	8
12. Other Farm Animals	—	—	—	—	—
Goats	1	12	0	0	12
13. Other Animals Ferrets	0	0	3	0	3
Horses	6	10	0	0	10
Gerbils	65	0	87	0	87
Cotton Rats	4	29	1126	0	1155

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.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

SIGNATURE OF C.E.O. OR I.O. | NAME AND TITLE OF C.E.O. OR I.O. (Type or Print) | DATE SIGNED

[redacted] (b)(6), (b)(7)c | 11/25/09

APHIS FORM 7023
AUG 2009

NP 12-7-09
NP 12/15/09

Merck & Co., Inc. Site Addresses
Certificate No. 22-R-0030
For USDA reporting year Oct 2008- Sept 2009

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

Registration number 22-R-0030, December 1, 2009

A Summary of exceptions to the regulations and standards:

Two exceptions to the canine exercise program are reported in this summary as follows: One dog was involved in a [redacted] study and was housed in special canine [redacted] kennels in order to ensure safe and accurate collection of excreta [redacted] The housing provided 100% of the required floor space, but less than the required space for exercise. The study lasted approximately 15 days. The second exercise program exemption was for housing of the canine in a unit that provided 100% of the required floor space, but less than the required space for exercise. The second exercise program exemption was for housing of the canine in a unit that provided 100% of the required floor space, but less than the required space for exercise. The model required reduced activity during the [redacted] The animal had unencumbered movement in the housing unit during the event that involved one dog for 7 days. Positive human interaction was greatly increased during this period. The protocols for this study, which includes these exceptions, were approved by the IACUC and were followed by the study personnel.

Two exceptions reported in this summary are related studies that required extended time periods in the same housing unit beyond the standard two weeks for complete sanitization. Please note that normal daily cleaning and sanitization did occur. One study, involving 23 dogs, required [redacted] that required that they stay in their kennel for up to 3-4 weeks. The kennel size was greater or equal to 200% of their required space. The other study involved 36 rhesus non-human primates on a sleep study and their cages were instrumented with [redacted] monitoring devices as well as interactive touch screens for cognitive testing for the rhesus. The studies took a minimum of 2-3 weeks and additional days were needed to affix and then remove the [redacted] devices and screens from the cages before the cages could be changed.

B) General Column 'E" Justification Statement

Two hundred and sixty-nine hamsters developed acute terminal complications or were humanely euthanized in an IACUC-approved study to determine the protective effect of [redacted] The use of pain relief and supportive care would alter the results of study, therefore they

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were not used. The animals are closely monitored and those animals with significant health issues were humanely euthanized.

Twenty-nine hamsters on an IACUC-approved study of a developed significant and unexpected clinical signs following administration of an experimental compound. The clinical event was acute. The hamsters were either humanely euthanized or expired on study. The suddenness and severity of illness did not allow time for consideration of medical intervention.

Two hundred and seventy-two guinea pigs were The studies are for the The signs can range from . 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.

Six guinea pigs that were part of several studies examining expired. Blood was collected The serum was examined to 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 was usually due to internal hemorrhage often inducing cardiac tamponade. Due to the lack of signs and sudden death, no medical intervention could not be administered.

Nine rabbits developed acute terminal renal complications on an IACUC-approved study that involved the The were lowered and no further problems were noted in other rabbits. The acute nature of illness prevented any medical intervention.

Ten rabbits developed acute terminal complications while in an IACUC-approved study. The unexpectedly acute nature of the event made medical intervention not possible. All animals are observed frequently and animals that are moribund or that display physical signs indicating pain or significant medical issues are humanely euthanized.

Seventeen rabbits developed acute terminal complications while in IACUC-approved A is needed to induce an but in a few cases the may lead to a significant Animals that appear to be developing such medical conditions are humanely euthanized; however in some cases their no clinical signs before sudden death. The adverse events were related to

and analgesics treatment was not medically appropriate. [redacted] long term studies to be better tolerated.

Twenty-seven dogs and one Rhesus non-human primate in IACUC-approved studies developed significant medical complications. The studies examined if there are [redacted] with test compounds as well as their [redacted] The studies were conducted in accordance with FDA regulations as published in the [redacted] The animals were closely monitored during the study by veterinary and research staff. Medical intervention would have confounded the study data, and the twenty dogs were humanely euthanized based on predetermined end-points [redacted] Seven dogs and 1 rhesus developed acute terminal complications before intervention with euthanasia could occur.

One Rhesus non-human primate developed an [redacted] Please note that prior to this study, the compound did not appear to have [redacted] issues in various in-vitro assays. Pain medications were withheld for the complete analysis including possible reversibility of the event without interference. [redacted] Studies and is approved by the IACUC.

One canine on an IACUC approved study for exploring new methods of treating [redacted] was found during a health check to have developed malaise and [redacted] The [redacted] was not reversible and the canine was humanely euthanized based on end point criteria established in the protocol.