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

1. CERTIFICATE NUMBER: 21-R-0088
CUSTOMER NUMBER: 339

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Pfizer Global Research & Development
Central Research Division
235 East 42nd Street
New York New York, NY 10017

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

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 tranquilliz 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		1503	580	382	2465
5. Cats		579	142	151	872
6. Guinea Pigs	97	4429	2248	1277	7954
7. Hamsters	220	28688	168	4631	33487
8. Rabbits	240	1176	5023	46	6245
9. Non-human Primates		776	51	7	834
10. Sheep		0	0	0	0
11. Pigs		188	40	0	228
12. Other Farm Animals					
Horses		45	0	20	65
13. Other Animals					
Ferrets		16	24	22	62
Gerbils		547	0	41	588

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		19 Nov 08

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)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

NOV 2 0 2008

USDA Annual Report of Research Facility - 2008
USDA APHIS Form 7023
Facility Locations
Registration Number: 21-R-0088
Customer Number: 339

Facility: Pfizer Global Research & Development
Mailstop - GRT - MS 8118-B3
235 East 42nd Street
New York, NY 10017

All redactions on this page are pursuant to (b)(2)high, (b)(7)f

Pfizer Global Research and Development [redacted]	[redacted]
Pfizer Global Research and Development [redacted]	[redacted]
Pfizer Global Research and Development [redacted]	

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

Attachment 1

Summary of IACUC Approved Exceptions Permitted by the Standards and Regulations For the 2007-2008 Annual Report of Research Facility, #21-R-0088 Pfizer Global Research and Development Groton, CT; La Jolla, CA; St. Louis, MO Veterinary Medicine R&D – Kalamazoo, MI Pfizer Global Manufacturing - Lincoln, NE Revised February 20, 2009

Pain/Distress Exceptions

Each of the following Animal Care and Use Procedures (ACUP) involved studies in which animals could have experienced pain and/or distress. The test substances being evaluated are novel compounds; consequently, data on how these compounds react in the animal model and with other chemical entities is very limited or non-existent. Therefore, the use of analgesics or other pain-relieving agents could defeat the objectives of the research by directly interfering with the end point parameter being measured. This interference could give results that are not reliable which would lead to repeating the studies, thus requiring the need to use more animals. For this reason, the Institutional Animal Care and Use Committees (IACUC) granted an exception for each. Any incident of pain or distress was limited in duration to that scientifically necessary, and in each exception noted below, the absolute minimum number of animals was used. Where euthanasia was required, it was conducted in a manner approved by the IACUC for the particular study. In actual practice, many animals involved in such studies were not observed by the investigator to experience pain and/or distress.

Species: **Dogs**

A. The study objective was to assess safety/toxicity evaluations, the results of which will be used to support registration of Pfizer proprietary compounds. Studies to characterize the toxicity of new pharmaceuticals are required in non-rodent species by all regulatory agencies that review and approve new human medications, and alternative methodologies alone are not sufficient. In a safety evaluation, administration of analgesics is not possible as analgesics may alter the animals' response to the test compound or otherwise confuse interpretation of the study, which would result in a need to repeat studies, using additional animals. However, other nursing and supportive care is provided by the veterinary staff, as approved by the IACUC for this study. Sixty-three (63) dogs showed signs of pain and/or distress based on investigator observations.

B. The study objective was to assess the [redacted] and [redacted] Sixty-three (63) dogs experienced varying degrees of pain/lameness during conduct of these studies. In this model, administration of [redacted] other than those being tested) is not possible during the testing regimen, as they may alter the animal's response to the test compound. However, these agents, as well as other nursing and supportive care, are provided post-procedurally by the veterinary staff, as approved by the IACUC for this study.

C. The study objective was to evaluate the efficacy of novel therapeutic compounds using a [redacted]. One hundred and five (105) dogs were used. Dogs developed clinical signs associated with [redacted] All 58 vaccinated animals had localized swelling at the injection site. This experimentally induced condition was necessary to provide an accurate model in which to test compounds designed to provide therapeutic benefit. Administration of [redacted] could alter the animals' response to the test compounds or otherwise confuse interpretation of the study, which would result in a need to repeat studies, using additional animals. The potential for confused interpretation is particularly a concern in infectious disease studies, where masking of clinical signs with pain relievers or anti-inflammatory drugs may provide false information on test article efficacy. However, in these situations, other supportive and nursing care is provided as indicated.

D. The study objective was to evaluate the efficacy of novel [redacted] One hundred forty-two (142) dogs were used. Dogs experienced [redacted] following [redacted] This experimentally induced condition was necessary to provide an accurate model in which to test compounds designed to provide therapeutic benefit. Administration of analgesic drugs could alter the animals'

response to the test compounds or otherwise confuse interpretation of the study, which would result in a need to repeat studies, using additional animals. The potential for confused interpretation is particularly a concern in infectious disease studies, where masking of clinical signs with pain relievers or anti-inflammatory drugs may provide false information on test article efficacy. However, in these situations, other supportive and nursing care is provided as indicated.

E. The study objective was to model t One (1) dog developed lameness. The lameness was intermittent and present for a few days, but at times the animal was not weight bearing. In this model, administration of analgesics is not possible during the testing regimen, as they may alter the animal's response to the test compound. This experimentally induced condition was necessary to provide an accurate model in which to test compounds designed to provide therapeutic benefit. Administration of analgesic drugs could alter the animals' response to the test compounds or otherwise confuse interpretation of the study, which would result in a need to repeat studies, using additional animals. The potential for confused interpretation is particularly a concern in studies, where may provide false information on test article efficacy. However, in these situations, other supportive and nursing care is provided as indicated.

F. The study objective was to determine the against in dogs and to confirm the other fractions do not interfere with Because the is , the test amounts to a minimum protective endpoint determination for the product being tested. Post challenge efficacy is demonstrated by significantly lowering the incidence of associated illness and reducing the incidence of in dogs. Demonstration of these signs is necessary to evaluate the minimum protective level of the test product. Efficacy must be demonstrated before a can be licensed. Humane endpoint intervention is now allowed when animals are observed to be moribund. Eight (8) dogs were removed from the study and euthanized as soon as it was determined they could not survive. Development of clinical signs would likely be impacted by the use of antibiotics, analgesics or anti-inflammatory drugs, although the exact effects are not known. Use of drugs, therefore, is expected to invalidate the scientific value of the protection endpoint. For this reason drugs are not administered to reduce pain or distress

Species: **Cats**

G. The study objective was to assess the . Eighteen (18) cats experienced varying degrees of pain/lameness during conduct of these studies. In this model, administration of (other than those being tested) is not possible during the testing regimen, as they may alter the animal's response to the test compound. However, these agents, as well as other nursing and supportive care, are provided post-procedurally by the veterinary staff, as approved by the IACUC for this study.

H. The study objective was to evaluate the efficacy of novel therapeutic compounds in a various models of o evaluate . One hundred thirty-three (133) cats were used. Reactions in these animals ranged as a result of intentional viral challenge. These experimentally induced conditions were necessary to provide accurate models in which to test compounds designed to provide therapeutic benefit. The potential for confused interpretation is particularly a concern in infectious disease studies, where masking of clinical signs with pain relievers or anti-inflammatory drugs may provide false information on test article efficacy. However, in these situations, other supportive and nursing care is provided as indicated.

Species: **Guinea Pigs**

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

Attachment 1

Summary of IACUC Approved Exceptions Permitted by the Standards and Regulations
For the 2007-2008 Annual Report of Research Facility, #21-R-0088
Pfizer Global Research and Development
Groton, CT; La Jolla, CA; St. Louis, MO
Veterinary Medical R&D – Kalamazoo, MI
Pfizer Global Manufacturing - Lincoln, NE

I. The study objective was to determine the potency of [redacted] in guinea pigs as outlined in code of Federal Regulations (CFR) [redacted] The tests are required as proof of [redacted] in each serial of vaccine produced. Death in this test has been used for many years to indicate lack of protection from [redacted] The rapid progression of the disease in the guinea pig makes intervention before death difficult. [redacted] causes [redacted] that can lead to open skin sores, lameness and death. Humane endpoint intervention is now allowed and one hundred and seventeen (117) guinea pigs were removed from studies and euthanized as soon as it was determined they could not survive. However, three hundred and twenty-three (323) animals died during the study. Survival would likely be impacted by the use of antibiotics, analgesics or anti-inflammatory drugs, although the exact effects are not known. Use of drugs, therefore, is expected to invalidate the scientific value of the protection endpoint. For this reason drugs are not administered to reduce pain or distress.

J. The study objective was to assess the efficacy of experimental compounds in a short-term model of inflammation. Eight hundred and thirty-seven (837) guinea pigs experienced localized inflammation during the conduct of these studies. In this model, administration of analgesics is not possible during the testing regimen, as they may alter the animal's response to the test compound.

Species: **Hamsters**

K. The study objective was to determine the potency of [redacted] in hamsters as outlined in [redacted] and as written in special outlines of production for certain vaccines to show protection for [redacted] The tests are required by regulation as proof of [redacted] potency in each serial of vaccine produced. Because the vaccine is given in a fractional dose, the test amounts to a protective endpoint determination for the vaccine being tested. Death in this test has been used for many years, and continues to be the regulatory standard required to indicate lack of protection from [redacted] generally causes peracute death in hamsters, which are very sensitive to these organisms, making intervention before death difficult. Humane endpoint intervention is now allowed when animals are observed to be moribund. One thousand four hundred and thirty-five (1435) hamsters were removed from the studies and euthanized as soon as it was determined they could not survive. However, three thousand one hundred ninety-six (3196) died during the study. Survival would likely be impacted by the use of antibiotics, analgesics or anti-inflammatory drugs, although the exact effects are not known. Use of drugs, therefore, is expected to invalidate the scientific value of the protection endpoint. For this reason, neither Pfizer INC nor USDA/CVB-L used any substance to reduce pain or distress.

Species: **Rabbits**

L. The study objective was to assess the potential [redacted] to support registration of Pfizer proprietary compounds. Twenty-two (22) rabbits showed variable signs of pain/distress and were humanely euthanized at the earliest opportunity.

M. The study objective was to assess the potential toxicity of various test compounds in the rabbit model, to support registration of Pfizer proprietary compounds. Twenty-four (24) rabbits were used on the study. Pain or distress was due to (1) complications due to implantation of device into vitreous of eye or (2) unexpected adverse events. Pain relieving agents were not provided due to the investigative nature of the study (study purpose was to document toxic effects of the treatment).

Species: **Nonhuman Primates**

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Summary of IACUC Approved Exceptions Permitted by the Standards and Regulations
For the 2007-2008 Annual Report of Research Facility, #21-R-0088
Pfizer Global Research and Development
Groton, CT; La Jolla, CA; St. Louis, MO
Veterinary Medical R&D – Kalamazoo, MI
Pfizer Global Manufacturing - Lincoln, NE

N. The study objective was to assess the potential toxicity of various test compounds in the [redacted] to support registration of Pfizer proprietary compounds. Six (6) animals experienced treatment-related systemic toxic effects that were potentially painful/distressful. One (1) animal died as a result of a gavage error.

Other Animals

Species: Ferrets

O. The study objective was to discover potential therapeutic agents for the treatment and/or prevention of [redacted] by testing newly synthesized, novel compounds for [redacted] Twenty two (22) animals experienced [redacted] based on investigator observations and received no intervention.

Species: Gerbils

P. The study objective was to discover and develop therapeutic agents for the prevention or treatment of a [redacted], specifically, to evaluate the [redacted] of new or known compounds against [redacted] Forty-one (41) animals showed signs of pain and /or distress based on investigator observations and were euthanatized.

Species: Horses

Q. The study objective was to use a [redacted] Twenty (20) horses were used. This product is currently the treatment of choice for [redacted] and is also an important [redacted] The procedure involves the use of [redacted] as part of an [redacted] as required in the outline of manufacture. These horses experienced a superficial reaction to the [redacted] administered. Appropriate nursing and supportive care was provided as indicated, but the product license does not permit any deviation from the outline of manufacture during the course of the protocol, including the administration of analgesics.

Attachment 1

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Pfizer Global Research and Development
Groton, CT; La Jolla, CA; St. Louis, MO
Veterinary Medical R&D – Kalamazoo, MI
Pfizer Global Manufacturing - Lincoln, NE

EXCEPTIONS TO STANDARDS

1. The IACUC has approved an exemption such that cat enclosures are not cleaned and sanitized every two weeks. This involved 222 cats during this reporting period, under three animal use protocols. These cats were on studies involving vaccination followed by challenge with [redacted] Because of the risk of contaminating other rooms if the cats were moved during sanitization, the rooms were only sanitized between studies. Granting an exception from the two-week sanitization schedule had little effect on the living conditions of the animals. The rooms and runs were washed down each day, all accessories were removed and replaced biweekly with sanitized items, and the veterinary staff monitored the living conditions.

2. The IACUC has approved a similar exemption under a protocol involving dogs. In this protocol, the sanitization period may be extended from 14 days to 22 days. This is to ensure that no cross-contamination occurs between treatment groups challenged with an infectious virus, as well as to minimize stress involved in moving animals that have been recently challenged. If cross contamination occurred, the study integrity could be compromised and the study could need to be repeated, which would require the use of additional animals. The critical period is the time following the challenge dose, after this time, sanitization will proceed as usual. This involved 193 dogs during this reporting period. Pens were washed down each day, the veterinary staff monitored the living conditions, and there was felt to be minimal impact on overall animal health.

EXEMPTIONS FROM EXERCISE OR ENRICHMENT PLAN BY PROTOCOL

1. Under one protocol, dogs were occasionally housed in stainless steel metabolism cages for the collection of urine and/or feces (providing at least 1X space) for pharmacokinetic and drug metabolism studies involving [redacted], necessitating limited exemptions from the enrichment plans for these species. This impacted thirteen (13) dogs for 30 days. They did have access to manipulanda, but not exercise outside of the cage during this time, due to the need for total urine collection and/or the collection of radioactive excreta.

NONHUMAN PRIMATE EXEMPTIONS FROM PAIR HOUSING/ENVIRONMENTAL ENRICHMENT

1. Sixty-six (66) Cynomolgus monkeys were exempted from pair housing, either permanently due to aggressive behavior towards cage mates, or temporarily, due to unavailable primate for pair housing. Monkeys did have visual and auditory contact with other monkeys and were provided all other enrichment opportunities.

2. Fifty-six (56) Cynomolgus monkeys were housed individually during [redacted] studies. Single housing was necessary because the receivers could only track one animal at a time. However, in non-study periods, the animals were pair housed unless the animals were incompatible with other primates due to aggressive behavior.

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

Attachment 2

Explanation for Animals Listed in Category E - APHIS Form 7023
For the 2007-2008 Annual Report of Research Facility, #21-R-0088
Pfizer Global Research and Development
Groton, CT; La Jolla, CA; St. Louis, MO
Veterinary Medicine R&D – Kalamazoo, MI
Pfizer Global Manufacturing - Lincoln, NE

Testing of proprietary compounds is conducted in animals to discover new human therapeutics and in response to federal regulatory requirements for safety evaluation of pharmaceuticals prior to human clinical trials. There are similar requirements prior to clinical trials of animal health products in food animals and companion animals. On occasion, the proprietary compounds cause unexpected pain or distress which cannot be foreseen, but which is nevertheless considered during the IACUC's review/approval process as stated in Attachment 1. Frequently, the use of pain relieving drugs is not scientifically appropriate in product safety assessment.

These studies are designed in accordance with the safety testing guidelines described in the following publications:

1. Code of Federal Regulations (CFR, 2002), Title 21, Chapter I, Part 58 (Good Laboratory Practices for Nonclinical Laboratory Studies).
2. Code of Federal Regulations (CFR, 2004) Title 9, Chapter 1, Part 113.106, Clostridium Chauvoei Bacterin & Part 113.107, Clostridium Haemolyticum Bacterin.
3. Code of Federal Regulations (CFR, 2004) Title 9, Chapter 1, Part 113.101, Leptospira Pomona Bacterin; Part 113.102, Leptospira Icterohaemorrhagiae Bacterin; 113.103, Leptospira Canicola Bacterin & 113.104, Leptospira Grippotyphosa Bacterin.
4. Code of Federal Regulations – (CFR 511 - New Animal Drugs for Investigational Use), (CFR 514 - New Animal Drug Applications)

There are also occasions when pain-relieving drugs cannot be used in drug discovery studies. In the following cases, pain-relieving drugs were not used because they would have adversely affected the scientific validity of the study. Any incident of pain or distress was limited in duration to that scientifically necessary. The numbers provided below reflect animals that experienced unrelieved pain and/or distress and were identified in the ACUP exceptions described in Attachment 1.

Also identified below with *, are animals that experienced pain/distress due to an unexpected compound or procedure reaction.

** Removed From Study (RFS)
** Remained on Study (ROS) but received nursing/supportive care (i.e. fluids, special diets, or other non-chemical interventions)

Species	Incident	Number Affected	IACUC Approved Exceptions (see Attachment 1)	Safety Guidelines as Described in Publications Listed Above	Unexpected Pain/Distress Resolution/Action
Dogs	[redacted]	63	A ROS	1	
Dog		63	B and E ROS	4	
Dogs		247	C and D ROS – 244 RFS – euthanatized 3	4	
Dogs		8	F RFS – Euthanatized	3	
Dog		1			Died

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Attachment 2

Explanation for Animals Listed in Category E - APHIS Form 7023
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Pfizer Global Research and Development
Groton, CT; La Jolla, CA; St. Louis, MO
Veterinary Medical R&D – Kalamazoo, MI
Pfizer Global Manufacturing - Lincoln, NE

Species	Incident	Number Affected	IACUC Approved Exceptions (see Attachment 1)	Safety Guidelines as Described in Publications Listed Above	Unexpected Pain/Distress Resolution/Action
	Total	**382**			
Cats	[redacted]	18	G ROS	4	
Cats		133	H ROS	4	
	Total	**151**			
Guinea Pigs	[redacted]	440	I RFS – euthanatized 117 Died - 323	2	
Guinea Pigs		837	J RFS - Euthanatized	1	
	Total	**1277**			
Hamsters	[redacted]	4631	K RFS – euthanatized 1435 Died - 3196	3	
	Total	**4631**			
Rabbits	[redacted]	22	L RFS - Euthanized	1	
Rabbits		24	M ROS	1	
	Total	**46**			
Nonhuman Primates	[redacted]	6	N ROS	1	

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Attachment 2

Explanation for Animals Listed in Category E - APHIS Form 7023
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Pfizer Global Research and Development
Groton, CT; La Jolla, CA; St. Louis, MO
Veterinary Medical R&D – Kalamazoo, MI
Pfizer Global Manufacturing - Lincoln, NE

Species	Incident	Number Affected	IACUC Approved Exceptions (see Attachment 1)	Safety Guidelines as Described in Publications Listed Above	Unexpected Pain/Distress Resolution/Action
Nonhuman Primates		1	N RFS Died	1	
	Total	**7**			
Ferrets		22	O ROS	1	
	Total	**22**			
Gerbils		41	P RFS - Euthanized	1	
	Total	**41**			
Horses		**20**	Q ROS	1	
	Total	**20**			

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