

Explanation For Animals Listed In Category E - APHIS Form 7023
 For The 1998-1999 Annual Report Of Research Facility, #21-R-0088
 Pfizer Central Research Division
 Groton, CT

21R0088

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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 can not be foreseen, but which is nevertheless considered during the IACUC's review/approval process. 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: the Code of Federal Regulations (CFR, 1988), Title 16, Subchapter C [Federal Hazardous Substances Act (FHSA) Regulations], Part 1500 (Hazardous Substances and Articles: Administration and Enforcement Regulations); and the Code of Federal Regulations (CFR, 1992), Title 49, Parts 173.136 (Test for Corrosive Materials) and 173.132 (Test for Toxicity by Skin Absorption) for the testing of materials according to the Department of Transportation (DOT) regulations; the Code of Federal Regulations (CFR, 1995), Title 21, Chapter I, Part 58 (Good Laboratory Practices for Nonclinical Laboratory Studies). 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.

<u>Species</u>	<u>Number Affected</u>	<u>Incident</u>
1. Dogs	1	Compound Reaction/Systemic*
2. Dogs	2	Compound Reaction/Central Nervous System*
3. Dogs	3	Compound Reaction/Emesis*
4. Dogs	14	Procedure Reaction/Arthritis
5. Dogs	30	Procedure Reaction/Gastroenteritis
6. Dogs	20	Procedure Reaction/Anxiety-Distress
7. Cats	3	Procedure Reaction/Cardiovascular*
8. Guinea pigs	205	Procedure Reaction/Anxiety-Distress
9. Guinea pigs	7	Compound Reaction/Musculoskeletal*
10. Hamsters	633	Procedure Reaction/Infectious Disease Model
11. Hamsters	14	Procedure Reaction/Respiratory
12. Non-human primates	70	Compound Reaction/Emesis*
13. Rabbits	8	Compound Reaction/Central Nervous System*
14. Rabbits	8	Compound Reaction/Systemic*
15. Ferrets	107	Compound Reaction/Emesis

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 21-R-0089

FORM APPROVED
OMB NO. 0579-0036

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

LaGuardia Community College
31-10 Thomson Avenue
235 East 42nd Street
Long Island City, NY 11101
Status: Active

OCT 25 1999

BY: _____

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

Oct 1, 1999 - Sept. 30, 2000

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
C111 Veterinary Technology Center
31-10 Thomson Avenue
Long Island City, NY 11101

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, 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 in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	9	0	9	0	9
5. Cats	19	0	19	0	19
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	12	0	12	0	12
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 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.
- Each principal investigator has considered alternatives to painful procedures.
- 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.
- 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)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

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