

result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

additional information.

DATE OF REPORT: 10/29/2008
 NAME OF FACILITY: J. DORAN

UNITED STATES DEPARTMENT OF AGRICULTURE
 ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 32-R-0003	CUSTOMER NO. 770	FORM APPROVED OMB NO. 0579-0036
2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)		
ELI LILLY AND COMPANY LILLY CORPORATE CENTER INDIANAPOLIS, IN 46285 (317) 278-2000		
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.)		

ANNUAL REPORT OF RESEARCH FACILITY
 (TYPE OR PRINT)

FACILITY LOCATIONS/sites

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 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	202	101	477	4	784
5. Cats					
6. Guinea Pigs			637	108	745
7. Hamsters			209		209
8. Rabbits	8	340	75	1	424
9. Non-Human Primates	66	106	127	3	302
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets	24	18	115		157
Gerbils			402		402

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 if 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 the 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 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)



DATE SIGNED

Oct 29, 2008

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T 1 - HEADQUARTERS

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ATTACHMENT TO ANNUAL REPORT OF RESEARCH FACILITY

For the period of October 1, 2007 through September 30, 2008

Category "E" Experimentation

**Eli Lilly and Company
Indianapolis, IN 46285**

**Registration No. 32-R-0003
Customer No. 770**

Animals upon which experiments, research, 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.

Species	Number of Animals	Explanation
<u>Guinea Pigs</u>	108	Pharmacology

These animals were used as a model to evaluate novel compounds for osteoarthritis in humans. Mild to moderate arthritis was induced. Animal models are an essential part of this research at present because no in vitro system is available to fully mimic this disease condition or to assess compound pharmacology. Analgesics could not be used because such compounds would interfere with and confound study results. The earliest possible endpoint was established and the minimum number of animals were used.

<u>Dogs</u>	4	Toxicology
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These animals were used in the toxicological evaluation of drug candidates, novel pharmaceuticals. In some studies, the degree of toxicity was unexpectedly severe. When adverse clinical signs were detected, animals were provided veterinary and supportive care. Animals were euthanized when it was determined that pain or distress could not be alleviated. Administration of analgesics or tranquilizers would have confounded interpretation of the experimental results. Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies used in the evaluation of new drug candidates may experience unanticipated events. U.S. and O.U.S. regulations and guidelines for animal studies to support human clinical trials, specifically 21 CFR 312.23 (a)(8)(ii) and ICH SF4, require these studies.

<u>Rabbits</u>	1	Toxicology
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This animal was used in the toxicological evaluation of drug candidates. In this case, the degree of toxicity was unexpectedly severe. When adverse clinical signs were detected, the animal was provided veterinary and supportive care, but was euthanized when it was determined that pain or distress could not be alleviated. Administration of analgesics or tranquilizers would have confounded interpretation of the experimental results. Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies used in the evaluation of new drug candidates may experience unanticipated events. U.S. and O.U.S. regulations and guidelines for

animal studies to support human clinical trials, specifically 21 CFR 312.23 (a)(8)(ii) and ICH SF4, require these studies.

Monkeys 3 Toxicology

These animals were used in the toxicological evaluation of drug candidates. In some studies, the degree of toxicity was unexpectedly severe. Animals received veterinary care but either died spontaneously or were euthanized. Administration of analgesics or tranquilizers would have confounded interpretation of the experimental results. Despite careful study design, supportive care, and adjustments to study protocols, animals in toxicology studies used in the evaluation of new drug candidates may experience unanticipated events. U.S. and O.U.S. regulations and guidelines for animal studies to support human clinical trials, specifically 21 CFR 312.23 (a)(8)(ii) and ICH SF4, require these studies.

ATTACHMENT TO ANNUAL REPORT OF RESEARCH FACILITY

For the period of October 1, 2007 through September 30, 2008

Exceptions to the Regulations and Standards

**Eli Lilly and Company
Indianapolis, IN 46285**

**Registration No. 32-R-0003
Customer No. 770**

1. Identify the IACUC approved exception to the standards: None
2. Describe the IACUC approved exception to the standards: Not applicable
3. Species of animal used: Not applicable
4. Number of animals used: Not applicable