

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 32R0003

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

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

EL Lilly and Company
Lilly Corporate Center
P.O. Box 95
Indianapolis, IN 46285
Status: Active

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or field for these purposes. Attach additional sheets if necessary.)

See Attached

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 | 229 | 330 | 211 | 32 | 573 |
| 5. Cats | | | 4 | | 4 |
| 6. Guinea Pigs | | 1682 | 1094 | | 2776 |
| 7. Hamsters | | 12 | 24 | | 36 |
| 8. Rabbits | | 1129 | 540 | 37 | 1706 |
| 9. Non-human Primates | 70 | 109 | 42 | 2 | 153 |
| 10. Sheep | | | | | |
| 11. Pigs | | 2 | | | 2 |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| Sand Rat | | | 55 | | 55 |
| Gerbil | | 3591 | 646 | 459 | 4696 |

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 provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

CERTIFICATION BY HEADQUARTER 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

(b)(6) & (b)(7)(C)

(b)(6) & (b)(7)(C)

11-12-99

32R0003

ATTACHMENT TO ANNUAL REPORT OF RESEARCH FACILITY

For the period of October 1, 1998 through September 30, 1999

Category "E" Experimentation

NOV 22 1999
 E.Y.
 Eli Lilly and Company
 Indianapolis, IN 46285

Registration No. 32-R-003

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 |
|---------|-------------------|-------------|
|---------|-------------------|-------------|

| | | |
|---------|---|------------|
| Monkeys | 2 | Toxicology |
|---------|---|------------|

These animals were used in the toxicological evaluation of drug candidates. In these studies the degree of toxicity was unexpectedly severe. In the case of one of these monkeys, test compound administration was suspended and supportive veterinary care was provided. The second animal was part of a group wherein compound administration was continued at a reduced dose. 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. These studies are required by U.S. and O.U.S. regulations and guidelines for animal studies to support human clinical trials; specifically CFR Volume 62, #227 and ICH M3.

| | | |
|------|----|-------------------|
| Dogs | 31 | Diabetes Research |
|------|----|-------------------|

These dogs were used in studies of insulin formulations, insulin like analogs, and or other experimental compounds in development as potential therapies for diabetes.

(b) (4)

In the course of the experimentation the dogs' basal blood sugar is measured at intervals over a total time course of thirty hours. The dogs are not fed for twelve hours prior to the experiment and for the duration of the experiment itself for a total time period of up to 30 hours. These activities have been reviewed and approved by the Institutional Animal Care and Use Committee and have been observed by the veterinary staff. The dogs are under constant observation during the procedure, are given free access to water and their blood sugar is augmented by