

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 55-R-0002 CUSTOMER NUMBER: 861	FORM APPROVED OMB NO. 0579-0036
Research Triangle Institute P.O. Box 12194 3040 Cornwallis Rd. Research Triangle Pa, NC 27709 Telephone: (919)-541-7288		

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 Attached 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 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 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 tranquiliz 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 reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0	12	0	0	12
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	47	0	0	47
7. Hamsters	0	0	0	0	0
8. Rabbits	18	422	315	19	774
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

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 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)

DATE SIGNED
11/15/08

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APHIS Form 7023 Site List**Registration Number:** 55-R-0002**Customer Number:** 861**Facility:** RESEARCH TRIANGLE INSTITUTE
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709
(919) 541-7288**APHIS Form 7023 Category E Explanation****Number of Category E Animals:** 19**Species:** Rabbits

Procedures: The Category E rabbits were used on developmental toxicity studies for chemicals regulated by the Food and Drug Administration (FDA). In order for developmental toxicity studies to be acceptable to government agencies, there must be dose-related toxicity at the top dose. When such dosing does result in maternal and/or embryofetal toxicity to the animals, one cannot ameliorate the distress since the use of anesthetics, analgesics, or tranquilizing drugs would interfere with the objectives of the study, which is to determine whether the drug under development causes any adverse effects to the maternal or prenatal offspring. Treatment of all animals, of only affected animals, or only of animals in certain dose groups may differentially affect the response to the test material in unforeseen ways. Acceptable, well-performed, reported and interpreted preclinical studies in animal models are required before new drugs can be tested in humans and subsequently approved for use in people.

Justification: These studies involved evaluation of a potential drug being developed for treatment of nervous disorders, including migraine headaches, nerve-muscle spasms, lower back pain, etc. Only live animals can determine the effects of maternal exposure during pregnancy on prenatal offspring survival, growth and development. These were range-finding developmental toxicity studies.

Federal Regulations: The International Conference on Harmonisation (ICH) and FDA guidelines require the rabbit for some Segment II studies. The regulations include:

21 CFR Part 312

FDA and ICH Guidelines for Segment II Toxicity Studies