

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

22-R-0009

FORM APPROVED
OMB NO 0579-0036

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

Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

519

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)

East Hanover, Buildings 404 & 406

DEC 01 1999

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	46	201	0	3	204
5. Cats	N/A	N/A	N/A	N/A	N/A
6. Guinea Pigs	N/A	N/A	N/A	N/A	N/A
7. Hamsters	N/A	N/A	N/A	N/A	N/A
8. Rabbits	0	612	0	66	678
9. Non-human Primates	411	278	0	18	296
10. Sheep	N/A	N/A	N/A	N/A	N/A
11. Pigs	N/A	N/A	N/A	N/A	N/A
12. Other Farm Animals	N/A	N/A	N/A	N/A	N/A
13. Other Animals	N/A	N/A	N/A	N/A	N/A

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 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

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

DATE SIGNED

22R 0009

OPTIONAL COLUMN E EXPLANATION FORM

52-WEEK ORAL GAVAGE TOXICOLOGY STUDY WITH A 4 WEEK-RECOVERY

1. Registration Number: 22-R-0009
2. Number of animals used in this study – 40. Number of animals classified as category "E" - 3.
3. Species (common name) _____ Dogs _____ of animals used in this study.
4. Explain the procedure producing pain and/or distress.

These dogs were dosed with a pharmaceutical compound.

On study day 52, the first dog demonstrated decreased locomotor activity, emesis and regurgitation, and was therefore euthanized. On study day 80, the second dog demonstrated decreased motor activity, reduced feces, emesis and labored respiration, and was euthanized. On study day 87, the third dog demonstrated decreased locomotor activity and labored respiration, and was euthanized.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

As soon as there were signs indicating that an animal was experiencing pain or distress, it was euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

The general reference is 21 CFR 312.23(a)(8). This reference indicates that there are guidelines available from the FDA that describe ways in which these requirements may be met. More specific guidelines may be found in the following:

- 1) M3 Nonclinical safety studies for the conduct of human clinical trials for pharmaceuticals published in the Federal Register on November 25, 1997 (62 FR 62922)