

22R0032

**Optional Column E Explanation Form**

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 22-R-0032
2. Number 18 of animals used in this study.
3. Species (common name) Dog of animals used in this study.

4. Explain the procedure producing pain and/or distress.

A total of 18 dogs used to evaluate drug candidates for clinical trials showed signs of toxicity. Thirteen dogs were given a cytotoxic chemotherapeutic drug for the treatment of cancer and 5 dogs were given a glucose lowering drug for the treatment of diabetes. During the studies, these dogs presented with clinical signs of inappetance, weight loss, lethargy, and diarrhea. The study design and procedures were conducted in accord with the guidelines established by global regulatory authorities including the Food and Drug Administration for drug candidates that are intended to proceed to clinical trials. All animals on these studies were observed daily by veterinary personnel and supportive therapy such as fluids and nutritional supplements were provided.

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)

NOV 15 1999

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):

Agency FDA CFR 21 CFR 58.3(d)

21 CFR 58.90

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
22-R-0036  
22R0036181

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)

Schering Corporation  
2015 Galloping Hill Road

Kenilworth, NJ 07033  
Status: Active

DEC 01 1990

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)

1. Schering-Plough Research Institute, 2015 Galloping Hill Road, Kenilworth, NJ 07033
2. Schering-Plough Research Institute, Safety Evaluation Center PO Box 32 Lafayette, NJ 07848

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	12	131	382	35	548
5. Cats	0	0	65	0	65
6. Guinea Pigs	0	5,660	7,529	0	13,189
7. Hamsters	0	17	8	0	25
8. Rabbits	8	600	118	58	776
9. Non-human Primates	107	286	384	38	708
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					
Gerbils	0	0	2,820	0	2,280

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 OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/30/90