

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
21-R-0032
21R0032

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

537

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
Roswell Park Cancer Institute
Office of Scientific Admin.
Elm & Carlton Streets
Buffalo, NY 14263-0001
Status: Active

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)

~~See Attached~~
Cell + Virus Building, Springville Labs
Cancer Cell Center
Grace Cancer Drug Center
Medical Research Complex

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	3	0	40	4	44
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	22	15	0	37
9. Non-human Primates					
10. Sheep	1	0	0	0	0
11. Pigs	0	0	28	0	28
12. Other Farm Animals Calves	0	0	63	0	63
13. Other Animals Wild mice	1052	3643	3		3646

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. DEC 06 1999
- 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)

(b)(6), (b)(7)(C)

INSTITUTIONAL OFFICIAL

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

DATE SIGNED

11/30/99

(b)(6), (b)(7)(C)

Registration # 21-R-0032

Subpart E. Explanation

Four dogs died during the conduct of preclinical toxicological evaluation of a new taxane derivative. The studies were conducted prior to registration of this new drug for human clinical trial. The studies were conducted under strict adherence to the Good Laboratory Practices Act of the U.S. Food and Drug Administration. The deaths were unexpected, as the previous escalation step was essentially without overt toxicity. No other dogs were treated at these doses after lethality was determined. Because of the nature of the study, analgesics are not permitted.

DEC 06 1999