

SIERRA BIOMEDICAL
SAN DIEGO DIVISION

RD	
SACS1	
SACS2	
A	B
C	D
E	

93R0262

Nov 8, 1999

USDA - Animal and Plant Health Inspection Services
9580 Micron Avenue, Suite J
Sacramento, CA 95827-2623

To Whom it May Concern,

The following is a more in depth explanation of the procedures producing pain or distress to animals listed in the E category:

Six canines were used to determine the cardiovascular effects of test article in conscious animals. Animals were anesthetized and instrumented with catheters to measure venous and arterial pressures, a flow probe to measure cardiac output, and ECG leads to measure cardiac rhythm. The animals recovered following the instrumentation surgery, and were studied in the conscious state, since conscious animals are more representatives of the responses, which might be observed in conscious humans. All surgical studies were conducted under sterile conditions with anesthesia.

Forty canines were used in a toxicity study. No concurrent medicines were allowed due to interference with the test article in the study.

Seven canines were used to evaluate the feasibility of intraprostatic electroporation. This was conducted under sterile conditions with anesthesia.

All 89 swine were used in a sterile surgical study that involved recovery of the animals. Analgesics were administered throughout the study.

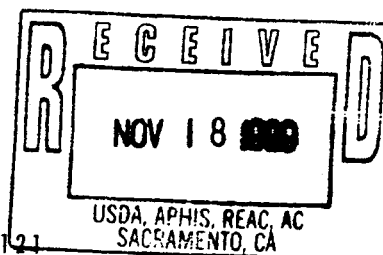
All animals were placed in this category due to unknown effects of the novel test articles being used, and were under supervision of a veterinarian throughout the studies.

Please contact me if there are any further questions.

Sincerely,

bb, b7c

*Per forecom, we
will receive
follow-up letter
to clarify -
mk
11/22/99*



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800-322-2605 • 619-623-0888 • FAX 619-623-0880

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

93-R-0189

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)

NORTHVIEW PACIFIC LABORATORIES
2800 SEVENTH STREET
BERKELEY, CA 94710

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)

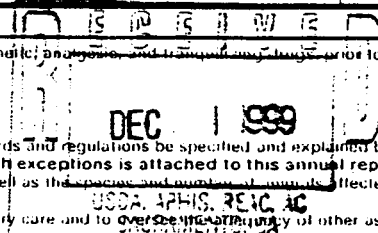
NVP, BERKELEY, CA 94710
(Same as #2)

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					
5. Cats					
6. Guinea Pigs	192	4652	0	2678	7330
7. Hamsters					
8. Rabbits	176	3741	518	0	4259
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

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 appropriateness 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 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

b6, b7c

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

b6, b7c

DATE SIGNED

11/29/99