

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 93-R-0189
CUSTOMER NUMBER: 1143

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Pacific Biolabs
551 Linus Pauling Drive
Hercules, CA 94547

Telephone: (510)-964-9000

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 ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o 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 reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	—	82	5	0	87
5. Cats	—	—	—	—	—
6. Guinea Pigs	114	2474	0	0	2474
7. Hamsters	—	9	0	0	9
8. Rabbits	42	4992	97	20	5109
9. Non-human Primates	—	—	—	—	—
10. Sheep	—	4	0	0	4
11. Pigs	—	5	1	0	6
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 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)

NOV 19 2008

NAME AND TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

(b)(6),(b)(7)(c)

(b)(6),(b)(7)(c)

11/11/08

Column E Explanation

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: 93-R-0189

2. Number 20 total of animals used in this study. *11 for dermal irritation
3 for OECD dermal irritation
6 for ocular irritation*

3. Species (common name) Rabbit of animals used in the study.

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

These studies were skin and eye irritation studies
The test article gave unexpected result - severe irritation
Once irritation was observed, rabbits were either given an
analgesic (ocular irritation studies), or immediately
euthanized (dermal irritation studies)

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 Item 6 below)

The results were unexpected. The pain/distress was relieved upon
observation via an analgesic (ocular irritation studies),
or immediate euthanasia (dermal irritation studies)

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 16 CFR 1500.40

ISO ISO 10993-10

OECD Guidelines for testing Chemicals 405

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