12R 0005

Diatide, Inc.
9 Delta Drive • Londonderry, New Hampshire 03053
(603) 437-8970 • FAX (603) 437-8977

ADDENDUM TO: ANNUAL REPORT FOR RESEARCH FACILITY
REGISTRATION No.: 12-R-005 (Diatide, Inc., 9 Delta Dr., Londonderry, NH 03053)
Re.: Explanation of animal care/use in Section E (APHIS form 7023)
Annual Report of Research Facility: fiscal 1998-1999

Those animals listed under Section E were rabbits used in an *E. coli* infection model to explore the ability of nuclear medicine imaging agents to identify focal infection sites. The protocol has been reviewed and approved by the Diatide IACUC.

The model requires rabbits to be innoculated with a specific amount of bacteria (E. coli) into the gastrocnemius muscle of the left (or right) hind leg. The infection is allowed to progress overnight to form an inflammatory focus. The animals are tested over a 2-12 hour period 18-48 hours after initiation of the inflammatory focus. The animals do not receive antibacterial or anti-inflammatory agents (steroidal or non-steroidal) as use of these agents inhibit/depress the uptake of the radiolabeled infection/inflammation-seeking agents. The animals have apparent, but mild, discomfort which is attributable to the inflammatory process, however, they are alert, mobile and the infection can resolve within several days. The model requires euthanasia (i.e., Somlethol®) at specific times after administration of the agents followed by complete necropsy, including the infection site, for determination of the percent of administered test article in tissues. Carcasses and tissues are disposed of per IACUC and radioactive materials approved protocols. The number of animals employed in this procedure over the past fiscal year (98-99) is 248.

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-0OA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0032 22R0032

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

180

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

Hoffmann-LaRoche, Inc.
Research & Development Div.
340 Kingsland Street
Nutley, NJ 07110
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

NOV 15 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	54	316	0	18	334
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	296	211	0	507
7. Hamsters	0	0	0	0	0
8. Rabbits	0	42	0	0	42
9. Non-human Primates	10	19	41	0	60
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					
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ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including approriate 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 all aspects of animal care and use.

Appr'd As To Form
LAW DEPT.
(b)(6)
By [redacted] (b)(7)(C)

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)

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

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
[redacted]	[redacted]	

APHIS FORM 7023
(AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.) (b)(6), (b)(7)(C)

PART 1 – HEADQUARTERS