GIBRALTAR LABORATORIES, INC.

Quality research & regulatory testing services since 1970

22R 0075

GIbraltar Laboratories, Inc.
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DEC 01 1999

Registration #: 22-R-0075

Section E - Explanation

1. Guinea Pig Maximization and Split-Adjuvant tests were performed on 213 guinea pigs which required light excoriation of the skin and injection of Freund's Complete Adjuvant. These procedures are performed to maximize the response of the test animals to potential allergens to increase the sensitivity and accuracy of the assays. The use of anesthetic and analgesic agents was avoided for these animals because usage of such agents has the potential to alter the results of the test by cross-reacting with the test material. Compromise of the immune systems of these animals was also a concern. These methods are referenced in ISO 10993, Section 10 - Tests for Irritation and Sensitization.

2. 352 rabbits were considered to have experienced transient pain as a result of the application of light epidermal abrasions administered during the course of Primary Dermal Irritation tests and Dermal Toxicity tests performed for the Consumer Product Safety Commission (CFR 16, part 1500), or were injected multiple times during USP 23 Biological Reactivity Tests, *In-Vivo* (chapter 88). If used in an irritation test, anesthetics and analgesics have the potential to effect the level of observable irritation and may cross-react with the test material. In a dermal toxicity test, administration of such agents may produce additional stress on the liver and other vital organs of the rabbit and produce a higher level of toxicity than is inherent in the test material and were therefore not used.

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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-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 22-R-0076 22R0076

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

189

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

Camden County College
PO Box 200
College Drive
Blackwood, NJ 08012
Status: Active

NOV 04 1999

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~~

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	4	0	4	0	4
5. Cats	2	0	2	0	0
6. Guinea Pigs	0	0	8	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	5	0	5	0	5
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals					
Chickens	0	12	0	0	12

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 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)

(b)(6), (b)(7)(C) [redacted]

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
[redacted] (b)(6) (b)(7)(C)	[redacted], Camden County College	

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete)

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