## FOOTNOTE KEY

(A) Two (2) rabbits used in skin irritation studies necessary for product safety assessment experienced severe skin irritation during the conduct of testing. A measured amount of test material was placed on the shaved skin of the rabbit to determine the effect the materials would have on the integrity of the skin. In these instances, the materials were severely irritating to the skin. In the investigator's judgment these animals may have experienced pain after dosing and were reported as such on the 1999 annual report. The Study Director did not administer any analgesics prior to testing because it was not obvious that the material would cause the severity of irritation seen during the test. Use of the analgesics after the administration of the test material could potentially inhibit or enhance the presence of any toxicological signs and would have required additional animals to act as control groups for the analgesics. Finally use of analgesics may have an adverse effect on the acceptability of the data to world wide regulatory bodies for which these studies are conducted.

In each case the animals experiencing pain and suffering were euthanized as soon as the study protocols and testing guidelines allowed.

Our test methods for this study are consistent with the following:

US EPA OPPTS: Series 870.2500: Acute Dermal Irritation OECD Guideline 404
Japan 59 NohSan No. 4200, Primary Dermal Irritation Study ECC Directive 92/69/EEC B.4.

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE 1. REGISTRATION NO 39 23R00

FORM APPROVED OMB NO 0579-0030

2. HEADQUARTERS RESEARCH FACILITY (Name and Albress as register of minustra) include Zip Code inin Pharmaceuticals Ind 5110 Campus Drive

dela

- OSSOL Old York Road Plymouth Meeting, PA 19462 Status: Active

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

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 (Siles)

See Attached Dept. of Pharmacology

A . Animals Covered By The Animal Wellare 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, leaching, research, surgery, or lests 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 leaching, experiments, research, surgery or lests 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 lests. (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	Ø				Ø
5. Cats	$\varphi$				Ø
6. Guinea Pigs	Ø				Ø
7. Hamslers	Ø				Ø
8. Rabbits	Ø				0
9. Non-human Primates	Ø				Ø
10. Sheep	Ø				Ø
11. Pigs	Ø				Ø
12. Other Farm Animals	Ø				Ø
13. Other Animals	P				Ø
	<del> </del>				<del>                                     </del>

## **ASSURANCE STATEMENTS**

- 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 HEADQUARTES RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official) Licertify that the above is true, correct, and complete (7 U.S.C. Section 2143)

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

DATE SIGNED 10/25/919

**APHIS FORM 7023** 

(Replaces VS FORM 18-23 (OCT 88), which is obsolete )

(AUG 91)