

23 R 0099

Argus Research Laboratories Inc.
905 Sheehy Drive
Horsham, PA 19044

Registration Number
23-R-0099

Column E Explanation

There were a total of 114 rabbits from 34 studies in Column E during this reporting period. These 34 studies were developmental and reproductive toxicity tests conducted for sponsors as required by the US FDA, US EPA or OECD government agencies. The federal regulations requiring these tests are cited on the attached pages.

Toxicity related to the product being tested resulted in the death of 114 rabbits. 31 rabbits were sacrificed due to adverse clinical observations associated with the toxicity and 83 rabbits were found dead while exhibiting normal to adverse signs associated with toxicity.



23 R 0099

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December 13, 1999

United States Department of Agriculture
Eastern Regional Office
920 Main Campus Drive
Suite 200, Unit 3040
Raleigh, NC 27606

RE: Annual Report of Research Facility
Registration Number: 23-R-0099 / 363

Dr. Dr. Goldentyer:

This letter is to inform your office of our amended Annual Report numbers for guinea pigs and hamsters. The numbers listed below are the amended numbers.

A.	B.	C.	D.	E.	F.
Guinea Pigs	0	28	0	30	58
Hamsters	0	157	1	49	207

The 30 guinea pigs in Column E during this reporting period represent one phototoxicity/photoallergy study conducted for a sponsor as required by the US FDA and the OECD government agencies. These guinea pigs received Freund's Complete adjuvant and were euthanized on their scheduled date of sacrifice three weeks after the Freund's injection. The federal regulations requiring this test are cited on the attached pages.

The 49 hamsters in Column E during this reporting period represent a developmental toxicity and a developmental toxicokinetic study conducted for a sponsor as required by the US FDA government agency. Toxicity related to the product being tested resulted in adverse clinical observations (skin abrasions) in these hamsters. The observations were present for eight days prior to scheduled sacrifice. The federal regulations requiring these tests are cited on the attached pages.

In addition, we would like to inform your office of our name change. Primedica Argus Research Laboratories is one of four laboratories within the Primedica organization. Primedica Corporation, a wholly owned subsidiary of Genzyme Transgenic Corporation, provides preclinical contract research services to pharmaceutical and chemical companies. Primedica Argus Research Laboratories specializes in reproductive and developmental toxicology and photobiology testing and conducts safety and efficacy studies for sponsors. These studies are intended for submission to government agencies for product approval.

Thank you for reviewing this amended Annual Report for the reporting period of October 1, 1998 through September 30, 1999.

Sincerely,

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