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

71-R-0014

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

DEC 8 1999

NOV 24 1999

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

GIC Redfield Laboratories
100 East Boone
P.O. Box 308
Redfield, AR 72132

~~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)*

~~Same as above~~

GIC Redfield Laboratories
100 East Boone/P.O. Box 308
~~Redfield, AR 72132~~

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	27	177		72	249
5. Cats					
6. Guinea Pigs		375		10	385
7. Hamsters					
8. Rabbits		873		87	960
9. Non-human Primates	9	64		2	66
10. Sheep					
11. Pigs	1	33	38	8	79
12. Other Farm Animals					
13. Other Animals					

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).

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
b6, b7C	b6, b7C	11/18/99

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

PART 1 - HEADQUARTERS

71R0014

Attachment to 1999 USDA Annual Report of Research Facility
GTC Redfield Laboratories
Registration Number 71-R-014

Redfield Laboratories is a division of Genzyme Transgenics Corporation (GTC). Redfield Laboratories is a general toxicology facility and one of the five GTC pre-clinical toxicology testing laboratories in the United States with the toxicology testing expertise needed to meet EPA, OECD, FDA, and Japanese regulatory requirements. Redfield Laboratories performs toxicology and pharmacology testing of drugs, medical devices, consumer products, agricultural and industrial chemicals, veterinary products, petrochemicals, and phytochemicals.

Individual research projects were classified in Column E on the accompanying report. These studies involved the administration of test articles to animals by a variety of routes. Under the procedures specified in each of the research protocols, many of the animals probably have been subjected to more than momentary or slight pain and distress since these studies were performed to determine the potential toxicity of test articles. All of these protocols were approved by Redfield Laboratories' Institutional Animal Care and Use Committee (IACUC) and no anesthetic, analgesic, or tranquilizing drugs were used during the conduct of the studies since these drugs could potentially adversely affect the results and/or interpretation of the studies. However, to prevent unnecessary pain and suffering, animals were closely monitored by the attending veterinarian, technical and animal care staff, and animals determined to be severely compromised and/or moribund were humanely euthanized.

Explanation of procedures resulting in a Column E classification:

Individual research studies were conducted with the animals in column E. These studies involved the administration of test articles to animals by various routes of exposure: oral (capsule or gavage), intradermal, subcutaneous or intravenous injection, dermal or ocular application. Under the procedures specified in the research protocols, animals were probably subjected to more than momentary or slight pain and distress, since these studies were performed to determine the potential toxicity of test articles. The use of drugs to relieve pain or distress would compromise these studies for the following reasons: 1) signs elicited by exposure to the test article could not be masked since the study objectives were to obtain and document toxic responses; 2) an analgesic drug may affect the metabolism or other actions of the material under test and thereby affect the research results; 3) it was not practicable to treat only affected animals because such treatment may affect response to the test material in unforeseen ways and preclude comparison with other, non-treated animals. To prevent unnecessary pain and suffering, any animals determined to be severely compromised and/or moribund were humanely euthanized upon approval of the Study Director or the attending veterinarian. All of the studies were conducted for clients/sponsors with reported results and conclusions to be submitted to various regulatory agencies to support applications for product approval.

Briefly listed are the **Column E** studies involving the animal species covered by the Animal Welfare Act (AWA) which were conducted during the period of October 1 through September 30 at Redfield Laboratories. See attached: