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:

(b)(4)