32R0003

ATTACHMENT TO ANNUAL REPORT OF RESEARCH FACILITY

For the period of October 1, 1998 through September 30, 1999

Exceptions to the Regulations and Standards

Eli Lilly and Company Indianapolis, IN 46285

, NOV 9. 9. 1999

Registration No. 32-R-003

1. Identify the IACUC approved exception to the standards

Withholding of food (but not water) from animals for a period in excess of 24 hours. (Reference: 9 CFR3.54 (a)

2. Describe the IACUC approved exception to the standards

Dogs:

These dogs were used in studies of insulin formulations, insulin like analogs, and or other experimental compounds in development as potential therapies for diabetes. The compounds in question are intended to regulate blood sugar over longer periods of time than the now currently marketed therapies. In the course of the experimentation the dogs' basal blood sugar is measured at intervals over a total time course of thirty hours. The dogs are not fed for twelve hours prior to the experiment and for the duration of the experiment itself for a total time period of up to 30 hours. These activities have been reviewed and approved by the Institutional Animal Care and Use Committee and have been observed by the veterinary staff. The dogs are under constant observation during the procedure, are given free access to water and their blood sugar is augmented by intravenous dextrose injections if needed. The animals do not show clinical indications of 'distress'.

Rabbits

Rabbits are used in studies of compounds that have antithrombotic activity previously observed in *in vitro* test systems. In studies where agents are evaluated for oral bioavailability, the animal must be fasted for a period long enough to assure that the stomach is empty and that there would be no interference between ingesta and the absorption of the compound. In the rabbit this period has been determined to be up to forty six hours. These activities have been reviewed and approved by the Institutional Animal Care and Use Committee and have been observed by the veterinary staff The animals do not show clinical indications of 'distress'.

3. Species of animal used

Dog Rabbit

4. Number of animals used

Dog: 31 Rabbit: 37

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Sites and Locations and Listing

Eli Lilly and Company Indianapolis, IN 46285

Registration No. 32-R-003

This institution has been designated by the Agency as a single "site". The animal care and use facilities within this site designation are in multiple buildings in two locations.

- Eli Lilly and Company, Lilly Corporate Center, Indianapolis, Indiana 46285
- · Lilly Research Laboratories, 2001 West Main Street, Greenfield, Indiana 46140

Any requests for information or access to the site should be made through the Corporate Center location.

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