

NOV 05 2014

BFQ#

NOTE REGARDING CLASSIFICATION E: An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act, and may be publicly available through the Internet via USDA's website.

Explanation for USDA Classification E

(This report is required to accompany USDA Form 7023 to support any USDA Classification E listings.)

This document must be typed.

Name of investigator (b) (6), (b) (7)(C)

Animal Study Protocol Title: An assessment of the potential of dietary supplements of concern to affect cardiovascular function in the guinea pig.

Species and number of animals listed in Classification E for each year: Guinea pig

Species: Guinea Pig
Number of animals: 366
year 1 - 112
year 2 - 112
year 3 - 112
Total: 336

These numbers represent the estimated number of animals that will be used on a 3 year protocol per year. The actual number of animals used on the protocol in 2014 was 37.

Description of project including reason(s) for species selection: For a description of the project please see Section F Experimental Design and Animal Procedures, Pages 5 – 10. With regards to test species selection: Animal experimentation is absolutely essential to meet the objectives outlined in this protocol. The guinea pig is an accepted experimental model to characterize systemic toxicity. The procedures for conducting Cardiovascular Toxicity testing using the guinea pig are well established and have been utilized extensively in Cardiovascular Testing laboratories around the world; therefore, a significant volume of toxicological data has been collected using the guinea pig as an experimental model. One of the most studied strains is the Charles River Dunkin Hartley Guinea Pig strain on which historical control data is available.

Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressing procedures is contraindicated:

If animals do exhibit signs of overt toxicity they will not be treated as the use of anesthetics, analgesics or tranquilizing drugs could adversely affect the results of the research. Should animals appear moribund (lethargic or emaciated and/or show signs of rapid respiration or rough fur), they will be euthanized immediately at the discretion of the principal investigator with recommendations from the veterinarian. At the completion of the study the principal investigator will inform the IACUC of the approximate number of exposed animals found to ultimately fall within the "E" pain code.

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

March 13, 2014
Date:

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

2 May 2014
Date: