Annual Report Addendum, 10/1/2010 to 9/30/2011, Facility No. 21-R-0209
Category E Explanation-Guinea Pigs

Guinea Pig Sensitization Tests determine the allergenicity of materials. The maximization test and the patch test are required by the FDA Modified ISO 10993-1 matrix for preclinical evaluations of Class II and III medical devices. During the maximization test, an adjuvant and extract are injected intradermally. The adjuvant enhances the immune response and results in lesion formation at the injection site. These lesions, ranging in size from 3mm to 20mm, are not treated due to the possible interference or enhancement of the sensitization response. In order to determine the health status of these animals, daily observations are performed and animal health technical personnel evaluate the sites. Any abnormal findings are reported to the Attending Veterinarian for assessment. The positive controls for the patch test result in hive formation during the challenge phase. As is the case with the maximization test, any abnormal findings are reported to the Attending Veterinarian for assessment. Over the duration of the year none of the 1428 guinea pigs used in these evaluations (defined as Category E) required additional veterinary care for problems related to the lesions.

In order to address pain and distress, the Attending Veterinarian researched analgesics and an appropriate oral medication which would not affect the animals' fluid intake was not available. The nature of the Guinea Pig Maximization Test and the Buehler Patch Test negates the use of topical analgesia. We also performed weight trends and the animals exhibited weight gain throughout the test procedure. The animals ambulated normally and only vocalized when handled (as is the case with untreated guinea pigs).

The Safety Test for Biologics is a FDA required test for the release of vaccines to the marketplace. One guinea pig used in a safety test was found dead during the study. The cause of death was attributed to a prolapsed uterus which may have resulted from the intraperitoneal injection of the vaccine. Over 1700 guinea pigs were injected intraperitoneally and this was the only animal that was affected in this manner.

Category E Explanation-Rabbits

The Pyrogen Test is a procedure requiring the use of rabbits to assess the pyrogenicity or fever-causing potential of vaccines, pharmaceuticals and medical devices. Animals that are chosen for this testing are first restrainer acclimated. After the acclimation is complete animals are used in testing. During the test, which lasts approximately 4 to 5 hours, animals are restrained. Animals are monitored at minimum every 15 minutes for the duration of the test. In In January, 2011 one animal died while restrained. A necropsy revealed internal trauma. This trauma may have occurred while in its cage or while being restrained. Over 3000 restraints occurred during this reporting period and this was the only incident of spontaneous death.