

PATHOLOGY PEER REVIEW REPORT

**26-WEEK CAPSULE TOXICITY STUDY WITH AMMONIUM PERFLUOROOCTANOATE
(APFO) IN CYNOMOLGUS MONKEYS**

Covance Study Number 6329-231

OBJECTIVE

A microscopic peer review of the all tissues from all high-dose animals, selected control animals, and the two animals that had an unscheduled sacrifice (IO5721 and IO5724) was performed. The objective of the review was to confirm and further elucidate if possible, the stated cause of moribundity of animals IO5721 and IO5724.

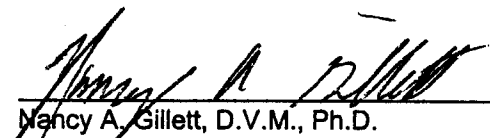
MATERIALS AND METHODS

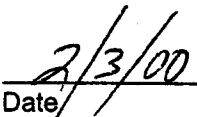
The slides from all tissues from all animals from Group 4, selected Group 1 animals, and animals that had an unscheduled sacrifice (IO5721 and IO5724) were reviewed and compared against the individual animal data tables prepared by the study pathologist.

RESULTS

The peer-review pathologist is in agreement with the original conclusions of the study, including the determination of the cause of moribundity for the Group 4 animal (IO5724). As stated by the study pathologist, the cause of the moribundity of the Group 2 animal (IO5721) was not determined. Although the relationship to treatment is not clear, it is unlikely that the moribund state of the animal is a result of APFO treatment based on the solitary occurrence of this spectrum of clinical signs, and the lack of histologic findings in animals receiving APFO at similar and higher dose levels.

REPORTED BY:


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Date