This pigment had histochemical staining properties that indicated a lipid-like character, but did not stain for iron, indicating that it was not hemosiderin. Additional histochemical stains and electron microscopy of this pigment in a companion study also suggest that it has properties of a complex carbohydrate in addition to being lipid-like.

Organs with relevant statistically significant alterations in time comparisons have already been discussed before.

No significant gender differences were detected in the dose-normalized AUC values.

No definitive cause of death could be established for animals that died prior to study termination. Microscopic observations were generally similar between animals that died prior to scheduled sacrifice and animals that survived to final necropsy. [Drug name]-related microscopic observations included atrophy of the uterus, cervix and vagina, increased mucification of the vagina and ovarian cystic follicles with hemorrhage (not seen in early death animals). Other [Drug name]-related microscopic observations included splenic and thymic lymphoid atrophy, adrenocortical X-zone necrosis and vacuolation (females only) and renal tubular degeneration.

**TEST ARTICLE(S) AND CONTROL ARTICLE(S)**

**7.1 Information**

The information ***(Section 7.1.1)*** refers to the original batch or lot of test-article supplied for the start of the study. Additional batches may be required during the course of the study. If this occurs, then full details of batch or lot usage will be maintained in the usage records but no protocol amendments will be issued. A certificate of analysis will be supplied with each batch or lot of test article.

**7.4 Administration**

The test article will be administered in the diet for at least 13 weeks and will be available ad libitum. The concentrations in the diet will remain constant and the diets will be replaced at least once weekly. The vehicle-control diet, Certified Rodent Diet #5002 (meal –ground pellets), will be offered at the same frequency as the test article diet.