Memorandum

To 171334M Study File

Re Report Amendment # 2

From G. W. Trimmer 29/May/09

cc

Date May 29, 2009

The final report for Study 171334M has been revised as follows:

Pages 1 – Abstract, fifth, sixth, and seventh sentences

PREVIOUS:

There was a statistically significant increase in the number of litters in the 10,000 mg/m^3 target concentration with visceral malformations. Visceral malformations in the 10,000 mg/m^3 target concentration included ectopia cordis, gastroschisis, and malrotated hindpaw. However, this increase was not considered toxicologically significant due to the lack of a dose response.

REVISION:

There was a statistically significant increase in the number of litters in the 10,000 mg/m^3 target concentration group with visceral malformations. There was also a finding of two unusual external malformations: ectopia cordis in one dead fetus at the 2000 mg/m^3 target concentration and in two live fetuses from one litter at the 10,000 mg/m^3 target concentration, and gastroschisis in one live fetus from the same litter. Neither the increase in visceral malformations nor the finding of these external malformations was considered toxicologically significant due to the lack of a dose response.

REASON FOR CHANGE: The abstract inadvertently referred to ectopia cordis and gastroschisis as visceral malformations while the data and the remainder of the report refers to them as external malformations.

Pages 10 – Summary, fifth paragraph, second, third and fourth sentences

PREVIOUS:

There was a statistically significant increase in the number of litters in the 10,000 mg/m^3 target concentration with visceral malformations. Visceral malformations in the 10,000 mg/m^3 target concentration included ectopia cordis, gastroschisis, and malrotated hindpaw. However, this increase was not considered toxicologically significant due to the lack of a dose response.

REVISION:

There was a statistically significant increase in the number of litters in the 10,000 mg/m^3 target concentration group with visceral malformations. There was also a finding of two unusual external malformations: ectopia cordis in one dead fetus at the 2000 mg/m^3 target concentration and in two live fetuses from one litter at the 10,000 mg/m^3 target concentration, and gastroschisis in one live fetus from the same litter. Neither the increase in visceral malformations nor the finding of these external malformations was considered toxicologically significant due to the lack of a dose response.

REASON FOR CHANGE: The summary inadvertently referred to ectopia cordis and gastroschisis as visceral malformations while the data and the remainder of the report refers to them as external malformations

Page 9 - QUALITY ASSURANCE STATEMENT

Review of Report Amendment entry

PREVIOUS:

Review of Report Amendment	09 Apr 09	09 Apr 09	9,27 Apr 09

REVISED

Review of Report Amendment 1	09 Apr 09	09 Apr 09	9,27 Apr 09
Review of Report Amendment 2	29 May 09	29 May 09	29 May 09

REASON FOR CHANGE: Report amended