

NOTICE OF DEVIATION

Section 1 (To Be Completed By The Person Discovering The Deviation)

Study Number: TOX210

Source Document(s): ☒ Protocol ☐ SOP (List SOP Number(s)):

Describe the Requirement (give section numbers for SOPs):

There was no requirement for histopathological examination of the lungs of the sentinel mice in the protocol.

Describe the Deviation: Date of Occurrence: May 6, 2008

Lungs were removed from each sentinel mouse, preserved and provided to Seventh Wave for histopathological examination. Seventh Wave conducted the examination and provided a report to RJRT.

Documented By: Paul H. Ayres

Date Jan. 20, 2009

Section 2 (To Be Completed By The Study Director)

Describe the Corrective Action(s) To Be Taken In Response To The Deviation:

No corrective action is possible. It should be noted that the data obtained from the histopathological examination can not be directly related to the health status of the study animals. The sentinel mice were retired breeders and therefore older than the mice used in this study.

Assessment Of The Deviation's Impact Upon The Outcome Of The Study:

This deviation had no effect on the outcome of the study. Again, the data from the histological examination of lungs of the sentinel mice are not directly comparable to the health status of the mice used on the study because of significant differences in the ages of the sentinel mice and the ages of the study mice.

Study Director's Signature:

Date

DAT024.001.010904