

Study Director Notification

Department: Report Services Study Number: 1228-007

Distribution:

President, Director of Operations	Study Director: <u>Rose Kovalcsik</u>
Executive Vice President, Director of Research	Alternate Contact: <u>Mark Johnson</u>
Quality Assurance Data Associate	Department Manager: <u>Christy Kubin</u>
Quality Assurance Auditor: <u>Jason Wilson</u>	Group Leader: _____
Report Coordinator: <u>Lisa Beverwyk</u>	Project Leader: <u>Zach Baker</u>
Department Director: <u>Mary Ann Scott</u>	Other: _____

Date(s) of Event: _____ Study Day(s)/Interval(s): Reporting

Reference

Protocol: _____ SOP: _____ GLP: _____ Method: _____

Informational: Yes

Please Note:

Per discussion with the Study Director, the following animals will be excluded from the QCA summary tables: unstented animals (animal numbers 711, 791, 806, 740, 782, 10741, 757, and 762), animals replaced due to dosing error (animal numbers 701-706, 708-710, 712, 713, and 722-725), and animals that did not survive to scheduled necropsy (animal numbers 710, 719, and 784). However, all individual data for these animals will be tabulated.

By: Lisa Beverwyk Date: 4/8/2008

Study Director Response
(check at least one)

- | | |
|---|---|
| <input type="checkbox"/> Authorize/Acknowledge as SOP deviation | <input type="checkbox"/> Protocol Amendment will be issued |
| <input type="checkbox"/> Indicate as a protocol deviation in the final report | <input type="checkbox"/> Indicate as GLP deviation in the final report |
| <input type="checkbox"/> Not considered to be a deviation | <input type="checkbox"/> Indicate as a method deviation in the final report |

Does this adversely affect the quality or integrity of the study? NO
 YES (Will be listed in Compliance Statement)

Comments: