

Study Director Notification

Department: Large Animal Toxicology - Swine 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>James Beckman</u> |
| Quality Assurance Auditor: _____ | Group Leader: <u>Travis Anderson</u> |
| Report Coordinator: _____ | Project Leader: <u>Aaron Shepherd</u> |
| Department Director: <u>Ben Culp</u> | Other: _____ |

Date(s) of Event: 7/26/2007 and 7/27/2007 Study Day(s)/Interval(s) Day 1 and 2

Reference

Protocol: 6.1 SOP: _____ GLP: _____ Method: _____

Informational: _____

Please Note:

Due to a scheduling error the following animals were not dosed per table 1 in section 6.1 of the protocol on the study days listed. Animals 701-706, and 708 (1M) were not dosed on study days 1 and 2. Animals 709, 710 (1M), 713, 712 (1F) and 722-725 (2M) were not dosed on study day 1. Please advise.

By: Aaron Shepherd Date: 8/1/2007

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:

Study Director: _____ Date: _____