

NOTICE OF DEVIATION

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

Study Number: TOX213

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

Describe the Requirement (give section numbers for SOPs):

“Diet formulation is planned to be conducted weekly during the study.”

Describe the Deviation: Date of Occurrence: ~ May 23, 2008

Only a single feed formulation was conducted for this study. This decision was based upon the availability of stability data for nicotine in the formulated feed of 30-day duration at room temperature. These data indicated that the formulated feed preparations were stable in respect to nicotine concentration for a period longer than the 14-day duration of this study. Therefore, a single preparation of the formulated feed was adequate for the purpose of this study.

Documented By: Paul Ayres

Date: Nov. 3, 08

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 was required.

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

The only impact this change in the protocol could produce is to insure a more consistent nicotine concentration in the formulated feed by eliminating an addition feed formulation. A single feed formulation did not impact the results of the study based upon the stability of nicotine in the formulated feed being longer than the duration of this study.

Study Director's Signature:

Date:

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