Dear Client,

KCAS, LLC in Shawnee Kansas operates as a contract bioanalytical, conducting its work under the United States Food and Drug Administration's (FDA) Good Laboratory Practices (GLPs). The FDA therefore periodically inspects our facility, including study specific audits and reviews of our Standard Operating Procedures (SOPs), so that the agency can satisfy itself that we are following applicable guidelines for the studies that our sponsors submit to the agency. We are not certified under the Clinical Laboratory Improvement Amendments (CLIA) or by the College of American Pathologists (CAP) since the focus of our laboratory work are the analysis of biological samples for drug content (pharmacokinetic type studies) and the analysis of pharmaceutical products. Our focus is not clinical laboratory services.

KCAS, LLC has a set of appropriate SOPs in place that management is satisfied are adequate to insure the integrity of the data generated during the course of a study and to direct the conduct our operations to be in compliance with GLP regulations. We also have a QA unit, responsible directly to management, which regularly monitors study conduct and data to ensure that results are properly obtained and documented.

The FDA does not certify or license any laboratories. We have been advised that this letter would be sufficient support for you to list us on a Form 1572, "Statement of Investigator," if necessary. Representatives of your company are; of course, welcome to visit our facilities to evaluate our technical and documentation procedures.

If you would like any additional information about these or other compliance matters, please contact us directly.

Sincerely,

Michael B. Lanman
VP, Operations

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