NP 1/8/18

Annual Report of Research Facility
Column E Explanation

1. Registration Number: 48-R-0111 (Xenometrics LLC)

2. Number of animals categorized as Column E used in this study: 3

3. Species (common name) of animals used in this study: Non-Human Primate (Cynomolgus)

4. Explain the procedure producing pain and/or distress.

Animals were on a nonclinical pharmacokinetic study in which more than momentary pain or distress was not expected. Following the completion of 30 days of once daily subcutaneous dosing, the animals began to experience tremors. The animals were monitored daily as per the veterinarian's orders, but no medical intervention was done to eliminate any pain and/or distress of the tremors.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Not applicable, as pain or distress was not expected and the protocol included a contingency plan for the treatment and/or euthanasia of unexpected pain of distress.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)

This study was conducted per Nonclinical Safety Studies for the conduct of Human Clinical Trials for Pharmaceuticals (CDER, January 2010; Section 1.4. General Principles).