Column E Explanation

This form is intended as an aid to complete the Column E explanation. It is not an official form and its use is voluntary. Annual Reports and explanations should NOT include PII information such as names (principle investigators and research staff), addresses, protocols, meeting notes (either in part of in full), the animals room numbers, grant information, veterinary care programs, and the like. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: 55-R-0127

2. Number 1818 of animals categorized as column E used in this study.

3. Species (common name) Guinea Pig of animals used in this study.

4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

   Tetanus Potency- To quantitate the potency of Tetanus Immune Globulin (Human) by using neutralization methodology Some of the animals will experience paralysis.

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For federally mandated testing, see Item 6 below).

   The testing is mandated by Product License Testing Requirements. Administration of anesthetics, analgesic or tranquilizer drugs would interfere with the outcome of the test.

6. What, if any, federal regulation 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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

   Agency FDA CFR 21CFR610.10