Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is <u>not</u> an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

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1. Registration Number: _____33-R-0122_____

2. Number _____74_____ **of animals used in this study.**

3. Species (common name) __cattle_____ **of animals used in this study.**

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

> Challenge with Haemophilus somnus I.V.
> This was done as required for potency testing in an attempt
> to obtain a new product license.
> Refer to Study#2134B-60-99-159 & 160

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 question 6 below)

> The use of anesthetics and/or analgesics could affect the clinical
> monitoring by either masking or mimicking symptoms.

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):

Agency_____**CFR**_____

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1. **Registration Number:** _____ 33-R-0122 _____

2. **Number** _____ 10 _____ **of animals used in this study.**

3. **Species (common name)** cattle _____ **of animals used in this study.**

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

   Challenge with Haemolyticum. (Clostridium)
   Evaluate challenge technique for upcoming host animal study and
   to help determine challenge titration.

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 question 6 below)**

   To use anesthetics and/or analgesics could interfere with monitoring
   post challenge clinical observations.

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):**

Agency_____**CFR**_____