

### Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not 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.

1. Registration Number: 42-R-0001

2. Number 4,093 of animals used in this study.

3. Species (common name) hamsters of animals used in the study.

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

*See attached page*

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)

*See attached page*

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 APHIS 9 CFR 113.101, 113.102,  
113.103, and 113.104

NOV 23 2011

4. *Leptospira* bacterins for cattle are tested in hamsters as described in the 9 CFR. *Leptospira* organisms are injected into hamsters to determine the potency of the bacterin and the LD<sub>50</sub> of the *Leptospira* challenge material. *Leptospira* causes death in susceptible hamsters. By comparing the number of vaccine-protected live hamsters to the number of unprotected, unvaccinated dead hamsters, the potency of the bacterin and the LD<sub>50</sub> are obtained.

5. Death as the endpoint for the control hamsters, and for the hamsters used to determine the LD<sub>50</sub>, is required per the 9 CFR. Interventions, such as antibiotics or analgesics, would likely prevent or delay death and thus interfere with the test results. According to the 9 CFR 117.4(e), test animals showing signs of clinical illness due to the test may be treated or humanely destroyed if illness has progressed to a point where death is certain to occur. The Center for Veterinary Biologics (CVB) Notice No. 04-09 allows for moribund animals exhibiting clinical signs of the expected disease pathogenesis that are unable to rise or move under their own power to be humanely euthanized and considered as deaths as referred to in 9 CFR 117.4 (e). Diamond Animal Health, Inc. received permission from the CVB to euthanize moribund hamsters exhibiting clinical signs of *Leptospirosis* and this policy is in effect. During this reporting period 1,088 moribund hamsters from Category E were euthanized, compared to 1,362 for the previous reporting period.