

Column E Explanation

1. Registration Number: 42-R-0001
2. Number of animals used in this study 549.
3. Species (common name) hamsters of animals used in the study.
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. *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 is obtained.

The firm was granted an exemption by the USDA for the back titration portion of the potency testing per CVB Notice No. 15-13, for *Leptospira canicola* and *L. icterohaemorrhagiae* on February 22, 2016, and per CVB Notice No. 17-06 for *L. grippityphosa* and *L. pomona* on June 22, 2017.

5. Death as the endpoint for the control hamsters is required per the 9 CFR. Please see explanation regarding exemption in item 4. above. The firm no longer uses back titration hamsters to determine LD₅₀.

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 has been in effect since FY 2005-2006. During the current reporting period 196/549 (36%) moribund hamsters from Category E were euthanized, compared to 258/688 (38%) for the previous reporting period.

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6. Agency APHIS

9 CFR 113.101, 113.102, 113.103, 113.104.

(b) (6), (b) (7)(C)



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Date

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