

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.		OMB APPROVED 0579-0036	
		Interagency Report Control No. 0180-DOA-AN	
		Fiscal year: 2020-2021	
UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE Annual Report of Research Facility Column E Explanation <i>(TYPE OR PRINT)</i>			
This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.			
1. REGISTRATION NUMBER 42-R-0001		2. Research Facility Headquarters address Diamond Animal Health 2538 S.E. 43rd Street Des Moines, IA 50327	
3. Number of animals used in the study. 20		4. Species (common name) of animals used in the study. Hamsters	
5. Explain the procedure producing pain and distress. 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. grippotyphosa and L. pomona on June 22, 2017. This research was requested by the customer due to a temperature excursion but was not required for serial release. The research followed the 9 CFR guidelines for potency testing and the research was approved by the IACUC. A literature search was conducted.			
6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight. Death as the endpoint for the control hamsters is required per the 9 CFR. Please see explanation regarding exemption in item 5 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.			
7. 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 USDA-APHIS		CFR 9 CFR 113.101, 113.102, 113.103, 113.104.	

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1. REGISTRATION NUMBER		2. Research Facility Headquarters address	
42-R-0001		Diamond Animal Health 2538 S.E. 43rd Street Des Moines, IA 50327	
3. Number of animals used in the study.		4. Species (common name) of animals used in the study.	
2,352		Hamsters	
5. Explain the procedure producing pain and distress.			
<p>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.</p> <p>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. grippotyphosa and L. pomona on June 22, 2017.</p>			
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Agency		CFR	
USDA-APHIS		9 CFR 113.101, 113.102, 113.103, 113.104.	