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 2 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

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 42-R-0001

Customer Number: 1573

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include ZIP Code)*

Diamond Animal Health, Inc.
2538 Se 43rd Street
Des Moines, IA 50327

Telephone: (515) 263 8600

3. REPORTING FACILITY *(List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)*

FACILITY LOCATIONS *(Sites)* *See Attached Listing*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A.)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats	0	8	0	0	8
6. Guinea Pigs	0	60	7	0	67
7. Hamsters	0	1,298	0	3,198	4,496
8. Rabbits	0	0	115	0	115
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1.) **Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.**

2.) Each principal investigator has considered alternatives to painful procedures.

3.) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4.) The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (I.O.))
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

(b)(6), (b)(7)c

DATE SIGNED
11-2-09

APHIS FORM 7023
AUG 2009

NOV - 5 2009

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-0001/1573

2. Number 3,198 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 CFR 9 CFR 113.101, 113.102, 113.103, and 113.104

NOV - 5 2009

Column E Explanation

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_{50} 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_{50} are obtained.

5. Death as the endpoint for the control hamsters, and for the hamsters used to determine the LD_{50}, 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 poser 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 1,752 moribund hamsters from Category E were euthanized, compared to 264 for the previous reporting period.