This report is required by law (7 USC 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 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 74-R-0106
CUSTOMER NUMBER: 9464

FORM APPROVED
OMB NO. 0579-0036

American Animal Health, Inc.
2619 Skyway Drive
Grand Prairie, TX 75052

Telephone: (972) -641-5420

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

FACILITY LOCATIONS (Sites) - See Atached 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 animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o 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 an 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 wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Cattle				49	49
13. Other Animals					
Goat		820			820

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese 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 ap 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 inc 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 provision 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 or Legally Responsible Institutional Official)

OCT - 1 2008 ✓

DATE SIGNED
9/29/08

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

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: 74-R-0106

2. Number 49 of animals used in this study.

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

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

   See Attachment

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 Attachment

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 USDA Vet. Service Memorandum No. 800.202 ~~CFR~~ General Licensing Consideration : Efficacy Studies.

Principal Investigator

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

Approved by the IACUC

OCT - 1 2008

ATTACHMENT FOR COLUMN E EXPLANATION

4. The animal were used in the challenge protection tests conducted to demonstrate host animal immunogenicity for the re-qualification of the reference for Pasteurella Haemolytica-Pasteurella Multocida Bacterin Toxoid, Codes #7935.00 and #7935.01. Out of the 49 animals used in the test, 6 were used as environmental controls that they were not challenged, however, they were also sacrificed at necropsy for comparison. The other 43 animals were used either as vaccinates or placeboes. They were all challenge 21 days post vaccination, if Code 7935.01 or 14 days post 2nd vaccination, if Code 7935.00. Since the USDA requires observation for clinical signs post challenge, we are sure that this requirement would produce some degree of pain and distress for animals depending on the degree of protection. For those placebos, the 14 animals were suffered throughout the post-challenge period of observation.

5. The above-mentioned Host Animal Immunogenicity work involved pneumonia protection. Although the pivotal analysis were based on lung lesion scores, the USDA requires whether products help mitigating clinical signs. Therefore, pain and/or distress could not be relieved.