

Attachment A for APHIS form 7023**1.0 Column E, Line 4, Animal – Dogs**

- 1.1 Forty dogs were used in studies for development of a preventative vaccine for a dog disease endemic in the United States. The development studies for this vaccine require challenge of dogs with this virulent agent in order to evaluate the vaccines efficacy and potency. This testing is required by the USDA for licensing of this product as stated in 9 CFR 113.209. Thirty-five dogs experienced neurological symptoms and/or death. Anesthetics, analgesics, and tranquilizing drugs are not appropriate treatment for this agent and would interfere with the evaluation of this vaccine.
- 1.2 Seventy-two dogs were used in studies for development of a preventative vaccine for a dog disease endemic in the United States. The development studies for this vaccine require challenge of dogs with this virulent agent in order to evaluate the vaccines efficacy and potency. This testing is required by the USDA for licensing of this product as stated in 9 CFR 113.317. Fifty-five dogs experienced neurological symptoms and/or death. Anesthetics, analgesics, and tranquilizing drugs are not appropriate treatment for this agent and would interfere with the evaluation of this vaccine.

2.0 Column E, Line 7, Animal – Hamsters

- 2.1 Seven thousand six hundred forty-five hamsters were used in testing bacterin prior to release for sale as required by 9 CFR 113.101 – 113.105. This testing requires challenging hamsters with the virulent agent in order to evaluate bacterin efficacy and potency. Two thousand two hundred ninety-four hamsters experienced weight loss, debilitation and/or death. Anesthetics, analgesics and tranquilizing drugs are not appropriate treatment for this agent and would interfere with the evaluation of this bacterin.

3.0 Column E, Line 13B, Animal – Ferrets

- 3.1 One hundred twenty-five ferrets were used in studies for development of a preventative vaccine for a ferret disease endemic in the United States. The development studies for this vaccine require challenge of ferrets with this virulent agent in order to evaluate the vaccines efficacy and potency. This testing is required by the USDA for licensing of this product as stated in 9 CFR 113.306. 86 ferrets experienced neurological symptoms and/or death. Anesthetics, analgesics, and tranquilizing drugs are not appropriate treatment for this agent and would interfere with the evaluation of this vaccine.

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UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 58-R-0007

58-R-0007 # 872

FORM APPROVED
OMB NO. 0579-0036

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

University of Miami

P.O. Box 016960

P.O. Box 5625

Miami, FL 33101

Status: Active

DEC 1 1999

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

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

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 in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	11		47		47
5. Cats			16		16
6. Guinea Pigs		9	126		135
7. Hamsters					
8. Rabbits	22	39	528	44	611
9. Non-human Primates	485		75		75
10. Sheep					
11. Pigs	11		464		464
12. Other Farm Animals					
Goats			75		75
13. Other Animals					
Fish			528		528
Wild rodents		120	100		220
Wild birds		262	308		570

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 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)

I certify that the above is true, correct, and complete (7 USC Section 2143)

SIGNATURE

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED