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| UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT) | 1. CERTIFICATE NUMBER: 35-R-0035 CUSTOMER NUMBER: 630 | FORM APPROVED OMB NO. 0579-0036 |
| United Vaccines Inc 2826 Latham Drive Madison, WI 53713 Telephone: (608) -277-2000 | | |

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 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 animal 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 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 reast 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 | 0 | 0 | 72 | 0 | 72 |
| 7. Hamsters | | | | | |
| 8. Rabbits | | | | | |
| 9. Non-human Primates | | | | | |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
| Ferrets | 0 | 26 | 0 | 26 | 52 |
| Mink | 360 | 498 | 3 | 304 | 805 |

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 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)

| | | |
|-------------------|--|-------------|
| SIGNATURE | NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) | DATE SIGNED |
| (b)(6), (b)(7)(C) | (b)(6), (b)(7)(C) | 19 Oct 05 |

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UNITED VACCINES, INC.

18 October 2005

ADDENDUM #1

The animals listed in Column E were utilized for safety and potency testing of this firm's products as specified in the following 9 CFR sections:

| Regulatory Justification | Description of Study | Species | Number | |
|--------------------------|----------------------|------------------------------|--------|----|
| 9 CFR | 113.109(c) | <i>Clostridium botulinum</i> | Mink | 43 |
| | 113.204(b) | Mink Enteritis Virus | Mink | 29 |
| | 113.302(c) | Mink Distemper Virus | Mink | 6 |

In addition, animal challenge testing was performed for the following studies:

1. Validation of the *Pseudomonas aeruginosa* bacterin, required by APHIS-CVB: Mink, 226.
Justification: United Vaccines, Inc. Special Outline #24, *Pseudomonas aeruginosa* Standard Reference Bacterin, requires that a new bacterin be selected and qualified every 2 years for use as a reference. Qualification of the new reference bacterin requires challenge of mink with virulent *Pseudomonas aeruginosa*. Due to the opportunistic nature of *Pseudomonas*, it is necessary to perform one or more practice challenges using each of three serotypes prior to the initiation of the study to ensure that unvaccinated mink are susceptible to current challenge preparations. The 226 mink listed above were used for practice challenges and final reference qualification for all three *Pseudomonas* serotypes used.
2. Pathogenicity testing of in-house challenge material for use in master seed testing: Ferrets, 26.
Justification: Challenge material procured from the CVB-NVSL has historically, in our experience, not been virulent enough to cause disease in > 80% of unvaccinated control mink, as required for a valid test by 9 CFR 113.302(c)(3)(i). In order to produce a more virulent virus for use in testing vaccine master seed, passages in ferrets were performed. In order to determine the strength and proper working dilution of the new challenge material, practice challenges with backtiters were performed.

Agencies that regulate the testing of biologics generally insist that these tests run their course without interference. In some instances, the symptoms may become protracted. In these cases, we do administer a euthanasia solution at an appropriate state to reduce pain and distress.

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(Registration Number: 35-R-0035)



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ADDENDUM #2

Facility Locations (Sites):

(b)(2)High, (b)(7)(F)

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

(Registration Number: 35-R-0035)

(b)(2)High, (b)(7)(F)