

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 35-R-0122 CUSTOMER NO. 40729

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

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

UNITED VACCINES INC  
2919 COMMERCE PARK DRIVE  
MADISON, WI 53719

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)

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					
5. Cats					
6. Guinea Pigs	1		87	2	89
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Mink	617	188	271	124	583

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 the 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 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL  (b)(6), (b)(7)(C)	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED  12/01/2008
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### APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 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.

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1. Registration Number: 35-R-0122

2/3. Species (common name) & Number of animals used in this study:

Mink (124)

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

Safety and potency testing of the firm's products.

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)

Safety and Potency testing is Federally mandated - see below

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: 9 CFR 113.109(c)

CFR:

### APHIS Form 7023 Column E Explanation

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1. Registration Number: 35-R-0122

2/3. Species (common name) & Number of animals used in this study:

Guinea Pigs (2)

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

Safety testing of the firm's in-process material.

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)

Federally mandated test; see below

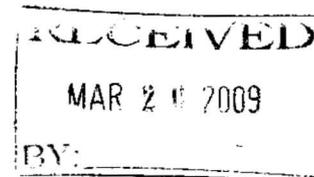
6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: 9 CFR 113.100(b)(1)

CFR:

ADDENDUM TO  
FY2008 ANNUAL REPORT OF RESEARCH FACILITY

UNITED VACCINES, INC.  
2919 Commerce Park Drive  
Madison, WI 53719  
(608) 276-5501  
Registration No.: 35-R-0122 / 40729



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

Regulatory Justification		Description of Study	Species	Number
Filed Outline for Production	Section IV.A.3	Verification of the inactivation of in-process <i>Clostridium botulinum</i> Type C bacterin-toxoid fluids via SQ injection of each of 2 guinea pigs with test material.	Guinea pigs	2
9 CFR	113.204(b)	Potency testing of products containing inactivated Mink Enteritis Virus according to 9 CFR 113.204(b), which requires challenge of vaccinate and control animals with virulent Mink Enteritis Virus.	Mink	40
	113.110(c)	Potency testing of products containing inactivated / detoxified <i>Clostridium botulinum</i> Type C bacterin-toxoid according to 9 CFR 113.110(c), which requires challenge of vaccinate and control animals with active <i>C. botulinum</i> Type C toxin.	Mink	29
APHIS – CVB		Validation of the <i>Pseudomonas aeruginosa</i> reference bacterin, required by APHIS-CVB. United Vaccines, Inc. Special Outline #24, <i>Pseudomonas aeruginosa</i> Standard Reference Bacterin, requires that a new bacterin be selected and qualified every 2-3 years for use as a reference. Qualification of the new reference bacterin requires challenge of vaccinate and control mink with virulent <i>Pseudomonas aeruginosa</i> .	Mink	55

Agencies that regulate the testing of biologics generally require that the tests run their course without interference. In all applicable cases, animals are administered a euthanasia solution to reduce pain and distress as soon as acceptable per regulatory requirements following onset of symptoms / illness.

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

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