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<p>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.</p>	<p>Interagency Report Control No. 0180-DOA-AN</p>
<p>Fiscal Year: 2009</p>	

**UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

**REGISTRATION NUMBER:** 14-R-0192

**Customer Number:** 23918

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

Biomedical Research Models Inc  
67 Millbrook St  
Worcester, MA 01606

Telephone: (508) 459 7544

OCT 23 2009

**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 Listing

(b)(2)High, (b)(7)f

**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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	30	0	25	17	42
7. Hamsters	0	0	0	0	0
8. Rabbits	2	0	32	0	34
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

**ASSURANCE STATEMENTS**

- 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.
- Each principal investigator has considered alternatives to painful procedures.
- 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.
- 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 (L.R.O.))  
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

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

DATE SIGNED  
10/20/09

(A) Error in numbers (b)(6), (b)(7)c 9/28/09  
(B) Error in only add columns C, D and E (b)(6), (b)(7)c 10/20/09  
NP 12/14/2009

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BY: \_\_\_\_\_

APHIS Form 7023 Site Addendum for FY: 2009

Registration Number: 14-R-0192

Customer ID Number: 23918

Facility Business Address Information:

Biomedical Research Models Inc

67 Millbrook St

Worcester, MA 01606

Telephone: (508) 459 7544

Facilities Site(s) Address Information:

Site Code(s):

(b)(2)High, (b)(7)f

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BY: \_\_\_\_\_

**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: 14-R-0192
2. Number: 42 animals, 17 of which reached a USDA pain category E were used in this study.
3. Species (common name): Guinea pigs were used in the study.
4. Explain the procedure producing pain and /or distress.

Mice and guinea pigs are the two major animal infection models established for the human herpes virus-2 (HSV-2) to evaluate protective efficacy of potential HSV-2 vaccines. Previously, we have successfully obtained satisfactory immune protection results using Balb/c mice that were immunized with our novel immunization strategy and challenged with HSV-2 viruses afterwards. To further prove the potency of the immunization regimen in another established animal model, the Hartley guinea pig was chosen to observe clinical signs, body weight and mortality post immunization and HSV-2 infection. The guinea pig is also a good model to study immune protection efficacy against recurrence of HSV-2 infection. The total number of animals used on study was the minimum required to properly characterize the protective candidate vaccination effects of the test vaccines.

Animals were dosed with test vaccines by subcutaneous, intramuscular and intranasal routes of administration followed by a HSV-2 viral intra-vaginal challenge. Post infection, animals were monitored daily for clinical signs of disease. The viral challenge of guinea pigs with HSV-2 can have varying clinical readouts from no clinical signs to morbidity. To evaluate the viral disease state we followed the established published literature for viral clinical scoring listed in the table below. Animals that reached a moribund state or exhibit a score of (4) or a loss of 20% body weight were immediately euthanized.

Observation	Score
No clinical signs of disease	0
Vaginal erythema	1
Single to a few modest herpetic lesions	2
Large or fused vesicles	3
Severe vaginal ulceration and paralysis	4
Found dead	5

In addition, cage side observations were performed daily to monitor animals for any associated clinical signs. Animals were also monitored daily for signs of pain and distress, including but not limited to, the animals' activity, behavior and mobility, appearance in grooming, appetite, excreta and signs of morbidity, vocalization upon handling and the absence of the righting reflex,

were monitored. If abnormalities were observed, the PI and/or facility veterinarian were notified immediately.

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.

Disease severity is scored using the clinical score scale described above in question 4. The use of analgesics may alter the physiological processes and clinical scores that are being observed for study and make the interpretation of the raised immune protection results technically difficult. The measurement of clinical scores is vital to the determination of the efficacy of the vaccine. Therefore, we propose not to use analgesics that could interfere with test results. Animals that reach a moribund state, exhibit pain or unrelieved distress or exhibit a score of (4) or a loss of 20% body weight will be immediately and humanely euthanized.

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:        NA                      CFR:

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