

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 93-R-0391 CUSTOMER NUMBER: 1737	FORM APPROVED OMB NO. 0579-0036
Medimmune Vaccines, Inc. 297 North Bernardo Avenue Mountain View, CA 94043 <div style="background-color: black; color: white; padding: 2px;">b6;b7c</div>		

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 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		94			94
7. Hamsters			100		100
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					1733
Ferrets	34	1024		109	1767
Cotton Rats			68		68

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)

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MAY 28 2008
 DATE SIGNED
 1/25/08

Column E Explanation

1. Registration Number: **93-R-0391**
2. Number of animals used in these studies: **109**
3. Species (common name) of animals used in the study: **Ferrets**
4. Explain the procedure producing pain and/or distress.

The 109 ferrets assigned to Block E were used in two different study types: (a)

[REDACTED] research studies and [REDACTED] mandated [REDACTED]

(a) [REDACTED] research studies involve understanding [REDACTED] when used in susceptible individuals. The ferret is the only laboratory animal model that exhibits clinical [REDACTED] similar to people and [REDACTED] a naturally [REDACTED] ferrets. Therefore, ferrets are the most relevant animal model to use for these studies. Ferrets are [REDACTED] with either [REDACTED] which may cause a mild to moderate [REDACTED]. Animals are observed and those that develop significant clinical signs of [REDACTED] such as [REDACTED] are placed in Block E since they will have experienced some unrelieved [REDACTED] and due to the study design which does not allow for alleviation of these signs with analgesics or [REDACTED] drugs. Animals are given supportive care such as food treats and fluids as needed. During research investigations, the ferret's [REDACTED] to [REDACTED] may also be studied. Animals may be receive [REDACTED] to enhance their [REDACTED] [REDACTED] which may cause them a mild to moderate degree of transient discomfort or pain.

(b) [REDACTED] are mandated by the FDA (see 6. below). Ferrets are [REDACTED] with the [REDACTED] as a positive control. Some of the [REDACTED] will develop clinical signs of [REDACTED] such as [REDACTED]. Only the animals which exhibit a significant [REDACTED] are classified as ill and therefore are assigned USDA category E. The test runs for three days from [REDACTED] to euthanasia of all animals and tissue collection for analysis.

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)

(a) In [REDACTED] research studies, analgesics cannot be used because many analgesics also have [REDACTED] effects which include [REDACTED] and [REDACTED] which would affect the very physiological functions that are under study – responses of the animal [REDACTED] to the [REDACTED] [REDACTED]. Methods used to determine that

analgesics might interfere with test results are based upon scientific publications of adverse responses to analgesics in animals and humans and upon known mechanisms of actions of these analgesics.

Literature search databases, dates and key words:

Entrez PubMed, AGRICOLA, and Medline

B4

(b) The B4 assay is used as a positive control against which are measured the B4 and performance of the B4. The use of analgesics in these animals would invalidate this assessment.

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: Food and Drug Administration (FDA) 21 CFR 610.1

"No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with the standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies."