

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. REGISTRATION NO. 93-R-0251	CUSTOMER NO. 1128	FORM APPROVED OMB NO. 0579-0036
2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code) AMGEN ONE AMGEN CENTER DRIVE THOUSAND OAKS, CA 91320-1789			
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)

(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 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		99	40		139
5. Cats					
6. Guinea Pigs		17			17
7. Hamsters					
8. Rabbits	34	420	456	115	991
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

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 b6, b7c	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print) b6, b7c	DATE SIGNED 11/20/2008

1. Registration Number: 93-R-0251 / 1128

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

Rabbits (115)

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

This animal model seeks novel therapies for mitigating pain secondary to inflammatory disease in a species that has high homology with humans for the targeted receptor. An inflammatory response is created, animals are dosed with novel compounds and the analgesic effect tested by scoring limb withdrawal following von Frey stimulation. Animals receiving vehicle controls or ineffective test compounds may experience very short periods of mild pain or distress associated with the induced inflammatory response.

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)

Use of analgesics and anti-inflammatory agents will interfere with outcomes observed in this inflammatory pain model. A review of the literature substantiates that anti-inflammatory agents will block the development of inflammation and pain hypersensitivity thereby confounding our ability to assess whether our novel compounds are having a pain-relieving effect. Similarly, the pain-relieving effects of analgesics such as opioids will confound our ability to determine whether our novel compounds are reducing pain. Since our goal is to model inflammatory pain states in humans and identify 1) changes in pain sensitivity and 2) efficacy of novel compounds, analgesics or anti-inflammatory agents cannot be administered.

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: N/A

CFR:

Approval Status:

Approved/Disapproved By:

Date:

Disapproved Reason: