

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.  
22-R-0139

CUSTOMER NO.  
35171

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)

SANOFI AVENTIS  
1041 ROUTE 202-206, MAILSTOP BRW JR2-203 A  
BRIDGEWATER, NJ 08807

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)**

SANOFI AVENTIS

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

SANOFI AVENTIS

(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	73	137	1	5	143
5. Cats					
6. Guinea Pigs		1211	5050	2	6263
7. Hamsters					
8. Rabbits		428	4	1	433
9. Non-Human Primates	4	17	40		57
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

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

b6,b7c

11/24/2008

### 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: 22-R-0139

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

Dogs (5)

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

Used: 159 Dogs

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)

Exploratory Range Finding Studies in support of General Toxicology

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: None

CFR:

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1. Registration Number: 22-R-0139

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

Rabbits (1)

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

Used: 341 Rabbits for this study, the remaining 92 animals were used in other study procedures.

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)

These studies are required to evaluate potential effects of compounds on embryo-fetal development when administered during gestation. The study evaluates potential maternal effects and effects on development of the embryo/fetus after exposure of the female to test article during the major period of organogenesis, from implantation to closure of the hard palate. The administration of analgesic or anesthetic agents to this animal was not considered as the animal did not demonstrate any clinical signs prior to being found dead.

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: Reproductive Toxicology Studies Agency: FDA CFR:  
Federal Food, Drug, and Cosmetic Act CFR: 505 (4) (1) (1) (A)

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1. Registration Number: 22-R-0139

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

Guinea Pigs (2)

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

Used: 5941 Guinea Pigs, the other 292 were used to support other study procedures.

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)

The guinea pig is a valuable animal model for the discovery and development of potential candidate drugs for asthma. The administration of analgesic or anesthetic agents to these animals was not considered as the animals did not demonstrate any adverse clinical signs.

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: None

CFR: