

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 42-R-0020  
CUSTOMER NUMBER: 1625

FORM APPROVED  
OMB NO. 0579-0036

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

Novartis Animal Health Us, I N C  
1447 140th Street  
Larchwood, IA 51241

Amendment to 11/3/08 Annual Report for  
Research Facility, Novartis Animal  
Health US, Inc.

(B)(6) (B)(7)(c)

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 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 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 )
Dogs					
Cats					
Guinea Pigs	0	465	214	44	723
Hamsters	0	4725	0	2381	7106
Rabbits	0	58	1538	0	1596
Non-human Primates					
Sheep					
Pigs					
Other Farm Animals					
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 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 )

(B)(6) (B)(7)(c)

DATE SIGNED

2/4/09

**Column E Explanations Referencing APHIS Form 7023**

**2008 Annual Report of Research Facility  
October 29, 2008**

**1. Registration Number 42-R-0020**

**2. Number of Animals Used in the Study:**

Forty-four (44) used in (b)(4) assay for release of serials of USDA regulated biological product (i.e. vaccine).

**3. Species (common name) of Animals Used in the Study:**

Guinea Pig

**4. Explanation of Procedure Producing Pain and/or Distress:**

(b)(4) Assay: This test is mandated by APHIS-Center for Veterinary Biologics (CVB) in the licensing of vaccines to protect animals from the effects of disease caused by infection (b)(4) This test is prescribed in Title 9 of the Code of Federal Regulations.

The test procedure involves (b)(4)

(b)(4)

As per 9 CFR 117.4 (e), and in accordance with APHIS-CVB communication of April 1, 2004 (RE: VBN 04-09), APHIS-CVB has approved a "non-death" endpoint in our production outlines that allows humane methods of euthanasia

**5. Scientific Justification as to Why Pain and /or Distress Could Not Be Relieved:**

This test is codified in the Title 9 Code of Federal Regulations. This codified test method has been promulgated by APHIS-CVB and to date; APHIS-CVB has not published guidance to licensed biological manufacturers that would allow for the use of drugs such as pain relievers to reduce pain and suffering prior to attaining the study endpoint.

To our knowledge, APHIS-CVB has not determined, nor communicated, what impact, use of drugs such as pain relievers would have on the validity of these assays.

In some species of animals, clinical signs indicative of an inevitable progression to death are difficult to assess. To prevent interference with the test objectives, while at the same time promote the most humane treatment/endpoints of test animals permissible, production outlines have been modified to include the humane euthanasia of moribund animals exhibiting clinical signs consistent with disease pathogenesis that are unable to rise or move under their own power.

**6. Identification of Federal Regulations Requiring This Procedure:**

- USDA (APHIS-CVB): (b)(4)

(B)(6) (B)(7)(c)

Date: 29 Oct 2008

**Column E Explanations Referencing APHIS Form 7023**

**2008 Annual Report of Research Facility  
October 24, 2008**

**1. Registration Number 42-R-0020**

**2. Number of Animals Used in the Study:**

Two thousand, three hundred and eighty-one (2,881)

**3. Species (common name) of Animals Used in the Study:**

Hamster

**4. Explanation of Procedure Producing Pain and/or Distress:**

(b)(4) Assay: These tests are mandated by APHIS-Center for Veterinary Biologics (CVB) in the licensing of vaccines to protect animals from the effects of disease caused by infection with multiple (b)(4) species. These tests are prescribed in Title 9 of the Code of Federal Regulations.

As per 9 CFR 117.4 (e), and In accordance with APHIS-CVB communication of April 1, 2004 (RE: VBN 04-09), APHIS-CVB has approved a "non-death" endpoint in our production outlines that allows humane methods of euthanasia.

**5. Scientific Justification as to Why Pain and /or Distress Could Not Be Relieved:**

These tests are codified in the Title 9 Code of Federal Regulations. These codified tests methods have been promulgated by APHIS-CVB and to date; APHIS-CVB has not published guidance to licensed biological manufacturers that would allow for the use of drugs such as pain relievers to reduce pain and suffering prior to attaining the study endpoint.

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**6. Identification of Federal Regulations Requiring This Procedure:**

- USDA (APHIS-CVB):
- USDA (APHIS-CVB): (b)(4)
- USDA (APHIS-CVB):
- USDA (APHIS-CVB):

(B)(6) (B)(7)(c)

Date: 4 Nov 2008