

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE  <b>ANNUAL REPORT OF RESEARCH FACILITY</b> ( TYPE OR PRINT )	1. CERTIFICATE NUMBER: 50-R-0003 CUSTOMER NUMBER: 27	FORM APPROVED OMB NO. 0579-0036
Intervet Inc 29160 Intervet Lane Millsboro, DE 19966  Telephone: (b)(2)High, (b)(7)f		

NOV 23 2005

**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 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 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		289	95		384
5. Cats		421	20	32	473
6. Guinea Pigs	68	314	1145	671	2130
7. Hamsters		1420	34	805	2259
8. Rabbits	52	4	1207	650	1861
9. Non-human Primates					
10. Sheep		38			38
11. Pigs		1539			1539
12. Other Farm Animals					
Bovine		2075			2075
13. Other Animals					
Equine	24	131			155

**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

*11/21/05*

**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 50-R-0003

2 Number 32 of animals used in this study

3 Species (common name) Feline of animals used in the study

4 Explain the procedure producing pain and/or distress

All Animals were challenged with (b)(4) Virus

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)

Requirements for acceptance in (b)(4) shall be (b)(4) due to (b)(4) in  
at least 80% of the controls.

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 APHIS 9 CFR (b)(4)

NOV 2 2005

Column E Explanation (2004-2005)

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 – 50-R0003
2. Number 671 of animals used in this study.
3. Species (common name) guinea pigs of animals used in the study.
4. Explain the procedure producing pain and/or distress.

*These animals were used for Codified (b)(4) for the product release testing of all Intervet (b)(4) containing products.*

*Per (b)(4) the guinea pigs used for (b)(4) are (b)(4) with (b)(4) and observed 3 day (b)(4) and all (b)(4) recorded. The (b)(4) causes (b)(4) lesion which causes distress.*

*Per (b)(4) the guinea pigs used for (b)(4) are (b)(4) with (b)(4) material and observed 3 day (b)(4) and all (b)(4) recorded. The (b)(4) causes (b)(4) lesion which causes distress*

*In both instances, per code, (b)(4) is the endpoint.*

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 the test results. (For federally mandated testing, see Item 6 below)

*(b)(4) is the end-point. Any intervention must be pre-approved by USDA/APHIS/VS/CVB as written in the filed Outline of Production or Special Outline. Currently no intervention criteria are written into these procedures.*

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 USDA/APHIS/VS/CVB

(b)(4)

NOV 2005

### 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 50-R-0003

2 Number 455 of animals used in this study

3 Species (common name) Hamsters of animals used in the study

4 Explain the procedure producing pain and/or distress

All Animals were (b)(4) with (b)(4)

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)

(b)(4) is the endpoint required to determine the (b)(4) of test (b)(4) occurs within 28/48 hours following the onset of symptoms. Due to the fact that (b)(4) is the required endpoint, there are no procedures available to limit discomfort, distress and pain during the 14 day observation period.

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 APHIS 9 CFR (b)(4)

NOV 23 2005

Column E Explanation (2004-2005)

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 – 50-R0003
2. Number 350 of animals used in this study.
3. Species (common name) hamsters of animals used in the study.
4. Explain the procedure producing pain and/or distress.

*These animals were used to qualify a reference for use in an (b)(4) test (b)(4) used for product release of all (b)(4) (b)(4) containing products.*

*Per (b)(4) tests must have a test reference which has undergone a vaccination/challenge study, either host or non-host.*

*Intervet submitted a study report after conducting a hamster (b)(4) study using the protocol approved by USDA/APHIS/VS/CVB. CVB requested that Intervet conduct additional studies to further endpoint the (b)(4) for the various dilutions used. (b)(4) was the endpoint in these studies*

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 the test results. (For federally mandated testing, see Item 6 below)

*(b)(4) is the end-point. Any intervention must be pre-approved by USDA/APHIS/VS/CVB as written in the filed Outline of Production or Special Outline. Currently no intervention criteria are written into these procedures.*

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 USDA/APHIS/VS/CVB (b)(4) with APHIS approved procedure in (b)(4)*

b4

## Column E Explanation (2004-2005)

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 – 50-R0003
2. Number 650 of animals used in this study.
3. Species (common name) rabbits of animals used in the study.
4. Explain the procedure producing pain and/or distress.

*These animals were used for a proprietary (b)(4) testing for the product release testing of all Intervet (b)(4) containing products.*

*Per our (b)(4) rabbits are used in a (b)(4) study. The rabbits used for (b)(4) are challenged with (b)(4) and observed 3 day (b)(4) and all (b)(4) are recorded. The (b)(4) causes (b)(4) lesion which causes distress. The validity requirement for the test is (b)(4)*

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 the test results. (For federally mandated testing, see Item 6 below)

*(b)(4) is the end-point parameter measured with this approved (b)(4) test. Any intervention must be pre-approved by USDA/APHIS/VS/CVB as would be written in the filed Outline of Production or Special Outline. Currently no intervention criteria are written into these procedures.*

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 USDA/APHIS/VS/CVB (b)(4) approved procedure in (b)(4)*