This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

DEC 0 2 2008

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 23-R-0007
CUSTOMER NUMBER: 281

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Covance Research Products Inc
310 Swampbridge Road Po Box 7200
Denver, PA 17517

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

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 Atached 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	0	1,024	44	7	1,075
5. Cats	96	33	7	0	40
6. Guinea Pigs	46	777	1	0	778
7. Hamsters	0	3	0	0	3
8. Rabbits	313	10,618	1,481	0	12,099
9. Non-human Primates	1	1,169	54	0	1,223
10. Sheep	36	151	3	0	154
11. Pigs	6	90	0	0	90
12. Other Farm Animals					
Goats	1	146	3	0	149
13. Other Animals					
Ferrets	0	21	40	0	61
Cotton Rats	0	82	0	0	82

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, 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)

b6, b7c

DATE SIGNED
1Dec2008

APHIS FORM 7023
(AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

NP

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: 23-R-0007

2. Number 40 of animals used in this study.

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

4. Explain the procedure producing pain and/or distress.
Dogs were administered experimental b4 against b4 b4 Dogs were then b4 with the (b)(4) and developed moderate clinical signs of b4 . (also known as b4 which resolved uneventfully.

THIS INFORMATION IS CONSIDERED PROPRIETARY AND SHOULD BE REDACTED.

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)

In order to demonstrate the b4 dogs against b4 from b4 the dogs had to experience any clinical signs from the b4 Administering anesthetics, analgesics, or tranquilizing would have interfered with the evaluation of how efficacious the vaccine was and invalidated the study.

THIS INFORMATION IS CONSIDERED PROPRIETARY AND SHOULD BE REDACTED.

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):

N/A

Agency_____ CFR_____

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: 23-R-0007

2. Number 18 of animals used in this study.

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

4. Explain the procedure producing pain and/or distress.
Dogs were administered a b4 and the animals developed clinical signs of b4

THIS INFORMATION IS CONSIDERED PROPRIETARY AND SHOULD BE REDACTED.

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)

In order to measure the levels of biomarkers and other indices under scientific development, involved with determination of b4 progression, anesthetics, analgesics, or tranquilizing agents were not administered. Administration of these agents would have interfered with the evaluation of the progression of b4 and invalidated the study.

THIS INFORMATION IS CONSIDERED PROPRIETARY AND SHOULD BE REDACTED.

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):

N/A

Agency_____ CFR_____