According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid CMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information

OMB APPROVED 0579-0036

This report is required by law (7 U.S.C. 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 2150. REGISTRATION NUMBER: 22-R-0138

Interagency Report Control No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA,

Johnson & Johnson Pharmaceutical R&D Llc P O Box 300 Route 202 South

Telephone: (908) 704 4310

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

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.) Number of animals upon Number of animals upon which teaching. experiments, research, surgery, or tests we conducted involving accompanying pain or which experiments, Number of animals Number of animals teaching, research, upon which surgery, or tests were conducted involving being bred, distress to the animals and for which the use of teaching, research, Animals Covered By conditioned or held appropriate anesthetic, analgesic, or TOTAL NUMBER experiments, or for use in teaching. accompanying pain or tranquilizing drugs would have adversely OF ANIMALS tests were Welfare Regulations testing, experiments, research, or surgery distress to the animals affected the procedures, results, or (Cols. C + D + E) and for which interpretation of the teaching, research, no pain, distress, or but not yet used for appropriate anesthetic, experiments, surgery, or tests. (An explanation use of pain-relieving analgesic, or of the procedures producing pain or distress on drugs. tranquilizing drugs were these animals and the reasons such drugs were not used must be attached to this report.) 4. Dogs 386 9 5. Cats 6. Guinea Pigs 142 7 Hamsters 8. Rabbits 9. Non-human Primates 10. Sheep 11. Pigs 12. Other Farm Animals 13. Other Animals ASSURANCE STATEMENTS

- 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.
- 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 3.) and approved by the 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 includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- The attending veterinarian for this research facility has appropriate authority to ensure the provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and

	CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer (C.E.O.) or Legally Responsible institutional Official (I.O.)) certify that the above is true, correct, and complete (7 U.S.C. Section 2145).		
SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR LO. (Turk or Print)	DATE SIGNED	
	(b)(6), (b)(7)c	11/19/09	
AP			

Appendix 1 USDA ANNUAL REPORT (2008-2009) Registration #: 22-R-0138

Species/protocol	Cat E usage	Procedure/Justification	
Dogs	102	Single and repeat dose (IV, Oral) Pharmacokinetic/Toxicology studies. Analgesics cannot be administered as they may potentially interfere with the goals/aims of the intended studies, primarily study of the physiologic and pathologic processes produced by toxicity of dosed investigational agents. These studies are performed in accord with "Harmonization of Guidelines for Toxicity testing of Pharmaceuticals by 1992," regulatory Toxicology and Pharmacology, Vol 12, 179-211 (1990).	
Guinea Pigs	110	Pulmonary Mechanics: These are animal models of pulmonary disease. Animals are subjected to intratracheal or intranasal instillation of inflammatory mediators, and in some cases for allergen challenge. Some animals may experience pronounced bronchoconstriction beginning shortly after exposure. The animals cannot be chronically treated for pain or distress without interrupting the elicited inflammation and interfering with the model developed.	
Guinea pigs	1	Analgesics were not administered due to potential interference with development of this ileitis model.	
Rabbits	14	Anti-infective protocol, animals injected with bacteria to study efficacy of anti-infective compounds. Administration of analgesics will adversely affect the ability to analyze & evaluate these effects.	

Appendix 2 USDA ANNUAL REPORT (2008-2009) Registration #: 22-R-0138

Dog Exercise

Exemptions

(October 1, 2008 - September 30, 2009)

The following Exemptions were approved by IACUC:

- 1. 6 dogs were granted exemption from the dog exercise plan for a period of 2-4 weeks during the conduct of radioactive studies.
- 2. 8 dogs were exercise less than 3 times/week